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Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

LSZ102, ribociclib (LEE011) and alpelisib (BYL719)

Trial Indication(s)

Advanced or metastatic Estrogen Receptor positive breast cancer

Protocol Number

CLSZ102X2101

Protocol Title

A phase I/Ib, open label study of LSZ102 single agent and LSZ102 in combination with either LEE011 (LSZ102 + LEE011) or BYL719 (LSZ102 + BYL719) in patients with advanced or metastatic ER+ breast cancer who have progressed after endocrine therapy

Clinical Trial Phase

Phase 1

Phase of Drug Development

Phase 1 (LSZ102) and Phase 4 (ribociclib and alpelisib)

Study Start/End Dates

Study Start Date: June 2016 (Actual)
Primary Completion Date: September 2021 (Actual)
Study Completion Date: September 2021 (Actual)

Reason for Termination (If applicable)

As of November 2019, after careful evaluation of the available clinical data, Novartis decided to halt recruitment to the study. The decision to halt recruitment was not due to any safety concerns. Any ongoing patients were permitted to continue on study as per the protocol.

Study Design/Methodology

This study was an open-label, phase I/Ib study with dose escalation and dose expansion parts of LSZ102 given as a single agent and in combination with ribociclib or alpelisib in patients with locally advanced or metastatic Estrogen Receptor positive (ER+) breast cancer who had progressed after endocrine therapy.

The dose escalation part was to determine the maximum tolerated dose(s) (MTD(s)) and or recommended dose(s) for expansion (RDE(s)) and to characterize the safety, tolerability and pharmacokinetics (PK) of the study treatments (LSZ102 single agent, LSZ102 + ribociclib combination and LSZ102 + alpelisib combination). The dose escalation of single agent LSZ102 also included an exploratory investigation of the effect of food comparing PK profiles of LSZ102 under fasted and fed conditions.

The dose escalation part began with the administration of LSZ102 single agent (Arm A). Following identification of a safe and tolerable single agent dose level, the following 3 parts were initiated:

1. The food effect cohort

A few patients from Arm A were enrolled in a food effect run-in period before each patient's treatment period. During the food effect run-in period, each patient received a single dose of LSZ102 450 mg after a high fat breakfast followed by a washout period of up to 7 days. Each patient then received the same single dose under fasted conditions, followed by another washout period of 2 days. After the second wash-out period, patients started the treatment period on Cycle 1 Day 1.

2. Combination treatment with LSZ102 and ribociclib (Arm B)

3. Combination treatment with LSZ102 and alpelisib (Arm C)

The expansion part of the study was planned to assess the clinical efficacy and further evaluate the safety of LSZ102 single agent, LSZ102 + ribociclib and LSZ102 + alpelisib. There were 4 dose expansion arms planned: LSZ102 single agent (Arm 1), LSZ102 + ribociclib (Arm 2 with ribociclib intermittent and Arm 3 with ribociclib continuous) and LSZ102 + alpelisib (Arm 4).

At the time of enrollment halt, dose escalation for all three arms (Arms A, B and C) had been completed and only dose expansion of LSZ102 QD + ribociclib 3 weeks on/1 week off (Arm 2) was ongoing. The other dose expansion arms (Arm 1, Arm 3 and Arm 4) were not opened for enrollment.

Centers

10 centers in 7 countries: Belgium(1), United States(3), Singapore(1), Italy(2), Japan(1), France(1), Germany(1)

Objectives:

The primary objective of the trial was to characterize the safety and tolerability of LSZ102 single agent and LSZ102 + ribociclib and LSZ102 + alpelisib in adult patients with locally advanced or metastatic ER+ breast cancer and identify a recommended dose and regimen. The following related endpoints were assessed:

- Incidence of Dose-Limiting Toxicities (DLTs) during the first cycle of treatment (dose escalation only)
- Incidence and severity of adverse events (AEs) and serious adverse events (SAEs)
- Dose interruptions, dose reductions and dose intensity

The secondary objectives were:

- To evaluate the preliminary antitumor activity of LSZ102, LSZ102 + ribociclib and LSZ102 + alpelisib. The following related endpoints were assessed:
  - Overall Response Rate (ORR) per RECIST v1.1
  - Disease Control Rate (DCR) per RECIST v1.1

  - Duration of Response (DOR) per RECIST v1.1
  - Progression-Free Survival (PFS) per RECIST v1.1
- To characterize the PK properties of LSZ102, ribociclib and alpelisib in the single agent and combination arms. The following related endpoints were assessed:
  - Maximum observed plasma concentration (Cmax), time to reach maximum plasma concentration (Tmax), area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) and accumulation ratio (Racc) of LSZ102, ribociclib and alpelisib
- To assess the effect of food on PK profiles of LSZ102 under fasted and fed conditions. The following related endpoints were assessed:
  - Cmax, Tmax and AUClast of LSZ102 under fed and fasted conditions
- To assess the pharmacodynamic (PD) effect of LSZ102, ribociclib and alpelisib in the single agent and combination arms. The following related endpoints were assessed:
  - Percentage change from baseline in Estrogen Receptor (ER) – H Score
  - Percentage change from baseline in Progesterone Receptor (PR) – H Score
  - Percentage change from baseline in PS6 – Nuclear H Score, Cytoplasmic Score and Membrane Score

Test Product (s), Dose(s), and Mode(s) of Administration

The study treatments were LSZ102 single agent, LSZ102 + ribociclib (LEE011) and LSZ102 + alpelisib (BYL719). All treatments were administered orally as tablets or capsules in different food conditions (fasted, with regular meal and without regards to food).

- LSZ102 single agent: Two regimens were assessed with increasing dose levels of LSZ102.
  - LSZ102 administered once daily (QD) on Days 1 to 28 of a 28-day cycle. The dose levels of LSZ102 ranged between 200 mg and 900 mg for the QD regimen.

  - LSZ102 administered twice daily (BID) on Days 1 to 28 of a 28-day cycle. The dose levels of LSZ102 ranged between 200 mg and 300 mg for the BID regimen.

- LSZ102 + ribociclib (LEE011): Three regimens were assessed with increasing dose levels of LSZ102 and ribociclib.
  - LSZ102 administered QD on Days 1 to 28 of a 28-day cycle in combination with ribociclib administered QD on Days 1 to 21 of a 28-day cycle (intermittent regimen). The dose levels ranged between 200 mg and 600 mg for LSZ102 and between 300 mg and 600 mg for ribociclib.
  - LSZ102 administered QD on Days 1 to 28 of a 28-day cycle in combination with ribociclib administered QD on Days 1 to 28 of a 28-day cycle (continuous regimen). The dose levels ranged between 450 mg and 600 mg for LSZ102 and between 300 mg and 400 mg for ribociclib.
  - LSZ102 administered BID on Days 1 to 28 of a 28-day cycle in combination with ribociclib administered QD on Days 1 to 28 of a 28-day cycle (continuous regimen). The dose levels were 200 mg or 300 mg for LSZ102 and 200 mg for ribociclib.

- LSZ102 + alpelisib (BYL719): One regimen was assessed with increasing dose levels of LSZ102 and alpelisib.
  - LSZ102 administered QD on Days 1 to 28 of a 28-day cycle in combination with alpelisib administered QD on Days 1 to 28 of a 28-day cycle. The dose levels ranged between 300 mg and 450 mg for LSZ102 and between 200 mg and 300 mg for ribociclib.

Patients continued treatment with LSZ102 single agent or LSZ102 + ribociclib or LSZ102 + alpelisib until disease progression, unacceptable toxicity and/or treatment was discontinued at the discretion of the investigator or by patient refusal. Patients who had disease progression and had evidence of clinical benefit, such as disease shrinkage at other sites or symptomatic improvement, were allowed to continue treatment following discussion and agreement with the Novartis Medical Monitor.

Statistical Methods

Primary endpoint: An adaptive Bayesian Hierarchical Logistic Regression Model (BHLRM) (LSZ102 single agent arm) and Bayesian Logistic Regression Model (BLRM) (LSZ102+ ribociclib and LSZ102 + alpelisib arms) guided by the Escalation with Overdose Control (EWOC) criteria were used to make dose recommendations and estimate the appropriate MTD during the dose escalation part of the study. The BHLRM/BLRM were fit on the Dose Limiting Toxicity (DLT) data (i.e. absence or presence of DLT) during the DLT assessment window accumulate throughout the dose escalation to model dose-toxicity relationship.

After each cohort of patients, the posterior distribution for probability of DLT rates at each dose level in each of the treatment arm were obtained. Dose recommendation was based on the summaries of posterior distribution and the probability that the true DLT rate for each dose level lies in one of the following categories: [0, 16%] under dosing; [16%, 33%] targeted toxicity; [33%, 100%] excessive toxicity. Dose recommendation was guided by the EWOC criteria, which mandates the dose for the next cohort to have less than 25% chance of excessive toxicity.

Tolerability was assessed by summarizing the number of dose interruptions and dose reduction by treatment group. Dose intensity was summarized by treatment group.

Secondary endpoints:

Efficacy

The variables used to evaluate antitumor activity were ORR, DOR, DCR and PFS based on RECIST v1.1 by local investigator assessment. Analysis of efficacy endpoints were performed using the Full Analysis Set (FAS). ORR, DCR and their corresponding 95% confidence intervals (CIs) based on the exact binomial distribution were reported. Kaplan Meier method was used to estimate PFS.

Pharmacokinetics

PK analyses were performed based on the Pharmacokinetic Analysis Set (PAS) unless stated otherwise. PK concentration data from patients in LSZ102 single agent fasted cohorts, treatment phase of LSZ102 single agent arm food effect cohorts,

LSZ102 + ribociclib arm and LSZ102 + alpelisib arm were used to characterize PK properties of LSZ102, ribociclib and alpelisib. PK parameters were calculated using noncompartmental methods and were summarized.

To evaluate the effect of food on LSZ102, PK concentration data from food effect period of LSZ102 single agent arm was used.

Pharmacodynamics

All biomarker data summary and analysis were based on the FAS. Biomarkers of interest as part of the secondary objectives include ER, PR and pS6. For all biomarkers, change from baseline were summarized in tables.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:
- Written informed consent obtained prior to any procedures
- Histologically and/or cytologically confirmed diagnosis of ER+/HER2- breast cancer
- Advanced or metastatic breast cancer
- Must be able to swallow tablets and capsules

Exclusion Criteria:
- Symptomatic central nervous system (CNS) metastases
- Patients whose laboratory values did not meet protocol criteria
- Clinically significant cardiac disease
- Impaired gastrointestinal function (GI) or GI disease that may significantly alter the absorption of oral medications

Participant Flow Table

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 450 mg QD fasted with food effect tested at 450 mg	LSZ102 450 mg Run-in only	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 600 mg QD fasted with food effect tested at 450 mg	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions. Before the treatment period, there was a food effect run-in period with LSZ102 450 mg	Food effect run-in period with LSZ102 450 mg. Patient discontinued before entering treatment period.	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions. Before the treatment period, there was a food effect run-in period with LSZ102 450 mg	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Started	4	6	10	6	5	1	15	4	5	6	4	6	6
Dose escalation part	4	6	10	6	5	1	15	4	5	6	4	6	6
Dose expansion part	0	0	0	0	0	0	0	0	0	0	0	0	0

Completed	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed	4	6	10	6	5	1	15	4	5	6	4	6	6
Adverse Event	0	0	0	0	0	0	1	0	0	0	1	0	1
Progressive disease	4	6	9	6	5	0	13	3	5	6	3	6	5
Subject/guardian decision	0	0	1	0	0	1	1	1	0	0	0	0	0
Physician Decision	0	0	0	0	0	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0	0	0	0	0	0

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**

Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Started	5	5	4	8	6	4	4	4	4
Dose escalation part	5	5	4	6	6	4	4	4	4
Dose expansion part	0	0	0	2	0	0	0	0	0
Completed	0	0	0	0	0	0	0	0	0
Not Completed	5	5	4	8	6	4	4	4	4
Adverse Event	0	1	1	2	0	0	0	0	0
Progressive disease	5	4	3	6	6	4	4	4	4
Subject/guardian decision	0	0	0	0	0	0	0	0	0
Physician Decision	0	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0	0

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Started	6	8	6	4	6	4
Dose escalation part	6	8	6	4	6	4
Dose expansion part	0	0	0	0	0	0
Completed	0	0	0	0	0	0
Not Completed	6	8	6	4	6	4
Adverse Event	0	0	0	0	0	0
Progressive disease	6	7	6	3	6	2
Subject/guardian decision	0	1	0	1	0	2
Physician Decision	0	0	0	0	0	0
Death	0	0	0	0	0	0

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal	Total
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	
Started	12	6	12	13	199
Dose escalation part	12	6	12	13	197
Dose expansion part	0	0	0	0	2
Completed	0	0	0	0	0
Not Completed	12	6	12	13	199
Adverse Event	0	0	2	0	9
Progressive disease	11	5	9	9	175
Subject/guardian decision	0	0	1	1	10
Physician Decision	0	1	0	1	2
Death	1	0	0	2	3

Baseline Characteristics

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 450 mg QD fasted with food effect tested at 450 mg	LSZ102 450 mg Run-in only	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 600 mg QD fasted with food effect tested at 450 mg	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions. Before the treatment period, there was a food effect run-in period with LSZ102 450 mg	Food effect run-in period with LSZ102 450 mg. Patient discontinued before entering treatment period.	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions. Before the treatment period, there was a food effect run-in period with LSZ102 450 mg	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants [units: participants]	4	6	10	6	5	1	15	4	5	6	4	6	6

Age Continuous (units: years) Mean ± Standard Deviation	60.0±8.76	54.8±12.98	62.0±6.60	52.8±10.53	60.8±15.02	60.0	56.5±10.65	58.0±4.55	50.2±16.60	60.3±7.15	57.5±7.85	58.0±7.01	58.5±14.75
Sex: Female, Male (units: participants) Count of Participants (Not Applicable)													
Female	4	6	10	6	5	1	15	4	5	6	4	6	6
Male	0	0	0	0	0	0	0	0	0	0	0	0	0
Race/Ethnicity, Customized (units: participants) Count of Participants (Not Applicable)													
Caucasian	3	4	9	4	5	0	10	4	3	5	3	3	5
Black	0	0	0	0	0	0	0	0	0	0	0	0	0
Asian	1	2	1	1	0	1	2	0	2	1	1	2	0
Unknown	0	0	0	1	0	0	2	0	0	0	0	0	0
Other	0	0	0	0	0	0	1	0	0	0	0	1	1

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**

Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants [units: participants]	5	5	4	8	6	4	4	4	4
Age Continuous (units: years) Mean ± Standard Deviation									
	56.4±7.77	61.0±10.49	67.0±10.52	60.1±7.61	59.7±8.21	56.0±9.90	64.3±6.50	54.0±8.12	65.5±9.43
Sex: Female, Male (units: participants) Count of Participants (Not Applicable)									
Female	5	5	4	8	6	4	3	4	4
Male	0	0	0	0	0	0	1	0	0
Race/Ethnicity, Customized (units: participants) Count of Participants (Not Applicable)									
Caucasian	4	4	4	5	6	4	4	2	3
Black	0	0	0	1	0	0	0	1	1
Asian	0	1	0	1	0	0	0	1	0
Unknown	1	0	0	1	0	0	0	0	0

