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Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Spartalizumab (PDR001), panobinostat (LBH589), everolimus (RAD001), HDM201, QBM076 and LCL161

Trial Indication(s)

Colorectal cancer (CRC), non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), renal cell carcinoma (RCC)

Protocol Number

CPDR001X2102

Protocol Title

Phase Ib, open-label, multi-center study to characterize the safety, tolerability and pharmacodynamics (PD) of PDR001 in combination with LCL161, everolimus (RAD001) or panobinostat (LBH589)

Clinical Trial Phase

Phase 1

Phase of Drug Development

Phase III (spartalizumab), phase IV (panobinostat), phase IV (everolimus), phase II (HDM201), phase II (QBM076) and phase II (LCL161)

Study Start/End Dates

Study Start Date: October 2016 (Actual)
Primary Completion Date: February 2022 (Actual)
Study Completion Date: February 2022 (Actual)

Study Design/Methodology

This was a phase Ib, multi-center, open-label study of PDR001 in combination with:

- LCL161, everolimus, panobinostat or QBM076 in patients with advanced/metastatic colorectal cancer (CRC), triple-negative breast cancer (TNBC) or non-small cell lung cancer (NSCLC)
- HDM201 in patients with TP53 wildtype microsatellite stable colorectal cancer (MSS-CRC) or renal cell carcinoma (RCC)

The study was comprised of a dose escalation part followed by a dose expansion part.

During the dose escalation part of the study, patients were treated with a fixed dose of PDR001, administered intravenously (i.v.), in combination with one of the combination partners, to determine safety, tolerability and the maximum tolerated dose/recommended dose for expansion (MTD/RDE). Dose escalation and determination of the MTD/RDE was guided by a Bayesian Logistic Regression Model (BLRM) with Escalation With Overdose Control (EWOC) criteria. Enrollment to the treatment groups PDR001+panobinostat and PDR001+QBM076 was closed during the dose escalation phase.

Once the MTD/RDE had been declared for a combination therapy, the respective dose expansion part could begin. The main objective of each expansion part was to further assess the safety and tolerability of any study treatment at the MTD/RDE. There was dose expansion phase for the following combination treatments: PDR001+everolimus, PDR001+HDM201 and PDR001+LCL161. The dose expansion phase for PDR001+panobinostat and PDR001+QBM076 was not initiated.

All patients enrolled in escalation part and expansion part were able to participate in the following study periods:

Molecular prescreening period (for PDR001+HDM201 only)

Potential eligible patients had to have documented confirmation of a tumor sample as TP53 wild type by DNA sequence analysis before them could be considered for full screening.

Screening period

Screening evaluations were performed within 21 days prior to the first dose of study treatment.

Treatment period 1

Treatment period 1 began on Cycle 1 Day 1. Study treatment during treatment period 1 was administered for six cycles of therapy unless the patient experienced unacceptable toxicity, had clinical evidence of disease progression and/or study treatment was

discontinued at the discretion of the investigator or the patient. Patients who had radiological evidence of disease progression but had evidence of clinical benefit were able to continue study treatment to complete six cycles.

Treatment interruption period

Once a patient had completed cycle 6 (treatment period 1), study treatment was interrupted and the patient entered the study treatment interruption period. Patients continued study visits as defined in the study protocol. Patients in the interruption period were able to resume study treatment following a discussion with the investigator. If they chose not to resume they were discontinued at the time of end of study.

Treatment period 2

Patients should resume study treatment at the same dose and schedule they were receiving at the time of their treatment interruption. For combination treatments that had been evaluated and did not offer clinical benefit beyond that expected for PD-1 blockade alone, or if an investigational agent was no longer available, patients could be treated with single agent PDR001.

All patients had to have a tumor assessment prior to resuming study treatment; this tumor assessment was used as treatment period 2 baseline. Following the completion of two cycles of study treatment, if a patient had not experienced any > grade 2 study treatment-related toxicities, he/she could continue on study under a reduced schedule of assessments per the institutions standard of care or every three months, whichever was more frequent. Patients who had radiological evidence of disease progression during treatment period 2 and had evidence of clinical benefit could continue study treatment.

Safety follow up period

All patients were followed for safety evaluations for 150 days following permanent discontinuation of PDR001.

Disease progression follow up

Patients who permanently discontinued study treatment within the treatment period 1 or treatment interruption period for any reason other than clinical or radiological disease progression, withdrawal of consent, lost to follow-up or death, were followed up for progression of disease or until initiation of subsequent anti-cancer therapy.