Other	0	0	0	0	0	0	0	0	0

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	**LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal**	**LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted**	**LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food**	**LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food**
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants [units: participants]	6	8	6	4	6	4
Age Continuous (units: years) Mean ± Standard Deviation						
	55.2±10.46	58.9±13.22	60.5±11.62	58.8±4.99	52.8±15.08	56.5±13.08
Sex: Female, Male (units: participants) Count of Participants (Not Applicable)						
Female	6	8	6	4	6	4
Male	0	0	0	0	0	0
Race/Ethnicity, Customized (units: participants) Count of Participants (Not Applicable)						
Caucasian	4	4	5	3	5	4
Black	0	1	1	0	0	0

Asian	0	1	0	1	1	0
Unknown	2	1	0	0	0	0
Other	0	1	0	0	0	0

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	**LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal**	**LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal**	**LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal**	**Total**
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	
Number of Participants [units: participants]	12	6	12	13	199
Age Continuous (units: years) Mean ± Standard Deviation					
	53.8±10.09	57.3±11.47	56.1±12.16	54.3±10.54	NA±NA[]
Sex: Female, Male (units: participants) Count of Participants (Not Applicable)					
Female	12	6	12	13	198
Male	0	0	0	0	1

Race/Ethnicity, Customized
(units: participants)
Count of Participants (Not Applicable)

Caucasian	10	6	8	11	154
Black	0	0	2	0	7
Asian	1	0	2	1	24
Unknown	1	0	0	1	10
Other	0	0	0	0	4

Primary Outcome Result(s)

Number of participants with Dose-Limiting Toxicities (DLTs) during the first cycle of treatment (dose escalation only)

(Time Frame: 28 days)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal

			run-in food effect cohort		run-in food effect cohort					
Number of Participants Analyzed [units: participants]	4	6	13	6	20	3	6	3	5	5
Number of participants with Dose-Limiting Toxicities (DLTs) during the first cycle of treatment (dose escalation only) (units: participants) Count of Participants (Not Applicable)										
	0 (%)	0 (%)	0 (%)	1 (16.67%)	1 (5%)	0 (%)	2 (33.33%)	0 (%)	0 (%)	0 (%)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions

Number of Participants Analyzed [units: participants]	5	4	3	5	6	4	4	4	3
Number of participants with Dose-Limiting Toxicities (DLTs) during the first cycle of treatment (dose escalation only) (units: participants) Count of Participants (Not Applicable)									
	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (66.67%)

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	**LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal**	**LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted**	**LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food**	**LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food**
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	5	4
Number of participants with Dose-Limiting Toxicities (DLTs) during the first cycle of treatment (dose escalation only) (units: participants) Count of Participants (Not Applicable)						

	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	5	11	12
Number of participants with Dose-Limiting Toxicities (DLTs) during the first cycle of treatment (dose escalation only) (units: participants) Count of Participants (Not Applicable)				
	2 (16.67%)	1 (20%)	5 (45.45%)	1 (8.33%)

Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs)

(Time Frame: From first dose of study medication in the Treatment period up to 30 days after last dose, with a maximum duration of 2.9 years)

LSZ102 single agent (1/4)

LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal

Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	4	6	15	6	20	4	6	4	6	6
Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) (units: participants) Count of Participants (Not Applicable)										
AEs	4 (100%)	6 (100%)	15 (100%)	6 (100%)	20 (100%)	4 (100%)	6 (100%)	4 (100%)	6 (100%)	6 (100%)
Treatment-related AEs	2 (50%)	6 (100%)	13 (86.67%)	4 (66.67%)	20 (100%)	4 (100%)	6 (100%)	4 (100%)	6 (100%)	5 (83.33%)
SAEs	1 (25%)	1 (16.67%)	3 (20%)	1 (16.67%)	7 (35%)	0 (%)	1 (16.67%)	2 (50%)	3 (50%)	2 (33.33%)
Treatment-related SAEs	0 (%)	0 (%)	0 (%)	0 (%)	1 (5%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
AEs leading to discontinuation	0 (%)	0 (%)	1 (6.67%)	0 (%)	1 (5%)	0 (%)	0 (%)	1 (25%)	0 (%)	1 (16.67%)

Treatment-related AEs leading to discontinuation	0 (%)	0 (%)	0 (%)	0 (%)	1 (5%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
AEs requiring dose interruption and/or change	1 (25%)	2 (33.33%)	3 (20%)	3 (50%)	5 (25%)	0 (%)	3 (50%)	1 (25%)	2 (33.33%)	1 (16.67%)
Treatment-related AEs requiring dose interruption and/or change	0 (%)	2 (33.33%)	2 (13.33%)	2 (33.33%)	5 (25%)	0 (%)	3 (50%)	0 (%)	1 (16.67%)	0 (%)
AEs requiring additional therapy	3 (75%)	6 (100%)	13 (86.67%)	6 (100%)	16 (80%)	2 (50%)	6 (100%)	4 (100%)	6 (100%)	5 (83.33%)
Treatment-related AEs requiring additional therapy	1 (25%)	3 (50%)	9 (60%)	3 (50%)	14 (70%)	2 (50%)	6 (100%)	4 (100%)	4 (66.67%)	5 (83.33%)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**

					staggered dosing	staggered dosing	regards to food		
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	5	5	4	8	6	4	4	4	4
Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) (units: participants) Count of Participants (Not Applicable)									
AEs	5 (100%)	5 (100%)	4 (100%)	8 (100%)	5 (83.33%)	4 (100%)	4 (100%)	4 (100%)	4 (100%)
Treatment-related AEs	5 (100%)	5 (100%)	3 (75%)	7 (87.5%)	5 (83.33%)	3 (75%)	4 (100%)	4 (100%)	4 (100%)
SAEs	1 (20%)	3 (60%)	1 (25%)	5 (62.5%)	0 (%)	2 (50%)	1 (25%)	0 (%)	4 (100%)
Treatment-related SAEs	0 (%)	2 (40%)	0 (%)	3 (37.5%)	0 (%)	0 (%)	1 (25%)	0 (%)	4 (100%)
AEs leading to discontinuation	0 (%)	1 (20%)	2 (50%)	2 (25%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Treatment-related AEs	0 (%)	1 (20%)	1 (25%)	2 (25%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

leading to discontinuation									
AEs requiring dose interruption and/or change	3 (60%)	3 (60%)	1 (25%)	4 (50%)	3 (50%)	2 (50%)	2 (50%)	2 (50%)	4 (100%)
Treatment-related AEs requiring dose interruption and/or change	2 (40%)	3 (60%)	1 (25%)	3 (37.5%)	3 (50%)	2 (50%)	2 (50%)	1 (25%)	4 (100%)
AEs requiring additional therapy	4 (80%)	4 (80%)	4 (100%)	7 (87.5%)	5 (83.33%)	4 (100%)	4 (100%)	4 (100%)	4 (100%)
Treatment-related AEs requiring additional therapy	2 (40%)	3 (60%)	3 (75%)	5 (62.5%)	5 (83.33%)	3 (75%)	4 (100%)	3 (75%)	4 (100%)

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	**LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal**	**LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted**	**LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food**	**LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food**
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered

	orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	orally QD on Days 1 to 28 of a 28-day cycle with regular meal	orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4
Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) (units: participants) Count of Participants (Not Applicable)						
AEs	6 (100%)	8 (100%)	6 (100%)	4 (100%)	6 (100%)	4 (100%)
Treatment-related AEs	6 (100%)	8 (100%)	6 (100%)	3 (75%)	6 (100%)	4 (100%)
SAEs	0 (%)	1 (12.5%)	0 (%)	0 (%)	1 (16.67%)	1 (25%)
Treatment-related SAEs	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	0 (%)
AEs leading to discontinuation	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Treatment-related AEs leading to discontinuation	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
AEs requiring dose interruption and/or change	1 (16.67%)	5 (62.5%)	4 (66.67%)	1 (25%)	4 (66.67%)	2 (50%)
Treatment-related AEs requiring dose interruption and/or change	1 (16.67%)	3 (37.5%)	3 (50%)	1 (25%)	4 (66.67%)	2 (50%)
AEs requiring additional therapy	5 (83.33%)	5 (62.5%)	5 (83.33%)	3 (75%)	5 (83.33%)	4 (100%)

Treatment-related AEs requiring additional therapy	4 (66.67%)	4 (50%)	5 (83.33%)	3 (75%)	5 (83.33%)	2 (50%)

LSZ102 + alpelisib

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	**LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal**	**LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal**	**LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal**
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13
Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) (units: participants) Count of Participants (Not Applicable)				
AEs	12 (100%)	6 (100%)	12 (100%)	13 (100%)
Treatment-related AEs	12 (100%)	6 (100%)	11 (91.67%)	13 (100%)
SAEs	4 (33.33%)	1 (16.67%)	10 (83.33%)	5 (38.46%)
Treatment-related SAEs	2 (16.67%)	0 (%)	6 (50%)	2 (15.38%)
AEs leading to discontinuation	2 (16.67%)	1 (16.67%)	4 (33.33%)	2 (15.38%)

Treatment-related AEs leading to discontinuation	2 (16.67%)	1 (16.67%)	0 (%)	1 (7.69%)
AEs requiring dose interruption and/or change	7 (58.33%)	4 (66.67%)	10 (83.33%)	8 (61.54%)
Treatment-related AEs requiring dose interruption and/or change	5 (41.67%)	3 (50%)	9 (75%)	6 (46.15%)
AEs requiring additional therapy	12 (100%)	6 (100%)	12 (100%)	12 (92.31%)
Treatment-related AEs requiring additional therapy	11 (91.67%)	5 (83.33%)	11 (91.67%)	11 (84.62%)

Number of participants with dose reductions and dose interruptions of LSZ102, ribociclib and alpelisib

(Time Frame: From first dose of study medication in the Treatment period up to last dose, with a maximum duration of 2.8 years)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal

			treatment period were enrolled in the run-in food effect cohort		treatment period were enrolled in the run-in food effect cohort					
Number of Participants Analyzed [units: participants]	4	6	15	6	20	4	6	4	6	6
Number of participants with dose reductions and dose interruptions of LSZ102, ribociclib and alpelisib (units: participants) Count of Participants (Not Applicable)										
LSZ102 dose reduction	0 (%)	0 (%)	1 (6.67%)	0 (%)	2 (10%)	0 (%)	4 (66.67%)	0 (%)	0 (%)	0 (%)
LSZ102 dose interruption	2 (50%)	2 (33.33%)	5 (33.33%)	4 (66.67%)	8 (40%)	1 (25%)	4 (66.67%)	2 (50%)	4 (66.67%)	2 (33.33%)
Ribociclib dose reduction (n=0)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)
Ribociclib dose interruption (n=0)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)
Alpelisib dose reduction (n=0)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)
Alpelisib dose interruption (n=0)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal	LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing	LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food	LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	5	5	4	8	6	4	4	4	4
Number of participants with dose reductions and dose interruptions of LSZ102, ribociclib and alpelisib (units: participants) Count of Participants (Not Applicable)									
LSZ102 dose reduction	0 (%)	0 (%)	1 (25%)	0 (%)	1 (16.67%)	0 (%)	0 (%)	0 (%)	1 (25%)
LSZ102 dose interruption	3 (60%)	3 (60%)	1 (25%)	6 (75%)	1 (16.67%)	2 (50%)	2 (50%)	2 (50%)	4 (100%)
Ribociclib dose reduction	0 (%)	1 (20%)	1 (25%)	0 (%)	0 (%)	0 (%)	1 (25%)	0 (%)	1 (25%)

Ribociclib dose interruption	5 (100%)	4 (80%)	3 (75%)	8 (100%)	6 (100%)	4 (100%)	4 (100%)	4 (100%)	4 (100%)
Alpelisib dose reduction (n=0)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)
Alpelisib dose interruption (n=0)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	**LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal**	**LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted**	**LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food**	**LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food**
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4

Number of participants with dose reductions and dose interruptions of LSZ102, ribociclib and alpelisib
(units: participants)
Count of Participants (Not Applicable)

LSZ102 dose reduction	1 (16.67%)	0 (%)	1 (16.67%)	0 (%)	1 (16.67%)	0 (%)
LSZ102 dose interruption	2 (33.33%)	4 (50%)	5 (83.33%)	1 (25%)	3 (50%)	4 (100%)
Ribociclib dose reduction	2 (33.33%)	1 (12.5%)	2 (33.33%)	0 (%)	2 (33.33%)	1 (25%)
Ribociclib dose interruption	2 (33.33%)	5 (62.5%)	5 (83.33%)	1 (25%)	4 (66.67%)	4 (100%)
Alpelisib dose reduction (n=0)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)
Alpelisib dose interruption (n=0)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	**LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal**	**LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal**	**LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal**
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13
Number of participants with dose reductions and dose interruptions of LSZ102, ribociclib and alpelisib (units: participants) Count of Participants (Not Applicable)				
LSZ102 dose reduction	0 (%)	0 (%)	2 (16.67%)	1 (7.69%)

LSZ102 dose interruption	9 (75%)	3 (50%)	10 (83.33%)	8 (61.54%)
Ribociclib dose reduction (n=0)	(NaN%)	(NaN%)	(NaN%)	(NaN%)
Ribociclib dose interruption (n=0)	(NaN%)	(NaN%)	(NaN%)	(NaN%)
Alpelisib dose reduction	2 (16.67%)	1 (16.67%)	4 (33.33%)	1 (7.69%)
Alpelisib dose interruption	9 (75%)	4 (66.67%)	10 (83.33%)	8 (61.54%)

Dose intensity of LSZ102, ribociclib and alpelisib

(Time Frame: From first dose of study medication in the Treatment period up to last dose, with a maximum duration of 2.8 years)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal

			period were enrolled in the run-in food effect cohort		period were enrolled in the run-in food effect cohort					
Number of Participants Analyzed [units: participants]	4	6	15	6	20	4	6	4	6	6
Dose intensity of LSZ102, ribociclib and alpelisib (units: mg/day) Median (Full Range)										
LSZ102	198.61 (196.4 to 200.0)	400.00 (394.3 to 443.2)	450.00 (155.8 to 450.0)	442.02 (217.2 to 450.0)	600.00 (331.9 to 600.0)	600.00 (557.9 to 600.0)	644.33 (362.5 to 900.0)	197.62 (96.3 to 200.0)	216.43 (144.6 to 225.0)	300.0 (150.0 to 300.0)
Ribociclib (n=0)										
Alpelisib (n=0)										

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg

	administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	5	5	4	8	6	4	4	4	4
Dose intensity of LSZ102, ribociclib and alpelisib (units: mg/day) Median (Full Range)									
LSZ102	196.95 (192.8 to 200.0)	389.74 (353.1 to 400.0)	396.55 (225.4 to 400.0)	447.21 (228.4 to 450.0)	450.00 (359.2 to 450.0)	439.13 (419.8 to 450.0)	437.47 (397.4 to 450.0)	589.49 (553.8 to 600.0)	528.93 (420.8 to 590.8)
Ribociclib	223.00 (215.8 to 233.3)	225.00 (154.3 to 300.0)	323.79 (169.7 to 400.0)	299.45 (149.3 to 400.0)	225.23 (173.4 to 230.4)	294.37 (222.8 to 317.0)	444.21 (410.2 to 450.0)	229.95 (221.1 to 257.1)	238.35 (176.7 to 293.9)
Alpelisib (n=0)									

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food

Number of Participants Analyzed [units: participants]	6	8	6	4	6	4
Dose intensity of LSZ102, ribociclib and alpelisib (units: mg/day) Median (Full Range)						
LSZ102	449.62 (342.1 to 450.0)	448.97 (443.6 to 450.0)	431.32 (311.9 to 450.0)	600.00 (390.7 to 600.0)	195.27 (167.3 to 200.0)	288.07 (278.7 to 298.3)
Ribociclib	299.44 (164.7 to 300.0)	393.61 (311.3 to 400.0)	316.38 (284.4 to 400.0)	300.00 (195.3 to 300.0)	185.19 (107.2 to 200.0)	186.63 (144.6 to 198.9)
Alpelisib (n=0)						

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	**LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal**	**LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal**	**LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal**
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13
Dose intensity of LSZ102, ribociclib and alpelisib (units: mg/day) Median (Full Range)				
LSZ102	297.28 (85.7 to 300.0)	291.79 (194.7 to 300.0)	244.51 (109.1 to 300.0)	429.07 (120.4 to 450.0)

Ribociclib (n=0)				
Alpelisib	183.89 (57.1 to 200.0)	207.84 (122.9 to 250.0)	185.85 (91.4 to 300.0)	190.70 (104.3 to 200.0)

Secondary Outcome Result(s)

Overall Response Rate (ORR) per RECIST v1.1

(Time Frame: From start of treatment until end of treatment, assessed up to 2.8 years)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	4	6	15	6	20	4	6	4	6	6

Overall Response Rate (ORR) per RECIST v1.1
(units: Percentage of participants)
Number (95% Confidence Interval)

	0.0 (0.0 to 60.2)	0.0 (0.0 to 45.9)	0.0 (0.0 to 21.8)	0.0 (0.0 to 45.9)	5.0 (0.1 to 24.9)	0.0 (0.0 to 60.2)	0.0 (0.0 to 45.9)	0.0 (0.0 to 60.2)	0.0 (0.0 to 45.9)	0.0 (0.0 to 45.9)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	5	5	4	8	6	4	4	4	4

Overall Response Rate (ORR) per RECIST v1.1
(units: Percentage of participants)
Number (95% Confidence Interval)

20.0 (0.5 to 71.6)	0.0 (0.0 to 52.2)	0.0 (0.0 to 60.2)	37.5 (8.5 to 75.5)	0.0 (0.0 to 45.9)	0.0 (0.0 to 60.2)	25.0 (0.6 to 80.6)	0.0 (0.0 to 60.2)	0.0 (0.0 to 60.2)

LZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4
Overall Response Rate (ORR) per RECIST v1.1 (units: Percentage of participants) Number (95% Confidence Interval)						
	33.3 (4.3 to 77.7)	25.0 (3.2 to 65.1)	0.0 (0.0 to 45.9)	25.0 (0.6 to 80.6)	50.0 (11.8 to 88.2)	25.0 (0.6 to 80.6)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28

	of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13
Overall Response Rate (ORR) per RECIST v1.1 (units: Percentage of participants) Number (95% Confidence Interval)				
	8.3 (0.2 to 38.5)	0.0 (0.0 to 45.9)	16.7 (2.1 to 48.4)	7.7 (0.2 to 36.0)

Disease Control Rate (DCR) per RECIST v1.1

(Time Frame: From start of treatment until end of treatment, assessed up to 2.8 years)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal

Number of Participants Analyzed [units: participants]	4	6	15	6	20	4	6	4	6	6
Disease Control Rate (DCR) per RECIST v1.1 (units: Percentage of participants) Number (95% Confidence Interval)										
	75.0 (19.4 to 99.4)	66.7 (22.3 to 95.7)	13.3 (1.7 to 40.5)	50.0 (11.8 to 88.2)	35.0 (15.4 to 59.2)	25.0 (0.6 to 80.6)	50.0 (11.8 to 88.2)	50.0 (6.8 to 93.2)	66.7 (22.3 to 95.7)	0.0 (0.0 to 45.9)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants	5	5	4	8	6	4	4	4	4

Analyzed [units: participants]									
Disease Control Rate (DCR) per RECIST v1.1 (units: Percentage of participants) Number (95% Confidence Interval)									
	60.0 (14.7 to 94.7)	60.0 (14.7 to 94.7)	25.0 (0.6 to 80.6)	50.0 (15.7 to 84.3)	66.7 (22.3 to 95.7)	50.0 (6.8 to 93.2)	75.0 (19.4 to 99.4)	75.0 (19.4 to 99.4)	75.0 (19.4 to 99.4)

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4
Disease Control Rate (DCR) per RECIST v1.1 (units: Percentage of participants) Number (95% Confidence Interval)						
	83.3 (35.9 to 99.6)	75.0 (34.9 to 96.8)	100.0 (54.1 to 100.0)	50.0 (6.8 to 93.2)	83.3 (35.9 to 99.6)	100.0 (39.8 to 100.0)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13
Disease Control Rate (DCR) per RECIST v1.1 (units: Percentage of participants) Number (95% Confidence Interval)				
	66.7 (34.9 to 90.1)	83.3 (35.9 to 99.6)	41.7 (15.2 to 72.3)	61.5 (31.6 to 86.1)

Duration of Response (DOR) per RECIST v1.1

(Time Frame: From first documented response to first documented disease progression or death due to any cause, assessed up to 2.8 years)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle

	under fasted conditions	under fasted conditions	conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	with regular meal	conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	with regular meal	under fasted conditions	without regards to food	with regular meal	with regular meal
Number of Participants Analyzed [units: participants]	0	0	0	0	1	0	0	0	0	0
Duration of Response (DOR) per RECIST v1.1 (units: days) Median (Full Range)					97 (97 to 97)					

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a

	28-day cycle under fasted conditions	28-day cycle under fasted conditions	28-day cycle under fasted conditions	28-day cycle with regular meal	28-day cycle with regular meal in staggered dosing	28-day cycle with regular meal in staggered dosing	28-day cycle without regards to food	28-day cycle under fasted conditions	28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	1	0	0	3	0	0	1	0	0
Duration of Response (DOR) per RECIST v1.1 (units: days) Median (Full Range)									
	90 (90 to 90)			254 (85 to 553)			166 (166 to 166)		

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	**LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal**	**LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted**	**LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food**	**LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food**
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	2	2	0	1	3	1
Duration of Response (DOR) per RECIST v1.1 (units: days) Median (Full Range)						

	387.5 (106 to 669)	497 (229 to 765)		140 (140 to 140)	238 (169 to 561)	813 (813 to 813)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	1	0	2	1
Duration of Response (DOR) per RECIST v1.1 (units: days) Median (Full Range)				
	148 (148 to 148)		171.5 (169 to 174)	596 (596 to 596)

Progression-Free Survival (PFS) per RECIST v1.1

(Time Frame: From start of treatment until first documented progression or death due to any cause, assessed up to 2.8 years)

LSZ102 single agent (1/4)

LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal

Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	4	6	15	6	20	4	6	4	6	6
Progression-Free Survival (PFS) per RECIST v1.1 (units: months) Median (95% Confidence Interval)										
	5.8 (1.7 to NA)[1]	7.4 (1.7 to NA)[1]	1.7 (1.6 to 1.8)	2.5 (0.9 to 3.6)	1.8 (1.6 to 4.8)	1.9 (1.4 to NA)[1]	2.7 (1.8 to 3.6)	2.7 (0.7 to NA)[1]	3.0 (1.6 to 3.9)	1.7 (0.7 to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**

					staggered dosing	staggered dosing	regards to food		
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	5	5	4	8	6	4	4	4	4
Progression-Free Survival (PFS) per RECIST v1.1 (units: months) Median (95% Confidence Interval)									
	4.4 (1.6 to NA)[1]	6.1 (1.7 to NA)[1]	1.6 (1.6 to NA)[1]	9.0 (2.9 to NA)[1]	4.9 (1.8 to NA)[1]	5.3 (1.7 to NA)[1]	6.3 (1.6 to NA)[1]	4.9 (1.6 to NA)[1]	6.5 (1.5 to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on

	of a 28-day cycle under fasted conditions	of a 28-day cycle under fasted conditions	of a 28-day cycle with regular meal	of a 28-day cycle under fasted conditions	Days 1 to 28 of a 28-day cycle without regards to food	Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4
Progression-Free Survival (PFS) per RECIST v1.1 (units: months) Median (95% Confidence Interval)						
	6.4 (6.0 to 7.0)	9.1 (1.8 to NA)[1]	6.0 (3.7 to NA)[1]	3.7 (1.6 to NA)[1]	7.8 (3.7 to 17.3)	6.2 (5.7 to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	**LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal**	**LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal**	**LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal**
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13
Progression-Free Survival (PFS) per RECIST v1.1 (units: months) Median (95% Confidence Interval)				
	3.5 (1.7 to 5.5)	3.6 (1.7 to NA)[1]	3.6 (1.8 to 9.4)	3.3 (1.8 to 6.3)

[1] Not estimable due to insufficient number of participants with events.

Maximum observed plasma concentration (Cmax) of LSZ102

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	4	6	15	6	20	3	6	3	6	6
Maximum observed plasma concentration (Cmax) of LSZ102 (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)										
Cycle 1 Day 1 (n=4,6,15,6,20,3,6, 3,6,6)	2040 (117.2 %)	4470 (42.1 %)	3970 (44.3 %)	1810 (68.4 %)	5310 (34.8 %)	7590 (20.1 %)	6060 (24.3 %)	1650 (46.9 %)	2240 (74.1 %)	3230 (61.6 %)

Cycle 1 Day 28 (n=4,5,12,5,17,3,5, 2,6,2)	1100 (146.2 %)	4200 (77.1 %)	3830 (44.4 %)	2620 (46.5 %)	6490 (37.7 %)	6330 (8.6 %)	6860 (31.4 %)	1990 (57.6 %)	2340 (111.0 %)	4350 (55.9 %)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	5	5	4	6	6	4	3	4	4

Maximum observed plasma concentration (Cmax) of LSZ102
(units: ng/mL)
Geometric Mean (Geometric Coefficient of Variation)

Cycle 1 Day 1 (n=5,5,3,6,6,4,2,4,4)	1750 (65.9 %)	2690 (196.6 %)	2030 (20.0 %)	3140 (51.5 %)	2140 (98.5 %)	4960 (35.0 %)	3300 (17.3 %)	2420 (90.8 %)	2700 (117.4 %)
Cycle 1 Day 28 (n=0)									

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	**LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal**	**LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted**	**LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food**	**LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food**
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4
Maximum observed plasma concentration (Cmax) of LSZ102 (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)						
Cycle 1 Day 1 (n=6,8,6,4,5,4)	2460 (82.0%)	2430 (71.1%)	5740 (26.1%)	3530 (40.6%)	1740 (41.8%)	1930 (34.2%)
Cycle 1 Day 28 (n=6,7,6,3,5,3)	3190 (39.0%)	3060 (61.9%)	4450 (35.6%)	3680 (45.5%)	2230 (52.4%)	2920 (33.9%)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13
Maximum observed plasma concentration (Cmax) of LSZ102 (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)				
Cycle 1 Day 1 (n=12,6,11,12)	3670 (55.7%)	3860 (19.4%)	2790 (69.2%)	5100 (37.8%)
Cycle 1 Day 28 (n=8,3,6,10)	3910 (52.9%)	3540 (10.5%)	3180 (27.3%)	5200 (34.7%)

Time to reach maximum plasma concentration (Tmax) of LSZ102

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once	LSZ102 400 mg administered orally once	LSZ102 450 mg administered orally once	LSZ102 450 mg administered orally once	LSZ102 600 mg administered orally once	LSZ102 600 mg administered orally once	LSZ102 900 mg administered orally once	LSZ102 200 mg administered orally twice	LSZ102 225 mg administered orally twice	LSZ102 300 mg administered orally twice

	daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	4	6	15	6	20	3	6	3	6	6
Time to reach maximum plasma concentration (Tmax) of LSZ102 (units: hours) Median (Full Range)										
Cycle 1 Day 1 (n=4,6,15,6,20,3,6,3,6,6)	2.03 (1.17 to 2.23)	2.00 (1.17 to 4.00)	2.08 (1.92 to 6.00)	2.08 (1.98 to 6.00)	2.04 (0.5 to 4.33)	2.08 (2.00 to 4.00)	3.05 (2.00 to 7.67)	2.00 (1.00 to 4.17)	3.03 (0.567 to 4.20)	2.06 (1.08 to 6.00)
Cycle 1 Day 28 (n=4,5,12,5,17,3,5,2,6,2)	2.17 (2.00 to 7.50)	2.00 (1.95 to 2.48)	2.03 (1.00 to 6.18)	2.25 (1.18 to 6.00)	2.05 (0.5 to 3.80)	1.08 (1.00 to 4.08)	3.00 (1.05 to 4.17)	2.50 (1.00 to 4.00)	2.56 (0.683 to 6.00)	3.17 (2.33 to 4.00)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1**

	week off fasted	week off fasted	week off fasted	with regular meal	with regular meal in staggered dosing	with regular meal in staggered dosing	without regards to food	week off fasted	week off fasted
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	5	5	4	6	6	4	3	4	4
Time to reach maximum plasma concentration (Tmax) of LSZ102 (units: hours) Median (Full Range)									
Cycle 1 Day 1 (n=5,5,3,6,6,4,2,4,4)	2.00 (0.783 to 3.83)	2.23 (0.5 to 6.25)	2.13 (2.12 to 3.50)	3.12 (2.00 to 4.15)	2.00 (1.98 to 4.25)	1.97 (0.983 to 2.00)	4.98 (4.03 to 5.92)	2.03 (1.13 to 4.18)	2.17 (1.32 to 5.97)
Cycle 1 Day 28 (n=0)									

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food

Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4
Time to reach maximum plasma concentration (Tmax) of LSZ102 (units: hours) Median (Full Range)						
Cycle 1 Day 1 (n=6,8,6,4,5,4)	2.17 (2.05 to 4.08)	4.00 (2.05 to 4.17)	2.15 (1.85 to 4.50)	2.17 (2.03 to 4.00)	4.00 (1.97 to 4.00)	3.00 (1.18 to 4.00)
Cycle 1 Day 28 (n=6,7,6,3,5,3)	2.15 (2.00 to 7.97)	3.92 (2.10 to 6.00)	2.00 (1.90 to 4.58)	2.12 (1.13 to 4.00)	2.00 (1.00 to 4.00)	2.00 (2.00 to 2.00)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	**LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal**	**LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal**	**LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal**
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13

Time to reach maximum plasma concentration (Tmax) of LSZ102
(units: hours)
Median (Full Range)

Cycle 1 Day 1 (n=12,6,11,12)	2.00 (0.717 to 5.17)	2.00 (0.717 to 4.00)	2.13 (1.03 to 7.58)	1.96 (0.65 to 4.15)
Cycle 1 Day 28 (n=8,3,6,10)	2.04 (0.667 to 4.17)	1.00 (0.983 to 1.00)	2.08 (1.00 to 7.60)	2.00 (0.583 to 4.00)

Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of LSZ102

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	4	6	15	6	20	3	6	3	6	6

Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of LSZ102
(units: hr*(ng/mL))
Geometric Mean (Geometric Coefficient of Variation)