Centers

25 centers in 7 countries/regions: Netherlands(4), Taiwan(1), Spain(3), Korea, Republic of(2), United States(9), United Kingdom(3), Germany(3)

Objectives:

The primary objective of the trial was to characterize the safety and tolerability of PDR001 in combination with LCL161, RAD001, LBH589, HDM201 or QBM076 and to identify recommended doses and schedules for future studies.

The secondary objectives were:

- To further characterize the safety of PDR001 in combination with LBH589
- To estimate the anti-tumor activity of PDR001 in combination with LCL161, RAD001, LBH589, HDM201 or QBM076
- To characterize the pharmacokinetics of all study drugs
- To assess immunogenicity of PDR001

Based on the primary and secondary objectives, the following endpoints were assessed:

Endpoint	Description
Primary: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period	Number of participants with AEs and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs. The on-treatment period is defined as the period from day of first dose of study treatment to 30 days after last dose of any study medication. Grades to characterize the severity of the biochemistry abnormalities were based on the Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. For CTCAE, Grade 1 = mild; Grade 2 = moderate; Grade 3 = severe; Grade 4 = life threatening; Grade 5 (death) was not used in this study.

Primary: Number of participants with shifts from baseline to the worst post-baseline hematology abnormalities based on CTC grades	Common toxicity criteria (CTC) grades to characterize the severity of the hematology abnormalities were based on the Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. For CTCAE, Grade 1 = mild; Grade 2 = moderate; Grade 3 = severe; Grade 4 = life threatening. Grade 5 (death) was not used. The number of participants in each category is reported in the table with results. 'All grades' represents participants with any grade 1, 2, 3 or 4 post-baseline.
Primary: Number of participants with shifts from baseline to the worst post-baseline biochemistry abnormalities based on CTC grades	Common toxicity criteria (CTC) grades to characterize the severity of the biochemistry abnormalities were based on the Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. For CTCAE, Grade 1 = mild; Grade 2 = moderate; Grade 3 = severe; Grade 4 = life threatening. Grade 5 (death) was not used. The number of participants in each category is reported in the table with results. 'All grades' represents participants with any grade 1, 2, 3 or 4 post-baseline.
Primary: Number of participants with notable changes from baseline in vital sign values	Vital sign parameters collected were systolic and diastolic blood pressure (mmHg), pulse rate (beats per minute), body temperature (°C), and weight (kg). Vital sign values considered notably abnormal were defined as follows: • Systolic blood pressure [mmHg]: >=180 mmHg with increase from baseline of >=20 mmHg /<=90 mmHg with decrease from baseline of >=20 mmHg • Diastolic blood pressure [mmHg]: >=105 mmHg with increase from baseline of >=15 mmHg /<=50 mmHg with decrease from baseline of >=15 mmHg • Pulse rate [bpm]: >=100 bpm with increase from baseline of >25% bpm /<=50 bpm with decrease from baseline of >25% bpm • Body temperature [°C]: >=39.1

	• Weight [kg]: >=10% decrease/increase from baseline The number of participants in each category is reported in the table with results.
Primary: Number of participants with Dose-Limiting Toxicities (DLTs) (Dose escalation only)	A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 assessed as unrelated to disease, disease progression, inter-current illness or concomitant medications that occurs within the first 56 days (first 2 cycles) of treatment with PDR001 in combination with LCL161, panobinostat, everolimus, HDM201 or QBM076 during the dose escalation part of the study. Other clinically significant toxicities could be considered to be DLTs, even if not CTCAE grade 3 or higher.
Primary: Number of participants with dose reductions or interruptions of PDR001, panobinostat, everolimus, HDM201, QBM076 and LCL161	Number of participants with dose reductions or interruptions of PDR001, panobinostat, everolimus, HDM201, QBM076 and LCL161 during the overall study period. Dose reductions of PDR001 were not permitted.
Primary: Relative dose intensity of PDR001, panobinostat, everolimus, HDM201, QBM076 and LCL161	Relative dose intensity of PDR001, panobinostat, everolimus, HDM201, QBM076 and LCL161 in each treatment period was calculated as actual dose intensity divided by planned dose intensity and multiplied by 100.
Secondary: Number of participants with changes from baseline in ECG parameters in the combination arm of PDR001 and panobinostat	Standard 12-lead electrocardiogram (ECG) were performed in triplicate on all patients assigned to PDR001 in combination with panobinostat. A local cardiologist could be consulted at any time during the study at the discretion of the investigator.