Cycle 1 Day 1 (n=4,6,15,6,20,3,6, 3,6,6)	5320 (62. 6%)	15400 (61. 5%)	15000 (38. 6%)	11200 (65. 3%)	23400 (40. 8%)	23800 (44. 1%)	45700 (30. 4%)	4000 (48. 5%)	5710 (62. 2%)	9690 (35.4 %)
Cycle 1 Day 28 (n=4,5,12,5,17,3,5, 2,6,2)	5210 (53. 4%)	15300 (74. 2%)	18300 (70. 6%)	11900 (29. 2%)	24900 (43. 2%)	23100 (44. 3%)	36800 (67. 7%)	4870 (12. 0%)	6820 (81. 4%)	15800 (40. 8%)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants	5	5	4	6	6	4	3	4	4

Analyzed [units: participants]									
Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of LSZ102 (units: hr*(ng/mL)) Geometric Mean (Geometric Coefficient of Variation)									
Cycle 1 Day 1 (n=5,5,3,6,6,4,2,4,4)	7040 (33.6 %)	13000 (83.7 %)	6780 (29.5 %)	12300 (75.4 %)	12600 (64.9 %)	14900 (19.0 %)	27500 (14.5 %)	9880 (95.6 %)	10400 (93.9 %)
Cycle 1 Day 28 (n=0)									

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4
Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of LSZ102 (units: hr*(ng/mL)) Geometric Mean (Geometric Coefficient of Variation)						
Cycle 1 Day 1 (n=6,8,6,4,5,4)	10200 (42.1%)	12100 (59.1%)	20900 (42.5%)	15400 (53.7%)	4800 (42.9%)	6810 (24.0%)

Cycle 1 Day 28 (n=6,7,6,3,5,3)	9380 (53.6%)	11100 (64.5%)	20700 (45.0%)	16900 (46.7%)	6320 (20.7%)	9090 (26.9%)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13
Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of LSZ102 (units: hr*(ng/mL)) Geometric Mean (Geometric Coefficient of Variation)				
Cycle 1 Day 1 (n=12,6,11,12)	11800 (44.3%)	12600 (31.2%)	13100 (56.4%)	18900 (32.1%)
Cycle 1 Day 28 (n=8,3,6,10)	12800 (57.7%)	12000 (28.0%)	15000 (57.5%)	22000 (29.7%)

Accumulation ratio (Racc) of LSZ102

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with	LSZ102 900 mg QD fasted	LSZ102 200 mg BID	LSZ102 225 mg BID with	LSZ102 300 mg BID

				regular meal		regular meal		without regards to food	regular meal	with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	3	5	9	4	16	3	4	1	3	1
Accumulation ratio (Racc) of LSZ102 (units: ratio) Geometric Mean (Geometric Coefficient of Variation)										
Cycle 1 Day 28 (n=3,5,9,4,16,3,4,1,3,1)	0.883 (36.7 %)	0.942 (43.0 %)	1.37 (36.9 %)	1.17 (47.8 %)	1.06 (30.7 %)	1.00 (32.0 %)	0.975 (38.6 %)	1.87	1.45 (71.0 %)	2.94

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**

					staggered dosing	staggered dosing	regards to food		
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	0	0	0	0	0	0	0	0	0
Accumulation ratio (Racc) of LSZ102 (units: ratio) Geometric Mean (Geometric Coefficient of Variation)									
Cycle 1 Day 28 (n=0)									

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day

	of a 28-day cycle under fasted conditions	of a 28-day cycle under fasted conditions	of a 28-day cycle with regular meal	of a 28-day cycle under fasted conditions	cycle without regards to food	cycle without regards to food
Number of Participants Analyzed [units: participants]	5	4	5	2	3	3
Accumulation ratio (Racc) of LSZ102 (units: ratio) Geometric Mean (Geometric Coefficient of Variation)						
Cycle 1 Day 28 (n=5,4,5,2,3,3)	1.06 (85.9%)	1.15 (23.5%)	1.05 (43.5%)	1.45 (203.8%)	1.00 (0.0%)	1.04 (7.0%)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	**LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal**	**LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal**	**LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal**
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	7	3	6	9
Accumulation ratio (Racc) of LSZ102 (units: ratio) Geometric Mean (Geometric Coefficient of Variation)				
Cycle 1 Day 28 (n=7,3,6,9)	1.20 (35.5%)	0.962 (64.7%)	0.945 (37.8%)	1.20 (37.4%)

Maximum observed plasma concentration (Cmax) of ribociclib

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

LSZ102 + ribociclib intermittent (1/2)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal	LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing	LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food	LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	5	5	4	6	6	4	3	4	4
Maximum observed plasma concentration (Cmax) of ribociclib (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)									
Cycle 1 Day 1 (n=5,5,3,6,6,4,2,4,4)	700 (87.5%)	599 (66.0%)	763 (78.4%)	720 (34.2%)	417 (69.8%)	367 (18.8%)	1730 (31.1%)	578 (107.4%)	620 (30.8%)

Cycle 1 Day 28
(n=0)

LSZ102 + ribociclib continuous (2/2)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4
Maximum observed plasma concentration (Cmax) of ribociclib (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)						
Cycle 1 Day 1 (n=6,8,6,4,5,4)	382 (79.1%)	610 (78.7%)	725 (59.6%)	451 (63.6%)	260 (40.1%)	253 (4.8%)
Cycle 1 Day 28 (n=6,7,6,3,5,3)	474 (66.0%)	745 (50.6%)	1040 (84.0%)	427 (34.9%)	732 (38.8%)	400 (75.7%)

Time to reach maximum plasma concentration (Tmax) of ribociclib

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

LSZ102 + ribociclib intermittent (1/2)

	LSZ102 200 mg QD +	LSZ102 400 mg QD +	LSZ102 400 mg QD +	LSZ102 450 mg QD +	LSZ102 450 mg QD +	LSZ102 450 mg QD +	LSZ102 450 mg QD +	LSZ102 600 mg QD +	LSZ102 600 mg QD +

	LEE011 300 mg QD 3 weeks on 1 week off fasted	LEE011 300 mg QD 3 weeks on 1 week off fasted	LEE011 400 mg QD 3 weeks on 1 week off fasted	LEE011 400 mg QD 3 weeks on 1 week off with regular meal	LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing	LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing	LEE011 600 mg QD 3 weeks on 1 week off without regards to food	LEE011 300 mg QD 3 weeks on 1 week off fasted	LEE011 400 mg QD 3 weeks on 1 week off fasted
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	5	5	4	6	6	4	3	4	4
Time to reach maximum plasma concentration (Tmax) of ribociclib (units: hours) Median (Full Range)									
Cycle 1 Day 1 (n=5,5,3,6,6,4,2,4,4)	2.00 (1.27 to 2.28)	2.22 (2.00 to 4.32)	3.50 (2.12 to 3.97)	2.15 (1.13 to 4.45)	2.43 (1.00 to 5.08)	1.93 (1.00 to 4.83)	3.99 (3.95 to 4.03)	1.99 (1.13 to 3.63)	2.17 (2.12 to 3.93)
Cycle 1 Day 28 (n=0)									

LSZ102 + ribociclib continuous (2/2)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4
Time to reach maximum plasma concentration (Tmax) of ribociclib (units: hours) Median (Full Range)						
Cycle 1 Day 1 (n=6,8,6,4,5,4)	3.08 (2.10 to 4.08)	3.16 (1.08 to 4.12)	2.24 (1.08 to 4.08)	2.06 (2.00 to 2.25)	4.00 (1.97 to 4.00)	2.00 (1.18 to 2.00)
Cycle 1 Day 28 (n=6,7,6,3,5,3)	2.06 (2.00 to 2.17)	3.93 (2.10 to 4.37)	1.53 (1.00 to 2.00)	2.07 (1.08 to 4.27)	1.93 (1.00 to 4.00)	2.00 (1.00 to 3.67)

Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of ribociclib

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

LSZ102 + ribociclib intermittent (1/2)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1	LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1	LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with	LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with	LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without	LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1	LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1

	week off fasted	week off fasted	week off fasted	regular meal	regular meal in staggered dosing	regular meal in staggered dosing	regards to food	week off fasted	week off fasted
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	5	5	4	6	6	4	3	4	4
under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of ribociclib (units: hr*(ng/mL)) Geometric Mean (Geometric Coefficient of Variation)									
Cycle 1 Day 1 (n=5,5,3,6,6,4,2,4,4)	5750 (87.7 %)	3870 (52.9 %)	5410 (125.2 %)	6800 (28.6 %)	3990 (57.4 %)	3860 (34.6 %)	18500 (29.1 %)	4280 (149.4 %)	4810 (36.6 %)
Cycle 1 Day 28 (n=0)									

LSZ102 + ribociclib continuous (2/2)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food

Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4
Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of ribociclib (units: hr*(ng/mL)) Geometric Mean (Geometric Coefficient of Variation)						
Cycle 1 Day 1 (n=6,8,6,4,5,4)	3310 (66.9%)	6180 (73.7%)	5900 (38.1%)	3830 (63.9%)	1150 (44.1%)	1000 (48.4%)
Cycle 1 Day 28 (n=6,7,6,3,5,3)	3410 (113.9%)	5660 (45.9%)	8000 (99.0%)	4720 (15.8%)	4200 (37.8%)	2150 (406%)

Accumulation ratio (Racc) of ribociclib

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

LSZ102 + ribociclib intermittent (1/2)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal	LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing	LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food	LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1	LSZ102 400 mg administered orally once daily (QD) on Days 1	LSZ102 400 mg administered orally once daily (QD) on Days 1	LSZ102 450 mg administered orally once daily (QD) on Days 1	LSZ102 450 mg administered orally once daily (QD) on Days 1	LSZ102 450 mg administered orally once daily (QD) on Days 1	LSZ102 450 mg administered orally once daily (QD) on Days 1	LSZ102 600 mg administered orally once daily (QD) on Days 1	LSZ102 600 mg administered orally once daily (QD) on Days 1

	to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	0	0	0	0	0	0	0	0	0
Accumulation ratio (Racc) of ribociclib (units: ratio) Geometric Mean (Geometric Coefficient of Variation)									
Cycle 1 Day 28 (n=0)									

LSZ102 + ribociclib continuous (2/2)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	**LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal**	**LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted**	**LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food**	**LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food**
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	7	6	3	4	3

Accumulation ratio (Racc) of ribociclib (units: ratio) Geometric Mean (Geometric Coefficient of Variation)						
Cycle 1 Day 28 (n=6,7,6,3,4,3)	1.03 (93.3%)	0.967 (62.0%)	1.36 (74.3%)	1.05 (49.6%)	3.53 (37.8%)	2.50 (48.0%)

Maximum observed plasma concentration (Cmax) of alpelisib

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	**LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal**	**LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal**	**LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal**
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13
Maximum observed plasma concentration (Cmax) of alpelisib (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)				
Cycle 1 Day 1 (n=11,6,11,11)	1420 (2.6%)	1950 (36.6%)	2220 (40.9%)	1380 (32.8%)
Cycle 1 Day 28 (n=8,2,6,9)	1610 (55.9%)	2590 (26.2%)	2170 (47.5%)	1490 (36.2%)

Time to reach maximum plasma concentration (Tmax) of alpelisib

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

	LSZ102 300 mg QD + BYL719 200 mg	**LSZ102 300 mg QD + BYL719 250 mg**	**LSZ102 300 mg QD + BYL719 300 mg**	**LSZ102 450 mg QD + BYL719 200 mg**

	QD continuous with regular meal	QD continuous with regular meal	QD continuous with regular meal	QD continuous with regular meal
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13
Time to reach maximum plasma concentration (Tmax) of alpelisib (units: hours) Median (Full Range)				
Cycle 1 Day 1 (n=11,6,11,11)	4.00 (1.63 to 4.13)	2.90 (2.00 to 4.00)	4.00 (1.97 to 8.05)	2.25 (0.967 to 4.12)
Cycle 1 Day 28 (n=8,2,6,9)	3.93 (1.00 to 4.17)	2.00 (2.00 to 2.00)	4.11 (2.02 to 7.60)	3.75 (1.42 to 6.00)

Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of alpelisib

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants	12	6	12	13

Analyzed [units: participants]				
Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of alpelisib (units: hr*(ng/mL)) Geometric Mean (Geometric Coefficient of Variation)				
Cycle 1 Day 1 (n=11,6,11,11)	14500 (38.0%)	18600 (37.6%)	24700 (45.3%)	15700 (30.7%)
Cycle 1 Day 28 (n=8,2,6,9)	14800 (77.9%)	32800 (40.3%)	14500 (70.0%)	17700 (52.9%)

Accumulation ratio (Racc) of alpelisib

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8 and 24 hours post dose on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 28 (C1D28). The duration of one cycle was 28 days.)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	6	2	2	8
Accumulation ratio (Racc) of alpelisib (units: ratio) Geometric Mean (Geometric Coefficient of Variation)				
Cycle 1 Day 28 (n=6,2,2,8)	1.32 (34.5%)	2.11 (15.2%)	0.497 (25.4%)	1.32 (40.8%)

Run-in period for food effect cohort: Maximum observed plasma concentration (Cmax) of LSZ102

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8, 24 and 48 hours post dose)

	LSZ102 450 mg QD Fed	LSZ102 450 mg QD Fasted
Arm/Group Description	LSZ102 450 mg administered orally as single dose with a high-fat high-calorie (HFHC) meal during the Run-in period	LSZ102 450 mg administered orally as single dose in Fasted conditions during the Run-in period
Number of Participants Analyzed [units: participants]	11	9
Run-in period for food effect cohort: Maximum observed plasma concentration (Cmax) of LSZ102 (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)		
	3260 (74.5%)	2570 (44.8%)

Statistical Analysis

Groups	LSZ102 450 mg QD Fed, LSZ102 450 mg QD Fasted
Method	Other Linear mixed effects model
Other Geometric mean ratio	1.17
90 % Confidence Interval 2-Sided	0.869 to 1.57

Run-in period for food effect cohort: Time to reach maximum plasma concentration (Tmax) of LSZ102

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8, 24 and 48 hours post dose)

	LSZ102 450 mg QD Fed	LSZ102 450 mg QD Fasted
Arm/Group Description	LSZ102 450 mg administered orally as single dose with a high-fat high-calorie (HFHC) meal during the Run-in period	LSZ102 450 mg administered orally as single dose in Fasted conditions during the Run-in period
Number of Participants Analyzed [units: participants]	11	9

Run-in period for food effect cohort: Time to reach maximum plasma concentration (Tmax) of LSZ102 (units: hours) Median (Full Range)		
	4.13 (1.10 to 8.17)	4.00 (0.467 to 6.00)

Run-in period for food effect cohort: Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of LSZ102

(Time Frame: pre-dose, 0.5, 1, 2, 4, 6, 8, 24 and 48 hours post dose)

	LSZ102 450 mg QD Fed	LSZ102 450 mg QD Fasted
Arm/Group Description	LSZ102 450 mg administered orally as single dose with a high-fat high-calorie (HFHC) meal during the Run-in period	LSZ102 450 mg administered orally as single dose in Fasted conditions during the Run-in period
Number of Participants Analyzed [units: participants]	11	9
Run-in period for food effect cohort: Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of LSZ102 (units: hr*(ng/mL)) Geometric Mean (Geometric Coefficient of Variation)		
	26900 (64.3%)	13700 (49.2%)

Statistical Analysis

Groups	LSZ102 450 mg QD Fed, LSZ102 450 mg QD Fasted
Method	Other Linear mixed effects model
Other Geometric mean ratio	1.78
90 % Confidence Interval 2-Sided	1.29 to 2.47

Percentage change from baseline in Estrogen Receptor - H Score

(Time Frame: Baseline (screening) and post-baseline (Cycle 1 Day 15). The duration of one cycle was 28 days.)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	3	4	10	2	10	2	4	0	2	4
Percentage change from baseline in Estrogen Receptor - H Score (units: percentage change) Median (Full Range)										
	-4.33 (-11.6 to 2.7)	-9.63 (-53.3 to 36.4)	-13.07 (-37.9 to 35.2)	-29.72 (-42.4 to -17.1)	-16.63 (-71.3 to 32.0)	-8.19 (-11.3 to -5.1)	-20.52 (-44.2 to -2.6)		-4.28 (-6.0 to -2.6)	-25.62 (-36.6 to 75.0)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal	LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing	LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food	LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	3	1	2	1	2	2	1	3	1
Percentage change from baseline in Estrogen Receptor - H Score (units: percentage change) Median (Full Range)									
	-32.06 (-37.2 to -26.2)	-26.61 (-26.61 to -26.61)	-5.72 (-5.9 to -5.5)	-31.67 (-31.67 to -31.67)	-29.33 (-43.5 to -15.2)	16.61 (-25.3 to 58.5)	-8.22 (-8.22 to -8.22)	9.15 (-20.3 to 113.9)	-28.51 (-28.51 to -28.51)

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg	LSZ102 450 mg QD + LEE011 400 mg	LSZ102 450 mg QD + LEE011 400 mg	LSZ102 600 mg QD + LEE011 300 mg	LSZ102 200 mg BID + LEE011 200 mg QD continuous	LSZ102 300 mg BID + LEE011 200 mg QD continuous

	QD continuous fasted	QD continuous fasted	QD continuous with regular meal	QD continuous fasted	without regards to food	without regards to food
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	3	2	3	3	2
Percentage change from baseline in Estrogen Receptor - H Score (units: percentage change) Median (Full Range)						
	-19.18 (-27.0 to 19.9)	-22.37 (-100.0 to 1.2)	-29.30 (-30.1 to -28.5)	-36.08 (-36.2 to -11.6)	-17.89 (-27.0 to -15.9)	22.14 (-43.3 to 87.5)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	5	1	2	5

Percentage change from baseline in Estrogen Receptor - H Score (units: percentage change) Median (Full Range)				
	-24.70 (-87.6 to -6.8)	-38.17 (-38.17 to -38.17)	-36.29 (-59.9 to -12.7)	-18.80 (-29.9 to 5.0)

Percentage change from baseline in Progesterone Receptor - H Score

(Time Frame: Baseline (screening) and post-baseline (Cycle 1 Day 15). The duration of one cycle was 28 days.)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	2	3	8	2	9	2	3	0	2	3

Percentage change from baseline in Progesterone Receptor - H Score (units: percentage change) Median (Full Range)	17126.32 (-100.0 to 34352.6)	-18.72 (-100.0 to 3.0)	4.95 (-45.9 to 4893.5)	3496.89 (-31.2 to 7025.0)	110.75 (-64.8 to 5337.2)	263.40 (173.8 to 353.0)	-52.67 (-100.0 to -8.0)		165.36 (-10.4 to 341.1)	15.27 (2.2 to 400.0)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	2	1	2	1	2	2	1	3	1
Percentage change from baseline in Progesterone Receptor - H Score (units: percentage change) Median (Full Range)									

110.09 (-5.5 to 225.7)	216.98 (216.98 to 216.98)	21.68 (-0.1 to 43.4)	-3.99 (-3.99 to -3.99)	-23.65 (-88.4 to 41.1)	288.79 (-89.3 to 666.9)	118.70 (118.70 to 118.70)	-5.42 (-73.4 to 569.9)	-21.74 (-21.74 to -21.74)

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	5	3	2	3	3	2
Percentage change from baseline in Progesterone Receptor - H Score (units: percentage change) Median (Full Range)						
	-5.46 (-100.0 to 158.1)	141.10 (31.0 to 500.4)	159.32 (139.0 to 179.6)	-53.83 (-64.6 to -17.0)	30.79 (-7.4 to 680.0)	150.0 (10.0 to 290.0)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal

Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	5	1	2	5
Percentage change from baseline in Progesterone Receptor - H Score (units: percentage change) Median (Full Range)				
	-71.59 (-100.0 to 280.0)	15.59 (15.59 to 15.59)	270.36 (-57.8 to 598.5)	0.75 (-100.0 to 841.7)

Percentage change from baseline in PS6 – Nuclear H Score, Cytoplasmic Score and Membrane Score

(Time Frame: Baseline (screening) and post-baseline (Cycle 1 Day 15). The duration of one cycle was 28 days.)

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal

			run-in food effect cohort		run-in food effect cohort					
Number of Participants Analyzed [units: participants]	3	4	2	0	3	0	3	0	0	0
Percentage change from baseline in PS6 – Nuclear H Score, Cytoplasmic Score and Membrane Score (units: percentage change) Median (Full Range)										
PS6 – Nuclear Score (n=1,4,2,0, 2,0,3,0,0,0)	-39.53 (-39.53 to -39.53)	-46.88 (-52.2 to 28.5)	85.80 (43.6 to 128.0)		30.15 (2.7 to 57.6)		19.18 (-10.0 to 205.4)			
PS6 – Cytoplasmic Score (n=3,4,2,0, 3,0,3,0,0,0)	4.70 (-2.5 to 7.2)	-11.60 (-47.9 to 10.1)	-44.67 (-55.8 to -33.5)		-9.55 (-21.4 to -1.2)		13.78 (-11.9 to 93.9)			
PS6 – Membrane Score (n=1,0,1,0, 0,0,0,0,0,0)	4.88 (4.88 to 4.88)		-100.00 (-100.00 to -100.00)							

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**

Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	3	0	0	0	0	0	0	0	0
Percentage change from baseline in PS6 – Nuclear H Score, Cytoplasmic Score and Membrane Score (units: percentage change) Median (Full Range)									
PS6 – Nuclear Score (n=3,0,0,0,0,0,0,0,0)	-15.27 (-25.6 to 47.5)								
PS6 – Cytoplasmic Score (n=3,0,0,0,0,0,0,0,0)	0.62 (-76.9 to 3.0)								
PS6 – Membrane Score (n=1,0,0,0,0,0,0,0,0)	-100.00 (-100.00 to -100.00)								

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	**LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal**	**LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted**	**LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food**	**LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food**

Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	0	0	0	0	0	0
Percentage change from baseline in PS6 – Nuclear H Score, Cytoplasmic Score and Membrane Score (units: percentage change) Median (Full Range)						
PS6 – Nuclear Score (n=0)						
PS6 – Cytoplasmic Score (n=0)						
PS6 – Membrane Score (n=0)						

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants	0	0	0	0

Analyzed [units: participants]
Percentage change from baseline in PS6 – Nuclear H Score, Cytoplasmic Score and Membrane Score (units: percentage change) Median (Full Range)
PS6 – Nuclear Score (n=0)
PS6 – Cytoplasmic Score (n=0)
PS6 – Membrane Score (n=0)

All-Collected Deaths

(Time Frame: Up to 2.9 years (on-treatment deaths) and 5.3 years (all deaths))

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted	LSZ102 400 mg QD fasted	LSZ102 450 mg QD fasted	LSZ102 450 mg QD with regular meal	LSZ102 600 mg QD fasted	LSZ102 600 mg QD with regular meal	LSZ102 900 mg QD fasted	LSZ102 200 mg BID without regards to food	LSZ102 225 mg BID with regular meal	LSZ102 300 mg BID with regular meal
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions, including the patients who before the treatment period were enrolled in the run-in food effect cohort	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal

Number of Participants Analyzed [units: participants]	4	6	15	6	20	4	6	4	6	6
All-Collected Deaths (units: participants)										
On-treatment deaths	0	1	3	0	1	0	0	0	0	0
Post-treatment deaths	1	1	2	1	4	1	1	0	1	1
All deaths	1	2	5	1	5	1	1	0	1	1

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted**
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a

	28-day cycle under fasted conditions	28-day cycle under fasted conditions	28-day cycle under fasted conditions	28-day cycle with regular meal	28-day cycle with regular meal in staggered dosing	28-day cycle with regular meal in staggered dosing	28-day cycle without regards to food	28-day cycle under fasted conditions	28-day cycle under fasted conditions
Number of Participants Analyzed [units: participants]	5	5	4	8	6	4	4	4	4
All-Collected Deaths (units: participants)									
On-treatment deaths	0	0	0	0	0	1	0	0	1
Post-treatment deaths	3	1	2	2	2	0	1	0	0
All deaths	3	1	2	2	2	1	1	0	1

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted	**LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted**	**LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal**	**LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted**	**LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food**	**LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food**
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food
Number of Participants Analyzed [units: participants]	6	8	6	4	6	4

All-Collected Deaths
(units: participants)

On-treatment deaths	1	0	0	0	0	0
Post-treatment deaths	0	0	0	0	0	0
All deaths	1	0	0	0	0	0

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal	**LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal**	**LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal**	**LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal**
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Number of Participants Analyzed [units: participants]	12	6	12	13
All-Collected Deaths (units: participants)				
On-treatment deaths	0	0	1	2
Post-treatment deaths	3	0	3	0
All deaths	3	0	4	2

Safety Results

All-Cause Mortality

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted N = 4	LSZ102 400 mg QD fasted N = 6	LSZ102 450 mg QD fasted N = 10	LSZ102 450 mg QD with regular meal N = 6	LSZ102 450 mg QD fasted with food effect tested at 450 mg N = 5	LSZ102 450 mg Run-in only N = 1	LSZ102 600 mg QD fasted N = 15	LSZ102 600 mg QD with regular meal N = 4	LSZ102 600 mg QD fasted with food effect tested at 450 mg N = 5	LSZ102 900 mg QD fasted N = 6	LSZ102 200 mg BID without regards to food N = 4	LSZ102 225 mg BID with regular meal N = 6	LSZ102 300 mg BID with regular meal N = 6
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions. Before the treatment period, there was a food effect run-in period with LSZ102 450 mg	Food effect run-in period with LSZ102 450 mg. Patient discontinued before entering treatment period	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions. Before the treatment period, there was a food effect run-in period with LSZ102 450 mg	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Total participants affected	0 (0.00 %)	1 (16.67 %)	2 (20.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted N = 5	LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted N = 5	LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted N = 4	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal N = 8	LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing N = 6	LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing N = 4	LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food N = 4	LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted N = 4	LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted N = 4
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Total participants affected	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted N = 6	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted N = 8	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal N = 6	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted N = 4	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food N = 6	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food N = 4
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in

	combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to foodLSZ102 300 mg BID + LEE011 200 mg BID cont WRF
Total participants affected	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal N = 12	**LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal N = 6**	**LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal N = 12**	**LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal N = 13**
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Total participants affected	0 (0.00%)	0 (0.00%)	1 (8.33%)	2 (15.38%)

Serious Adverse Events by System Organ Class

Time Frame	From first dose of study medication up to 30 days after last dose, with a maximum duration of 2.9 years
Additional Description	Any sign or symptom that occurs during the study treatment plus 30 days after last dose.
Source Vocabulary for Table Default	MedDRA (24.1)
Assessment Type for Table Default	Systematic Assessment

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted N = 4	LSZ102 400 mg QD fasted N = 6	LSZ102 450 mg QD fasted N = 10	LSZ102 450 mg QD with regular meal N = 6	LSZ102 2 450 mg QD fasted with food effect tested at 450 mg N = 5	LSZ102 2 450 mg Run-in only N = 1	LSZ102 600 mg QD fasted N = 15	LSZ102 2 600 mg QD with regular meal N = 4	LSZ102 600 mg QD fasted with food effect tested at 450 mg N = 5	LSZ102 900 mg QD fasted N = 6	LSZ102 200 mg BID without regards to food N = 4	LSZ102 225 mg BID with regular meal N = 6	LSZ102 300 mg BID with regular meal N = 6
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions. Before the treatment period, there was a food effect run-in period with LSZ102 450 mg	Food effect run-in period with LSZ102 450 mg. Patient discontinued before entering treatment period	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions. Before the treatment period, there was a food effect run-in period with LSZ102 450 mg	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Total participants affected	1 (25.00%)	1 (16.67%)	3 (30.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	6 (40.00%)	0 (0.00%)	1 (20.00%)	1 (16.67%)	2 (50.00%)	3 (50.00%)	2 (33.33%)

Blood and lymphatic system disorders													
Anaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Febrile neutropenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thrombocytopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Cardiac disorders													
Angina pectoris	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bundle branch block right	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sinoatrial block	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eye disorders													
Vitreous floaters	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal disorders													
Abdominal pain	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Ascites	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Colitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diarrhoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)

Dyspepsia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Enterocolitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Faecal vomiting	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haemoperitoneum	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)
Intestinal obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Large intestinal obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nausea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)
Stomatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vomiting	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)
General disorders and administration site conditions													
Fatigue	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)
Multiple organ dysfunction syndrome	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pyrexia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatobiliary disorders													

Haemobilia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatic failure	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatic function abnormal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Hepatic haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypertransamina saemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infections and infestations													
Cellulitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Clostridium difficile infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Herpes simplex	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumocystis jirovecii pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Upper respiratory tract infection	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injury, poisoning and procedural complications													

Overdose	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Post procedural haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Investigations													
Alanine aminotransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Aspartate aminotransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lipase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Troponin increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metabolism and nutrition disorders													
Decreased appetite	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dehydration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperglycaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypokalaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypophosphataemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal and connective tissue disorders													

Back pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neck pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pain in extremity	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pain in jaw	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Spinal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)													
Endometrial cancer	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Malignant neoplasm progression	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metastases to central nervous system	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nervous system disorders													
Aphasia	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dizziness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysarthria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Haemorrhagic stroke	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)
Headache	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Seizure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Syncope	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Psychiatric disorders													
Confusional state	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mental status changes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal and urinary disorders													
Acute kidney injury	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory, thoracic and mediastinal disorders													
Aphonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dyspnoea	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)
Pleural effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Pneumothorax	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pulmonary embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pulmonary oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin and subcutaneous tissue disorders													
Rash	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash maculo-papular	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vascular disorders													
Peripheral embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted N = 5	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted N = 5**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted N = 4**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal N = 8**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing N = 6**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing N = 4**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food N = 4**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted N = 4**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted N = 4**
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in

	combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Total participants affected	1 (20.00%)	3 (60.00%)	1 (25.00%)	5 (62.50%)	0 (0.00%)	2 (50.00%)	1 (25.00%)	0 (0.00%)	4 (100.00%)
Blood and lymphatic system disorders									
Anaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Febrile neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders									
Angina pectoris	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bundle branch block right	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Sinoatrial block	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders									
Vitreous floaters	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Gastrointestinal disorders									
Abdominal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Dyspepsia	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Enterocolitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Faecal vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Haemoperitoneum	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Large intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Stomatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General disorders and administration site conditions									
Fatigue	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Multiple organ dysfunction syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Hepatobiliary disorders									
Haemobilia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic function abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertransaminasaemia	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations									
Cellulitis	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Clostridium difficile infection	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes simplex	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumocystis jirovecii pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications									
Overdose	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (25.00%)
Post procedural haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations									
Alanine aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspartate aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Troponin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Metabolism and nutrition disorders									
Decreased appetite	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Hyperglycaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypokalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Hypophosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Musculoskeletal and connective tissue disorders									
Back pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neck pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in extremity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in jaw	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified									