Secondary: Best Overall Response (BOR) per RECIST v1.1	BOR is defined as the best response recorded from the start of the treatment until disease progression/recurrence. BOR was based on overall responses over treatment period 1 until disease progression, or start of new anti-neoplastic therapy, or discontinuation of study due to reasons other than progressive disease (PD), whichever occurs earlier assessed locally by the Investigator at each evaluation. The assessment criteria was Response Evaluation Criteria In Solid Tumors (RECIST) v1.1. Complete Response (CR) and Partial Response (PR) were confirmed by repeat assessments that were performed not less than four weeks after the criteria for response were first met.
Secondary: Best Overall Response (BOR) per irRC	BOR is defined as the best response recorded from the start of the treatment until disease progression/recurrence. BOR was based on overall responses over treatment period 1 until disease progression, or start of new anti-neoplastic therapy, or discontinuation of study due to reasons other than progressive disease (PD), whichever occurs earlier assessed locally by the Investigator at each evaluation. The assessment criteria was Immune-related Response Criteria (irRC). Immune-related Complete Response (irCR) and Immune-related Partial Response (irPR) were confirmed by repeat assessments that were performed not less than four weeks after the criteria for response were first met. Additionally, Immune-related Progressive Disease (irPD) was confirmed in a similar manner.
Secondary: Progression-Free Survival (PFS) per RECIST v1.1	PFS is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause over treatment period 1. PFS was estimated using the Kaplan-Meier Method.

	For the analysis of PFS, subjects without documented disease progression or death were censored at the time of last valid tumor assessment documenting non-progression (one of CR, PR, or stable disease (SD)). Subjects without any valid post baseline tumor assessment response (one of CR, PR, SD, or PD) were censored on the start date of treatment. Subjects who had a PFS event (progression or death) after two or more consecutive missing assessments from the last valid tumor assessment were censored on the last valid tumor assessment (or on the start date of treatment among those without a post baseline tumor assessment).
Secondary: Progression-Free Survival (PFS) per irRC	PFS is defined as the time from the date of start of treatment to the date of the first documented and confirmed progression or death due to any cause over treatment period 1. Progressive disease should be confirmed by a repeat assessment that should be performed not less than 4 weeks after the criteria for progression are first met. The date of progression will then be the date of the first of these two assessments. For patients without a confirmation assessment, and with no subsequent assessments of SD or better, a single assessment will be used as date of progression. PFS was estimated using the Kaplan-Meier Method. For the analysis of PFS, subjects without documented and confirmed disease progression or death were censored at the time of last valid tumor assessment documenting non-progression (one of irCR, irPR, or irSD). Subjects without any valid post baseline tumor assessment response (one of irCR, irPR, irSD, or irPD) were censored on the start date of treatment.

Secondary: Treatment Free Survival (TFS)	Treatment Free Survival (TFS) is defined as time from interruption of study combination at the completion of six cycles of treatment (=last exposure to study treatment in treatment period 1 + 1 day) to date of clinical disease progression or disease progression as per irRC and/or RECIST 1.1, whichever should trigger the resume of the treatment, or date of death due to disease. If a patient had not had an event (PD or death due to disease), TFS was censored at the date of the last adequate tumor evaluation during the treatment interruption (treatment free) period. Treatment free survival is only defined for subjects who entered the treatment interruption period. TFS was estimated using the Kaplan-Meier Method.
Secondary: Maximum observed concentration (Cmax) of PDR001, panobinostat, everolimus, HDM201, QBM076 and LCL161	Pharmacokinetic (PK) parameters were calculated based on the concentrations of PDR001 in serum, everolimus in whole blood and panobinostat, HDM201, QBM076 and LCL161 in plasma by using non-compartmental methods. Cmax is defined as the maximum (peak) observed concentration following a dose.
Secondary: Time to reach maximum serum concentration (Tmax) of PDR001, panobinostat, everolimus, HDM201, QBM076 and LCL161	PK parameters were calculated based on the concentrations of PDR001 in serum, everolimus in whole blood and panobinostat, HDM201, QBM076 and LCL161 in plasma by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) serum concentration following a dose. Actual recorded sampling times were considered for the calculations.
Secondary: Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of PDR001	PK parameters were calculated based on PDR001 serum concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUClast calculation.
Secondary: Pre-dose trough concentration (Ctrough) of PDR001	PK parameters were calculated based on PDR001 serum concentrations by using non-compartmental methods. Ctrough is defined as the concentration reached by PDR001 immediately before the next dose is administered.

Secondary: Number of participants with anti-drug antibodies (ADA) against PDR001	Immunogenicity was evaluated in serum in a validated three-tiered assay approach. Samples were screened for potential anti-PDR001 antibodies and positive screen results were confirmed using a confirmatory assay. For confirmed ADA positive samples, titers were determined. Number of participants with overall prevalence of ADA samples (i.e at least one ADA-positive sample) are reported in the table with results.