(incl cysts and polyps)									
Endometrial cancer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malignant neoplasm progression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metastases to central nervous system	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders									
Aphasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dizziness	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysarthria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhagic stroke	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seizure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders									
Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mental status changes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Renal and urinary disorders									
Acute kidney injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Anuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders									
Aphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Pulmonary oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders									
Rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Rash maculo-papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders									

Peripheral embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted N = 6	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted N = 8	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal N = 6	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted N = 4	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food N = 6	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food N = 4
Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to foodLSZ102 300 mg BID + LEE011 200 mg BID cont WRF
Total participants affected	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (25.00%)
Blood and lymphatic system disorders						
Anaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Febrile neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders						
Angina pectoris	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Bundle branch block right	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinoatrial block	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders						
Vitreous floaters	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders						
Abdominal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspepsia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Enterocolitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Faecal vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemoperitoneum	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Large intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stomatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
General disorders and administration site conditions						
Fatigue	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Multiple organ dysfunction syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Hepatobiliary disorders						
Haemobilia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic function abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertransaminasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations						
Cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Clostridium difficile infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes simplex	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumocystis jirovecii pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Injury, poisoning and procedural complications						
Overdose	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Post procedural haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Investigations						
Alanine aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspartate aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Troponin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders						
Decreased appetite	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperglycaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypokalaemia	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypophosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders						
Back pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Musculoskeletal chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neck pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Pain in extremity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in jaw	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Endometrial cancer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malignant neoplasm progression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metastases to central nervous system	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders						
Aphasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dizziness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysarthria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhagic stroke	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seizure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Psychiatric disorders						
Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mental status changes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders						
Acute kidney injury	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders						
Aphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Pulmonary oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders						
Rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash maculo-papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders						

Peripheral embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal N = 12	LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal N = 6	LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal N = 12	LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal N = 13
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Total participants affected	4 (33.33%)	1 (16.67%)	10 (83.33%)	5 (38.46%)
Blood and lymphatic system disorders				
Anaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Febrile neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders				
Angina pectoris	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bundle branch block right	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinoatrial block	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders				
Vitreous floaters	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Gastrointestinal disorders				
Abdominal pain	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Diarrhoea	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)
Dyspepsia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Enterocolitis	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Faecal vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemoperitoneum	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Large intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Stomatitis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Vomiting	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
General disorders and administration site conditions				
Fatigue	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Multiple organ dysfunction syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Hepatobiliary disorders				
Haemobilia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hepatic function abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertransaminasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations				
Cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Clostridium difficile infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes simplex	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumocystis jirovecii pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	1 (8.33%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications				
Overdose	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Post procedural haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations				
Alanine aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Aspartate aminotransferase increased	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Troponin increased	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders				
Decreased appetite	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperglycaemia	1 (8.33%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Hypokalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Hypophosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders				
Back pain	1 (8.33%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Musculoskeletal chest pain	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Neck pain	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Pain in extremity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in jaw	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal pain	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Endometrial cancer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Malignant neoplasm progression	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Metastases to central nervous system	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders				
Aphasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dizziness	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Dysarthria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhagic stroke	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seizure	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders				
Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mental status changes	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Renal and urinary disorders				
Acute kidney injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders				

Aphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Pleural effusion	1 (8.33%)	0 (0.00%)	0 (0.00%)	2 (15.38%)
Pneumothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders				
Rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash maculo-papular	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Vascular disorders				
Peripheral embolism	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)

Other Adverse Events by System Organ Class

Time Frame	From first dose of study medication up to 30 days after last dose, with a maximum duration of 2.9 years
Additional Description	Any sign or symptom that occurs during the study treatment plus 30 days after last dose.
Source Vocabulary for Table Default	MedDRA (24.1)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

LSZ102 single agent (1/4)

	LSZ102 200 mg QD fasted N = 4	LSZ102 400 mg QD fasted N = 6	LSZ102 450 mg QD fasted N = 10	LSZ102 450 mg QD with regular meal N = 6	LSZ102 450 mg QD fasted with food effect tested at 450 mg N = 5	LSZ102 450 mg Run-in only N = 1	LSZ102 600 mg QD fasted N = 15	LSZ102 600 mg QD with regular meal N = 4	LSZ102 600 mg QD fasted with food effect tested at 450 mg N = 5	LSZ102 900 mg QD fasted N = 6	LSZ102 200 mg BID without regards to food N = 4	LSZ102 225 mg BID with regular meal N = 6	LSZ102 300 mg BID with regular meal N = 6
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions. Before the treatment period, there was a food effect run-in period with LSZ102 450 mg	Food effect run-in period with LSZ102 450 mg. Patient discontinued before entering treatment period	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions. Before the treatment period, there was a food effect run-in period with LSZ102 450 mg	LSZ102 900 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 225 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle with regular meal
Total participants affected	4 (100.00%)	6 (100.00%)	9 (90.00%)	6 (100.00%)	5 (100.00%)	1 (100.00%)	15 (100.00%)	4 (100.00%)	5 (100.00%)	6 (100.00%)	4 (100.00%)	6 (100.00%)	5 (83.33%)
Blood and lymphatic system disorders													
Anaemia	2 (50.00%)	1 (16.67%)	2 (20.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	4 (26.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)	2 (33.33%)	1 (16.67%)

Eosinophilia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Leukopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lymphopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Neutropenia	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thrombocytope nia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cardiac disorders													
Angina pectoris	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bradycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bundle branch block right	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mitral valve disease	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Palpitations	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Sinus bradycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tachycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear and labyrinth disorders													
Ear congestion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Ear discomfort	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tinnitus	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vertigo	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Endocrine disorders													
Hyperthyroidism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eye disorders													
Blindness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cataract	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diplopia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dry eye	1 (25.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eye irritation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eye pruritus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Foreign body sensation in eyes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Iridocyclitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Lacrimation increased	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Periorbital swelling	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Photophobia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vision blurred	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Visual acuity reduced	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Visual field defect	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Visual impairment	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vitreous floaters	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal disorders													
Abdominal discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal distension	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Abdominal pain	1 (25.0 0%)	1 (16.6 7%)	2 (20.0 0%)	2 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	3 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Abdominal pain upper	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	1 (25.0 0%)	1 (20.0 0%)	0 (0.00 %)	1 (25.0 0%)	2 (33.3 3%)	1 (16.6 7%)
Anal incontinence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ascites	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cheilitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Colitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Constipation	1 (25.0 0%)	0 (0.00 %)	5 (50.0 0%)	1 (16.6 7%)	1 (20.0 0%)	0 (0.00 %)	4 (26.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	2 (33.3 3%)	0 (0.00 %)
Diarrhoea	2 (50.0 0%)	6 (100. 00%)	4 (40.0 0%)	3 (50.0 0%)	3 (60.0 0%)	0 (0.00 %)	11 (73.3 3%)	0 (0.00 %)	3 (60.0 0%)	6 (100. 00%)	3 (75.0 0%)	4 (66.6 7%)	3 (50.0 0%)
Dry mouth	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dyspepsia	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (13.33 %)	1 (25.0 0%)	1 (20.0 0%)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysphagia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Eosinophilic oesophagitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eructation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Flatulence	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	1 (16.6 7%)	1 (20.0 0%)	0 (0.00 %)	1 (6.67%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal sounds abnormal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrooesophageal reflux disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Haemorrhoids	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Lip oedema	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lower gastrointestinal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Melaena	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mouth ulceration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nausea	3 (75.0 0%)	2 (33.3 3%)	7 (70.0 0%)	2 (33.3 3%)	2 (40.0 0%)	0 (0.00 %)	11 (73.3 3%)	4 (100. 00%)	4 (80.0 0%)	5 (83.3 3%)	3 (75.0 0%)	4 (66.6 7%)	4 (66.6 7%)
Odynophagia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oesophagitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pancreatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Stomatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Toothache	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vomiting	1 (25.0 0%)	2 (33.3 3%)	3 (30.0 0%)	2 (33.3 3%)	2 (40.0 0%)	1 (100. 00%)	8 (53.33 %)	2 (50.0 0%)	2 (40.0 0%)	3 (50.0 0%)	2 (50.0 0%)	1 (16.6 7%)	1 (16.6 7%)
General disorders and administration site conditions													
Asthenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Axillary pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Catheter site pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Chest discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Chills	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Device related thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Early satiety	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fatigue	2 (50.0 0%)	1 (16.6 7%)	3 (30.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	5 (33.33 %)	1 (25.0 0%)	2 (40.0 0%)	1 (16.6 7%)	3 (75.0 0%)	2 (33.3 3%)	2 (33.3 3%)
Generalised oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Influenza like illness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Malaise	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Medical device site joint inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Non-cardiac chest pain	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oedema peripheral	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (20.0 0%)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Pyrexia	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (16.6 7%)	0 (0.00 %)
Hepatobiliary disorders													
Hepatic pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (20.0 0%)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperbilirubinaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Hypertransaminasaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)

Jaundice	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Immune system disorders													
Hypersensitivit y	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infections and infestations													
Bacterial vulvovaginitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Biliary sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Bronchitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bronchitis viral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Conjunctivitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cystitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Epstein-Barr virus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Escherichia urinary tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fungal skin infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal viral infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Genital herpes zoster	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Herpes virus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Herpes zoster	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hordeolum	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Influenza	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Laryngitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Localised infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nasopharyngitis	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral herpes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pharyngitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Pneumonia fungal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory tract infection viral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sialoadenitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sinusitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Skin infection	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tooth abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Upper respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Upper respiratory tract infection bacterial	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)
Vaginal infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Viral infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Viral upper respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vulvovaginal candidiasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Wound infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injury, poisoning and procedural complications													
Animal bite	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Contusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Fall	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Post procedural discharge	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Procedural pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Procedural vomiting	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Product dispensing error	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin abrasion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Wound	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Wound complication	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Wound secretion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Investigations													
Alanine aminotransfera se increased	2 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (20.0 0%)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	1 (25.0 0%)	1 (16.6 7%)	1 (16.6 7%)
Amylase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	2 (33.3 3%)	0 (0.00 %)
Aspartate aminotransfera se increased	2 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	2 (33.3 3%)	1 (20.0 0%)	0 (0.00 %)	4 (26.67 %)	1 (25.0 0%)	1 (20.0 0%)	0 (0.00 %)	2 (50.0 0%)	1 (16.6 7%)	1 (16.6 7%)
Bilirubin conjugated increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Blood alkaline phosphatase increased	2 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (20.0 0%)	0 (0.00 %)	4 (26.67 %)	1 (25.0 0%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood bilirubin increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (50.0 0%)	0 (0.00 %)	0 (0.00 %)
Blood bilirubin unconjugated increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood cholesterol increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood creatine phosphokinase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood creatinine increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Blood thyroid stimulating hormone increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood triglycerides increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Electrocardiogram QT prolonged	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gamma-glutamyltransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (20.0 0%)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	2 (40.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Glomerular filtration rate decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Glucose urine present	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lipase	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lipase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Lymphocyte count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neutrophil count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Platelet count decreased	1 (25.0 0%)	1 (16.6 7%)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (16.6 7%)
Troponin I increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Weight decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Weight increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
White blood cell count decreased	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metabolism and nutrition disorders													
Decreased appetite	2 (50.0 0%)	1 (16.6 7%)	2 (20.0 0%)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	3 (20.00 %)	0 (0.00 %)	2 (40.0 0%)	2 (33.3 3%)	1 (25.0 0%)	3 (50.0 0%)	0 (0.00 %)
Dehydration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Gout	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Hyperamylasaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypercalcaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperchloraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypercholesterolaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperglycaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	1 (25.0 0%)	0 (0.00 %)	1 (16.6 7%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Hyperkalaemia	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperlipasaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperlipidaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperphosphataemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypertriglyceridaemia	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoalbuminaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Hypocalcaemia	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoglycaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypokalaemia	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Hypomagnesaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Hyponatraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)

Hypophosphataemia	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (20.0 0%)	0 (0.00 %)	2 (13.33 %)	1 (25.0 0%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoproteinaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypovolaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Malnutrition	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal and connective tissue disorders													
Arthralgia	3 (75.0 0%)	2 (33.3 3%)	2 (20.0 0%)	3 (50.0 0%)	1 (20.0 0%)	0 (0.00 %)	3 (20.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	2 (33.3 3%)	0 (0.00 %)
Back pain	1 (25.0 0%)	1 (16.6 7%)	0 (0.00 %)	2 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bone pain	1 (25.0 0%)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Flank pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Groin pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Joint stiffness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Muscle spasms	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Muscular weakness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Musculoskeletal pain	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Myalgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neck pain	0 (0.00 %)	0 (0.00 %)	2 (20.00%)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Osteonecrosis of jaw	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pain in extremity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)
Pain in jaw	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Plantar fasciitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Spinal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Temporomandibular joint syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)													
Cancer pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metastases to peritoneum	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tumour associated fever	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Tumour pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nervous system disorders													
Dizziness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Dysgeusia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Extrapyramidal disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Facial paralysis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Headache	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	2 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	3 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (16.6 7%)
Hypoaesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lethargy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neuralgia	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neuropathy peripheral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Paraesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Peripheral sensory neuropathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Piriformis syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Restless legs syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Sciatica	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sensory disturbance	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Somnolence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Syncope	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Taste disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tremor	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Product issues													
Device breakage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Psychiatric disorders													
Agitation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anxiety	1 (25.0 0%)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	2 (40.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Confusional state	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Depressed mood	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Depression	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Insomnia	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Panic attack	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Restlessness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal and urinary disorders													
Acute kidney injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Chronic kidney disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cystitis noninfective	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haematuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Microalbuminuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Micturition urgency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nocturia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pollakiuria	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal colic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary incontinence	1 (25.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Reproductive system and breast disorders													
Breast pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Endometrial thickening	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Genital burning sensation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Intermenstrual bleeding	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pelvic pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vaginal discharge	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	2 (33.3 3%)
Vaginal haemorrhage	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Vulvovaginal inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vulvovaginal pruritus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory, thoracic and mediastinal disorders													
Cough	1 (25.0 0%)	1 (16.6 7%)	1 (10.0 0%)	2 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	1 (25.0 0%)	1 (16.6 7%)	1 (16.6 7%)
Dysphonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dyspnoea	1 (25.0 0%)	0 (0.00 %)	2 (20.0 0%)	1 (16.6 7%)	1 (20.0 0%)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	3 (50.0 0%)	1 (16.6 7%)

Dyspnoea exertional	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)
Interstitial lung disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nasal congestion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nasal inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oropharyngeal pain	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pleural effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pleuritic pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)
Pneumonitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Productive cough	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)
Rhinorrhoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Upper-airway cough syndrome	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Wheezing	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)
Skin and subcutaneous tissue disorders													
Alopecia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Dermal cyst	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dermatitis acneiform	0 (0.00 %)	1 (16.6 7%)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dermatitis contact	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dermatitis exfoliative generalised	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dry skin	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Eczema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Erythema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperhidrosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nail disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Night sweats	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Palmar-plantar erythrodysaesthesia syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Photosensitivity reaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pityriasis rosea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pruritus	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Psoriasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (25.0 0%)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash erythematous	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash maculo-papular	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash pruritic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Skin atrophy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin discolouration	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin hyperpigmentation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin lesion	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urticaria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vascular disorders													
Deep vein thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hot flush	0 (0.00 %)	1 (16.6 7%)	2 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (13.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Hypertension	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypotension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Lymphoedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Venous thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

LSZ102 + ribociclib intermittent (2/4)

	LSZ102 200 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted N = 5	**LSZ102 400 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted N = 5**	**LSZ102 400 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted N = 4**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal N = 8**	**LSZ102 450 mg QD + LEE011 300 mg QD 3 weeks on 1 week off with regular meal in staggered dosing N = 6**	**LSZ102 450 mg QD + LEE011 400 mg QD 3 weeks on 1 week off with regular meal in staggered dosing N = 4**	**LSZ102 450 mg QD + LEE011 600 mg QD 3 weeks on 1 week off without regards to food N = 4**	**LSZ102 600 mg QD + LEE011 300 mg QD 3 weeks on 1 week off fasted N = 4**	**LSZ102 600 mg QD + LEE011 400 mg QD 3 weeks on 1 week off fasted N = 4**
Arm/Group Description	LSZ102 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 400 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle with regular meal in staggered dosing	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 600 mg administered orally QD on Days 1 to 21 of a 28-day cycle without regards to food	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 21 of a 28-day cycle under fasted conditions
Total participants affected	5 (100.00%)	4 (80.00%)	4 (100.00%)	8 (100.00%)	5 (83.33%)	4 (100.00%)	4 (100.00%)	4 (100.00%)	4 (100.00%)

Blood and lymphatic system disorders									
Anaemia	4 (80.00%)	1 (20.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	2 (50.00%)	1 (25.00%)	1 (25.00%)	2 (50.00%)
Eosinophilia	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukopenia	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphopenia	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenia	3 (60.00%)	0 (0.00%)	0 (0.00%)	2 (25.00%)	1 (16.67%)	1 (25.00%)	1 (25.00%)	0 (0.00%)	2 (50.00%)
Thrombocytopenia	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders									
Angina pectoris	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)
Bundle branch block right	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mitral valve disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palpitations	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Ear and labyrinth disorders									
Ear congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tinnitus	1 (20.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vertigo	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endocrine disorders									
Hyperthyroidism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Eye disorders									
Blindness	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cataract	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diplopia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)
Dry eye	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	1 (25.00%)
Eye irritation	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye pruritus	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Foreign body sensation in eyes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Iridocyclitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lacrimation increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periorbital swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Photophobia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vision blurred	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Visual acuity reduced	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Visual field defect	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Visual impairment	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitreous floaters	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders									
Abdominal discomfort	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal distension	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)
Abdominal pain	1 (20.00%)	2 (40.00%)	2 (50.00%)	4 (50.00%)	1 (16.67%)	2 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain upper	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (25.00%)	2 (33.33%)	1 (25.00%)	1 (25.00%)	1 (25.00%)	0 (0.00%)
Anal incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Cheilitis	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	1 (20.00%)	1 (20.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	3 (75.00%)	2 (50.00%)
Diarrhoea	2 (40.00%)	3 (60.00%)	3 (75.00%)	1 (12.50%)	2 (33.33%)	2 (50.00%)	2 (50.00%)	2 (50.00%)	3 (75.00%)
Dry mouth	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspepsia	1 (20.00%)	2 (40.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphagia	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eosinophilic oesophagitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eructation	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flatulence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal sounds abnormal	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrooesophageal reflux disease	0 (0.00%)	2 (40.00%)	1 (25.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (25.00%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lower gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Melaena	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mouth ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	3 (60.00%)	3 (60.00%)	2 (50.00%)	2 (25.00%)	3 (50.00%)	2 (50.00%)	3 (75.00%)	4 (100.00%)	3 (75.00%)
Odynophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Oesophagitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Pancreatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stomatitis	2 (40.00%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Toothache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Vomiting	1 (20.00%)	2 (40.00%)	1 (25.00%)	2 (25.00%)	2 (33.33%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	3 (75.00%)
General disorders and administration site conditions									
Asthenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Axillary pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chills	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)
Device related thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Early satiety	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	1 (20.00%)	1 (20.00%)	2 (50.00%)	2 (25.00%)	2 (33.33%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	2 (50.00%)
Generalised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza like illness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Malaise	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Medical device site joint inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Non-cardiac chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Pyrexia	1 (20.00%)	2 (40.00%)	1 (25.00%)	2 (25.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)
Hepatobiliary disorders									
Hepatic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperbilirubinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertransaminasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Jaundice	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Immune system disorders									
Hypersensitivity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations									
Bacterial vulvovaginitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Biliary sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Conjunctivitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cystitis	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Epstein-Barr virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Escherichia urinary tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal viral infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Genital herpes zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hordeolum	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	1 (20.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Laryngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Localised infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasopharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)

Oral herpes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Pneumonia fungal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Respiratory tract infection viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sialoadenitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinusitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin infection	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection bacterial	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	0 (0.00%)	1 (20.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Vaginal infection	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vulvovaginal candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications									
Animal bite	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Contusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Post procedural discharge	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Product dispensing error	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin abrasion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound complication	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound secretion	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations									
Alanine aminotransferase increased	1 (20.00%)	2 (40.00%)	1 (25.00%)	2 (25.00%)	2 (33.33%)	2 (50.00%)	1 (25.00%)	0 (0.00%)	2 (50.00%)
Amylase increased	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (50.00%)
Aspartate aminotransferase increased	1 (20.00%)	1 (20.00%)	1 (25.00%)	1 (12.50%)	2 (33.33%)	2 (50.00%)	2 (50.00%)	0 (0.00%)	2 (50.00%)
Bilirubin conjugated increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Blood alkaline phosphatase increased	1 (20.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood bilirubin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Blood bilirubin unconjugated increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood cholesterol increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Blood creatine phosphokinase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatinine increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	0 (0.00%)	1 (25.00%)
Blood thyroid stimulating hormone increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Blood triglycerides increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Electrocardiogram QT prolonged	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gamma-glutamyltransferase increased	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	1 (25.00%)	1 (25.00%)	0 (0.00%)	1 (25.00%)
Glomerular filtration rate decreased	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glucose urine present	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (25.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	0 (0.00%)	2 (50.00%)
Lymphocyte count decreased	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutrophil count decreased	2 (40.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Platelet count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Troponin I increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight decreased	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (25.00%)
Weight increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White blood cell count decreased	2 (40.00%)	1 (20.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (50.00%)	0 (0.00%)	0 (0.00%)

Metabolism and nutrition disorders									
Decreased appetite	0 (0.00%)	2 (40.00%)	0 (0.00%)	1 (12.50%)	1 (16.67%)	1 (25.00%)	1 (25.00%)	1 (25.00%)	1 (25.00%)
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Gout	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperamylasaemia	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypercalcaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Hyperchloraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypercholesterolaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Hyperglycaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (25.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperkalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperlipasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperlipidaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperphosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertriglyceridaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoalbuminaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Hypocalcaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Hypoglycaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypokalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	1 (25.00%)
Hypomagnesaemia	1 (20.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (25.00%)
Hyponatraemia	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)
Hypophosphataemia	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	1 (25.00%)	1 (25.00%)	1 (25.00%)	2 (50.00%)
Hypoproteinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Hypovolaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Malnutrition	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)

Musculoskeletal and connective tissue disorders									
Arthralgia	1 (20.00%)	1 (20.00%)	0 (0.00%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)
Back pain	1 (20.00%)	3 (60.00%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	2 (50.00%)
Bone pain	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flank pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Groin pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint stiffness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle spasms	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Muscular weakness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal chest pain	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Myalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neck pain	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Osteonecrosis of jaw	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in extremity	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Pain in jaw	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Plantar fasciitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Temporomandibular joint syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									

Cancer pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metastases to peritoneum	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour associated fever	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders									
Dizziness	0 (0.00%)	1 (20.00%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)
Dysgeusia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Extrapyramidal disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Facial paralysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	2 (40.00%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	3 (75.00%)	0 (0.00%)
Hypoaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lethargy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)
Neuralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neuropathy peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paraesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral sensory neuropathy	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Piriformis syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Restless legs syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sciatica	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sensory disturbance	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Somnolence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Taste disorder	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Tremor	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Product issues									
Device breakage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Psychiatric disorders									
Agitation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anxiety	0 (0.00%)	1 (20.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)
Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Depressed mood	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Depression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Insomnia	0 (0.00%)	2 (40.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Panic attack	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Restlessness	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders									
Acute kidney injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Chronic kidney disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Cystitis noninfective	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematuria	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Microalbuminuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Micturition urgency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nocturia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pollakiuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Renal colic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)

Urinary incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract pain	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Reproductive system and breast disorders									
Breast pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endometrial thickening	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Genital burning sensation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Intermenstrual bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pelvic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vaginal discharge	2 (40.00%)	2 (40.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Vaginal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vulvovaginal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vulvovaginal pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Respiratory, thoracic and mediastinal disorders									
Cough	2 (40.00%)	2 (40.00%)	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	3 (75.00%)
Dysphonia	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	1 (20.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (50.00%)	1 (25.00%)	1 (25.00%)
Dyspnoea exertional	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Interstitial lung disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasal congestion	0 (0.00%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oropharyngeal pain	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pleuritic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Productive cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinorrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Upper-airway cough syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wheezing	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders									
Alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Dermal cyst	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis acneiform	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis contact	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis exfoliative generalised	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry skin	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Eczema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperhidrosis	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nail disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Night sweats	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palmar-plantar erythrodysaesthesia syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Photosensitivity reaction	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pityriasis rosea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pruritus	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (25.00%)	1 (25.00%)	0 (0.00%)
Psoriasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (25.00%)
Rash erythematous	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash maculo-papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash pruritic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin atrophy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin discolouration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin hyperpigmentation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Skin lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urticaria	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders									
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hot flush	2 (40.00%)	1 (20.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Hypertension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Lymphoedema	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Venous thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

LSZ102 + ribociclib continuous (3/4)

	LSZ102 450 mg QD + LEE011 300 mg QD continuous fasted N = 6	LSZ102 450 mg QD + LEE011 400 mg QD continuous fasted N = 8	LSZ102 450 mg QD + LEE011 400 mg QD continuous with regular meal N = 6	LSZ102 600 mg QD + LEE011 300 mg QD continuous fasted N = 4	LSZ102 200 mg BID + LEE011 200 mg QD continuous without regards to food N = 6	LSZ102 300 mg BID + LEE011 200 mg QD continuous without regards to food N = 4

Arm/Group Description	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 400 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 600 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle under fasted conditions	LSZ102 200 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to food	LSZ102 300 mg administered orally twice daily (BID) on Days 1 to 28 of a 28-day cycle in combination with ribociclib 200 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle without regards to foodLSZ102 300 mg BID + LEE011 200 mg BID cont WRF
Total participants affected	6 (100.00%)	8 (100.00%)	6 (100.00%)	4 (100.00%)	6 (100.00%)	4 (100.00%)
Blood and lymphatic system disorders						
Anaemia	1 (16.67%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	3 (50.00%)	1 (25.00%)
Eosinophilia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukopenia	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	1 (25.00%)
Lymphopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenia	2 (33.33%)	4 (50.00%)	1 (16.67%)	1 (25.00%)	3 (50.00%)	3 (75.00%)
Thrombocytopenia	1 (16.67%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders						
Angina pectoris	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bundle branch block right	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Mitral valve disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palpitations	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Sinus bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear and labyrinth disorders						
Ear congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tinnitus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vertigo	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Endocrine disorders						
Hyperthyroidism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders						
Blindness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cataract	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Diplopia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry eye	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye irritation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Foreign body sensation in eyes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Iridocyclitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Lacrimation increased	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periorbital swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Photophobia	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vision blurred	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)

Visual acuity reduced	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Visual field defect	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Visual impairment	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitreous floaters	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders						
Abdominal discomfort	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal distension	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain	2 (33.33%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	2 (33.33%)	1 (25.00%)
Abdominal pain upper	0 (0.00%)	0 (0.00%)	1 (16.67%)	2 (50.00%)	3 (50.00%)	0 (0.00%)
Anal incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cheilitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colitis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	1 (16.67%)	2 (25.00%)	1 (16.67%)	1 (25.00%)	4 (66.67%)	1 (25.00%)
Diarrhoea	3 (50.00%)	2 (25.00%)	2 (33.33%)	1 (25.00%)	2 (33.33%)	1 (25.00%)
Dry mouth	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspepsia	1 (16.67%)	0 (0.00%)	2 (33.33%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Dysphagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Eosinophilic oesophagitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eructation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flatulence	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Gastrointestinal sounds abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrooesophageal reflux disease	1 (16.67%)	1 (12.50%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lower gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Melaena	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mouth ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	4 (66.67%)	3 (37.50%)	5 (83.33%)	2 (50.00%)	3 (50.00%)	3 (75.00%)
Odynophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oesophagitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pancreatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stomatitis	1 (16.67%)	1 (12.50%)	0 (0.00%)	1 (25.00%)	2 (33.33%)	1 (25.00%)
Toothache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vomiting	1 (16.67%)	1 (12.50%)	5 (83.33%)	1 (25.00%)	1 (16.67%)	2 (50.00%)
General disorders and administration site conditions						
Asthenia	1 (16.67%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Axillary pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site pain	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Chills	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)

Device related thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Early satiety	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	3 (50.00%)	4 (50.00%)	4 (66.67%)	3 (75.00%)	3 (50.00%)	0 (0.00%)
Generalised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza like illness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malaise	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Medical device site joint inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Non-cardiac chest pain	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	0 (0.00%)	2 (25.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Hepatobiliary disorders						
Hepatic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperbilirubinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertransaminasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Jaundice	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune system disorders						
Hypersensitivity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations						

Bacterial vulvovaginitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Biliary sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Conjunctivitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Cystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Ear infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Epstein-Barr virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia urinary tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Fungal skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal viral infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Genital herpes zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Herpes virus infection	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Hordeolum	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Laryngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Localised infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasopharyngitis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral herpes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Pneumonia	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia fungal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory tract infection viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sialoadenitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinusitis	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)
Upper respiratory tract infection bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	1 (25.00%)
Vaginal infection	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Viral infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vulvovaginal candidiasis	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications						
Animal bite	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Contusion	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Post procedural discharge	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Procedural pain	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Product dispensing error	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin abrasion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound secretion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations						
Alanine aminotransferase increased	1 (16.67%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Amylase increased	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspartate aminotransferase increased	1 (16.67%)	2 (25.00%)	2 (33.33%)	1 (25.00%)	2 (33.33%)	1 (25.00%)
Bilirubin conjugated increased	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood alkaline phosphatase increased	1 (16.67%)	0 (0.00%)	2 (33.33%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Blood bilirubin increased	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Blood bilirubin unconjugated increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood cholesterol increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatine phosphokinase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatinine increased	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood thyroid stimulating hormone increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood triglycerides increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Electrocardiogram QT prolonged	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gamma-glutamyltransferase increased	1 (16.67%)	0 (0.00%)	2 (33.33%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Glomerular filtration rate decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glucose urine present	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Lymphocyte count decreased	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutrophil count decreased	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (25.00%)	1 (16.67%)	0 (0.00%)

Platelet count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (25.00%)
Troponin I increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Weight decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White blood cell count decreased	2 (33.33%)	2 (25.00%)	2 (33.33%)	0 (0.00%)	3 (50.00%)	2 (50.00%)
Metabolism and nutrition disorders						
Decreased appetite	2 (33.33%)	0 (0.00%)	3 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dehydration	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gout	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperamylasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypercalcaemia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Hyperchloraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypercholesterolaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperglycaemia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	1 (25.00%)
Hyperkalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Hyperlipasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperlipidaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperphosphataemia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Hypertriglyceridaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hypoalbuminaemia	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypocalcaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoglycaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypokalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Hypomagnesaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Hypophosphataemia	1 (16.67%)	1 (12.50%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Hypoproteinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypovolaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malnutrition	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders						
Arthralgia	2 (33.33%)	1 (12.50%)	2 (33.33%)	1 (25.00%)	2 (33.33%)	1 (25.00%)
Back pain	1 (16.67%)	1 (12.50%)	1 (16.67%)	1 (25.00%)	1 (16.67%)	1 (25.00%)
Bone pain	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flank pain	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Groin pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint stiffness	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle spasms	1 (16.67%)	2 (25.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscular weakness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (16.67%)	0 (0.00%)

Musculoskeletal discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Myalgia	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (25.00%)
Neck pain	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Osteonecrosis of jaw	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Pain in extremity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in jaw	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Plantar fasciitis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal pain	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Temporomandibular joint syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Cancer pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metastases to peritoneum	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour associated fever	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Tumour pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Nervous system disorders						
Dizziness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysgeusia	0 (0.00%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Extrapyramidal disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Facial paralysis	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	0 (0.00%)	1 (12.50%)	1 (16.67%)	2 (50.00%)	2 (33.33%)	1 (25.00%)
Hypoaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lethargy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neuralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neuropathy peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paraesthesia	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Peripheral sensory neuropathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Piriformis syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Restless legs syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sciatica	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sensory disturbance	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Somnolence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Taste disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tremor	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Product issues						
Device breakage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders						

Agitation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anxiety	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (16.67%)	0 (0.00%)
Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Depressed mood	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Depression	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Insomnia	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Panic attack	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Restlessness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders						
Acute kidney injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chronic kidney disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cystitis noninfective	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Microalbuminuria	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Micturition urgency	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Nocturia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pollakiuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal colic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Reproductive system and breast disorders						
Breast pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Endometrial thickening	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Genital burning sensation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intermenstrual bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pelvic pain	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vaginal discharge	1 (16.67%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vaginal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Vulvovaginal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vulvovaginal pruritus	1 (16.67%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders						
Cough	3 (50.00%)	3 (37.50%)	2 (33.33%)	0 (0.00%)	2 (33.33%)	0 (0.00%)
Dysphonia	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea exertional	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Interstitial lung disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasal congestion	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Nasal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oropharyngeal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleuritic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonitis	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Productive cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinorrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper-airway cough syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wheezing	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders						
Alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Dermal cyst	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis acneiform	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis contact	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis exfoliative generalised	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry skin	0 (0.00%)	1 (12.50%)	0 (0.00%)	2 (50.00%)	2 (33.33%)	0 (0.00%)
Eczema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperhidrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Nail disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Night sweats	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palmar-plantar erythrodysaesthesia syndrome	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)
Photosensitivity reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pityriasis rosea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Pruritus	1 (16.67%)	2 (25.00%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	1 (25.00%)
Psoriasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Rash erythematous	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash maculo-papular	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash pruritic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin atrophy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin discolouration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin hyperpigmentation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urticaria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders						
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hot flush	2 (33.33%)	1 (12.50%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hypertension	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	1 (16.67%)	1 (25.00%)
Hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphoedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Venous thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

LSZ102 + alpelisib (4/4)

	LSZ102 300 mg QD + BYL719 200 mg QD continuous with regular meal N = 12	**LSZ102 300 mg QD + BYL719 250 mg QD continuous with regular meal N = 6**	**LSZ102 300 mg QD + BYL719 300 mg QD continuous with regular meal N = 12**	**LSZ102 450 mg QD + BYL719 200 mg QD continuous with regular meal N = 13**
Arm/Group Description	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 250 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 300 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 300 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal	LSZ102 450 mg administered orally once daily (QD) on Days 1 to 28 of a 28-day cycle in combination with alpelisib 200 mg administered orally QD on Days 1 to 28 of a 28-day cycle with regular meal
Total participants affected	12 (100.00%)	6 (100.00%)	11 (91.67%)	13 (100.00%)
Blood and lymphatic system disorders				
Anaemia	2 (16.67%)	0 (0.00%)	2 (16.67%)	4 (30.77%)
Eosinophilia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukopenia	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenia	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders				

Angina pectoris	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bundle branch block right	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mitral valve disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palpitations	1 (8.33%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Sinus bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear and labyrinth disorders				
Ear congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear pain	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tinnitus	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vertigo	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endocrine disorders				
Hyperthyroidism	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders				
Blindness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cataract	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diplopia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry eye	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye irritation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye pruritus	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Foreign body sensation in eyes	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)

Iridocyclitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lacrimation increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periorbital swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Photophobia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vision blurred	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Visual acuity reduced	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Visual field defect	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Visual impairment	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitreous floaters	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders				
Abdominal discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal distension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain	2 (16.67%)	0 (0.00%)	2 (16.67%)	1 (7.69%)
Abdominal pain upper	2 (16.67%)	0 (0.00%)	0 (0.00%)	2 (15.38%)
Anal incontinence	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Cheilitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Constipation	3 (25.00%)	0 (0.00%)	2 (16.67%)	1 (7.69%)
Diarrhoea	9 (75.00%)	5 (83.33%)	8 (66.67%)	11 (84.62%)
Dry mouth	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Dyspepsia	2 (16.67%)	0 (0.00%)	0 (0.00%)	2 (15.38%)

Dysphagia	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Eosinophilic oesophagitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eructation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flatulence	1 (8.33%)	0 (0.00%)	1 (8.33%)	1 (7.69%)
Gastrointestinal sounds abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrooesophageal reflux disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lip oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lower gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Melaena	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mouth ulceration	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Nausea	9 (75.00%)	2 (33.33%)	8 (66.67%)	8 (61.54%)
Odynophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Oesophagitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pancreatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stomatitis	2 (16.67%)	2 (33.33%)	2 (16.67%)	2 (15.38%)
Toothache	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Vomiting	5 (41.67%)	2 (33.33%)	6 (50.00%)	4 (30.77%)
General disorders and administration site conditions				
Asthenia	1 (8.33%)	0 (0.00%)	3 (25.00%)	2 (15.38%)
Axillary pain	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Catheter site pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chills	1 (8.33%)	0 (0.00%)	1 (8.33%)	1 (7.69%)
Device related thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Early satiety	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	6 (50.00%)	3 (50.00%)	3 (25.00%)	8 (61.54%)
Generalised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Influenza like illness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malaise	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Medical device site joint inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Non-cardiac chest pain	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	2 (16.67%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Pyrexia	2 (16.67%)	0 (0.00%)	2 (16.67%)	3 (23.08%)
Hepatobiliary disorders				
Hepatic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperbilirubinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Hypertransaminasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Jaundice	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune system disorders				

Hypersensitivity	1 (8.33%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Infections and infestations				
Bacterial vulvovaginitis	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Biliary sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis viral	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Conjunctivitis	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Epstein-Barr virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia urinary tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal viral infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Genital herpes zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hordeolum	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Laryngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Localised infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Nasopharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Oral herpes	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Pharyngitis	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Pneumonia fungal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory tract infection viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Sialoadenitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Sinusitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Tooth abscess	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (15.38%)
Upper respiratory tract infection bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	1 (8.33%)	1 (16.67%)	2 (16.67%)	0 (0.00%)
Vaginal infection	1 (8.33%)	1 (16.67%)	0 (0.00%)	1 (7.69%)
Viral infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vulvovaginal candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Injury, poisoning and procedural complications				
Animal bite	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Contusion	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Post procedural discharge	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Product dispensing error	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin abrasion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound secretion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations				
Alanine aminotransferase increased	5 (41.67%)	1 (16.67%)	2 (16.67%)	1 (7.69%)
Amylase increased	1 (8.33%)	0 (0.00%)	2 (16.67%)	0 (0.00%)
Aspartate aminotransferase increased	4 (33.33%)	2 (33.33%)	3 (25.00%)	3 (23.08%)
Bilirubin conjugated increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood alkaline phosphatase increased	1 (8.33%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Blood bilirubin increased	1 (8.33%)	0 (0.00%)	2 (16.67%)	1 (7.69%)

Blood bilirubin unconjugated increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood cholesterol increased	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatine phosphokinase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatinine increased	2 (16.67%)	0 (0.00%)	0 (0.00%)	2 (15.38%)
Blood thyroid stimulating hormone increased	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood triglycerides increased	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Electrocardiogram QT prolonged	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gamma-glutamyltransferase increased	3 (25.00%)	0 (0.00%)	0 (0.00%)	2 (15.38%)
Glomerular filtration rate decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glucose urine present	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Lipase increased	2 (16.67%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Lymphocyte count decreased	1 (8.33%)	1 (16.67%)	1 (8.33%)	1 (7.69%)
Neutrophil count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Platelet count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)

Troponin I increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight decreased	2 (16.67%)	1 (16.67%)	2 (16.67%)	3 (23.08%)
Weight increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White blood cell count decreased	0 (0.00%)	1 (16.67%)	1 (8.33%)	0 (0.00%)
Metabolism and nutrition disorders				
Decreased appetite	2 (16.67%)	1 (16.67%)	6 (50.00%)	6 (46.15%)
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gout	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Hyperamylasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypercalcaemia	4 (33.33%)	0 (0.00%)	1 (8.33%)	1 (7.69%)
Hyperchloraemia	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Hypercholesterolaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperglycaemia	4 (33.33%)	3 (50.00%)	4 (33.33%)	6 (46.15%)
Hyperkalaemia	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (7.69%)
Hyperlipasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperlipidaemia	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperphosphataemia	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertriglyceridaemia	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoalbuminaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (15.38%)
Hypocalcaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Hypoglycaemia	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (7.69%)
Hypokalaemia	3 (25.00%)	1 (16.67%)	5 (41.67%)	4 (30.77%)

Hypomagnesaemia	1 (8.33%)	0 (0.00%)	2 (16.67%)	1 (7.69%)
Hyponatraemia	0 (0.00%)	1 (16.67%)	1 (8.33%)	2 (15.38%)
Hypophosphataemia	3 (25.00%)	0 (0.00%)	4 (33.33%)	2 (15.38%)
Hypoproteinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypovolaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malnutrition	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders				
Arthralgia	3 (25.00%)	2 (33.33%)	0 (0.00%)	2 (15.38%)
Back pain	1 (8.33%)	1 (16.67%)	1 (8.33%)	1 (7.69%)
Bone pain	2 (16.67%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Flank pain	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Groin pain	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)
Joint stiffness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle spasms	2 (16.67%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Muscular weakness	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Musculoskeletal chest pain	1 (8.33%)	1 (16.67%)	1 (8.33%)	1 (7.69%)
Musculoskeletal discomfort	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myalgia	1 (8.33%)	1 (16.67%)	0 (0.00%)	1 (7.69%)
Neck pain	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Osteonecrosis of jaw	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)

Pain in extremity	1 (8.33%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Pain in jaw	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Plantar fasciitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal pain	1 (8.33%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Temporomandibular joint syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Cancer pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metastases to peritoneum	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour associated fever	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders				
Dizziness	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)
Dysgeusia	1 (8.33%)	2 (33.33%)	0 (0.00%)	1 (7.69%)
Extrapyramidal disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Facial paralysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	0 (0.00%)	1 (16.67%)	2 (16.67%)	1 (7.69%)
Hypoaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lethargy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neuralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neuropathy peripheral	2 (16.67%)	1 (16.67%)	0 (0.00%)	1 (7.69%)

Paraesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Peripheral sensory neuropathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Piriformis syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Restless legs syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sciatica	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Sensory disturbance	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Somnolence	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Taste disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tremor	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Product issues				
Device breakage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders				
Agitation	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (7.69%)
Anxiety	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Depressed mood	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Depression	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Insomnia	1 (8.33%)	0 (0.00%)	1 (8.33%)	1 (7.69%)
Panic attack	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Restlessness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Renal and urinary disorders				
Acute kidney injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chronic kidney disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cystitis noninfective	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Microalbuminuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Micturition urgency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nocturia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pollakiuria	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Renal colic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary incontinence	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Urinary tract pain	0 (0.00%)	1 (16.67%)	1 (8.33%)	0 (0.00%)
Reproductive system and breast disorders				
Breast pain	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Endometrial thickening	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Genital burning sensation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intermenstrual bleeding	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Pelvic pain	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)

Vaginal discharge	2 (16.67%)	1 (16.67%)	0 (0.00%)	2 (15.38%)
Vaginal haemorrhage	2 (16.67%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Vulvovaginal inflammation	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Vulvovaginal pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders				
Cough	2 (16.67%)	0 (0.00%)	1 (8.33%)	3 (23.08%)
Dysphonia	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Dyspnoea	2 (16.67%)	0 (0.00%)	2 (16.67%)	6 (46.15%)
Dyspnoea exertional	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Interstitial lung disease	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Nasal congestion	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Nasal inflammation	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Oropharyngeal pain	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (7.69%)
Pleural effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleuritic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Pneumonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Productive cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Respiratory disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinorrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Upper-airway cough syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wheezing	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders				
Alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)
Dermal cyst	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis acneiform	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis contact	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dermatitis exfoliative generalised	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry skin	2 (16.67%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Eczema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Erythema	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperhidrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nail disorder	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Night sweats	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Palmar-plantar erythrodysaesthesia syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Photosensitivity reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pityriasis rosea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pruritus	3 (25.00%)	1 (16.67%)	2 (16.67%)	2 (15.38%)
Psoriasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash	4 (33.33%)	1 (16.67%)	2 (16.67%)	1 (7.69%)

Rash erythematous	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash maculo-papular	1 (8.33%)	1 (16.67%)	2 (16.67%)	2 (15.38%)
Rash pruritic	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Skin atrophy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin discolouration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin hyperpigmentation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urticaria	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders				
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hot flush	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertension	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypotension	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
Lymphoedema	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Venous thrombosis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)

Conclusion:

In this phase I study CLSZ102X2101, LSZ102 given as a single drug or in combination with ribociclib or alpelisib for the treatment of ER+ advanced breast cancer was considered to have a tolerable safety profile in line with other compounds of the same class and the known safety profile of the individual study drugs. No evidence of additive toxic effects of the combinations were observed. The recommended doses for the planned expansion phase were LSZ102 450 mg once daily alone, LSZ102 450 mg QD in combination with ribociclib 400 mg QD (3 weeks on /1 week off schedule or continuous, fasted or with low to regular calorie meal), and LSZ102 300 mg QD in combination with alpelisib 250 mg QD with regular meal.

Modest antitumor activity of LSZ102 as single agent and in combination with ribociclib or with alpelisib in ER+ advanced breast cancer patients was observed. The study recruitment was halted and this study was terminated earlier due to the observed limited antitumor activity and not due to any safety concerns.

Date of Clinical Trial Report

21-Jun-2022