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

In this study, the terms "investigational drug" or "study drug" refer to PDR001, panobinostat, everolimus, HDM201, QBM076 or LCL161 and “study treatment” refers to the combination of PDR001 given at a fixed dose with each of the other five combination partners.

All participants were treated with PDR001 at the recommended phase 2 dose of 400 mg every 4 weeks (Q4W). PDR001 was given as an intravenous infusion.

Panobinostat (LBH589) 10 mg was administered orally as a capsule. Two dose regimens were assessed: three times a week (TIW) 1 week on/1 week off and TIW 2 weeks on/1 week off.

Everolimus (RAD001) 5 mg was administered orally as a tablet once per week (QW).

HDM201 was administered orally as a capsule on Day 1 and Day 8 of every cycle at a dose of 60 mg (recommended dose for expansion) and 100 mg.

QBM076 was administered orally as a capsule twice daily (BID) 2 week on/2 week off at a dose of 75 mg and 150 mg.

LCL161 was administered orally as a tablet once per week (QW) at a dose of 300 mg, 600 mg and 900 mg.

Statistical Methods

The data were analyzed by Novartis personnel using SAS version 9.4 and higher, and for Bayesian modeling, R version 3.2.3 and higher and JAGS version 4.0.0. PK parameters were calculated using non-compartmental methods available in Phoenix WinNonlin version 6.4.

Data from participating centers were combined, so that an adequate number of subjects were available for analysis. No center effect was assessed. The data were summarized with respect to demographic and baseline characteristics, efficacy observations and measurements, safety observations and measurements, and all relevant PK and PD measurements using descriptive statistics for quantitative data and contingency tables (frequencies and percentages) for qualitative data.

Treatment group was defined by the dose level and regimen of the study treatment (e.g. PDR001 400mg Q4W + RAD001 5mg QW is one treatment group). Therefore, a treatment group could consist of more than one cohort.

Across the dose escalation and expansion parts of the study, subjects in the same disease group (TNBC, NSCLC, RCC or CRC) treated at RDE in the same dose combination (dose levels and regimen) were pooled into a single treatment disease group.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

- Written informed consent prior to any procedure
- Patients with advanced/metastatic cancer, with measurable disease as determined by RECIST version 1.1, who have progressed despite standard therapy or are intolerant to SOC, or for whom no standard therapy exists. Patients must fit into one of the following groups:

• CRC •NSCLC • TNBC• RCC

- ECOG ≤ 2
- Patient must have a site of disease for biopsy, and be a candidate for tumor biopsy according to the institution’s guidelines. Patient must be willing to undergo a new tumor biopsy at screening, and again during therapy on this study.

- Prior therapy with PD-1/PDL-1 inhibitors is allowed provided any toxicity attributed to prior PD-1- or PD-L1-directed therapy did not lead to discontinuation of therapy.

Exclusion Criteria:
- Presence of symptomatic central nervous system (CNS) metastases, or CNS metastases that require local CNS-directed therapy within prior 2 weeks.
- Patients with known hypersensitivity to any of the components of an investigational treatment will be excluded from participation in the corresponding arm but are eligible for participation in other study arm; Patients that have a history of hypersensitivity to rapamycin derivatives will be excluded from participation in the everolimus arm
- History of or current drug-induced interstitial lung disease or pneumonitis grade ≥2
- Out of range lab values as defined in protocol
- Impaired cardiac function or clinically significant cardiac disease
- Active, known or suspected autoimmune disease
- Human Immunodeficiency Virus (HIV), or active Hepatitis C (HCV) virus. Escalation: active Hepatitis B (HBV); Expansion: Patients with Chronic HBV currently on medication will not be excluded.
- Impairment of gastrointestinal (GI) function
- Malignant disease, other than that being treated in this study
- Systemic anti-cancer therapy within 2 weeks of the first dose of study treatment. For cytotoxic agents that have major delayed toxicity and washout period is 6 weeks; prior immunotherapy - washout is 4 weeks
- Active infection requiring systemic antibiotic therapy.
- Patients requiring chronic treatment with systemic steroid therapy, other than replacement dose steroids or treatment with low, stable dose of steroid (<10 mg/day prednisone or equivalent) for stable CNS metastatic disease.
- Patients receiving systemic treatment with any immunosuppressive medication.
- Major surgery within 2 weeks of the first dose of study treatment

- Radiotherapy within 2 weeks of the first dose of study drug
- Participation in an interventional, investigational study within 2 weeks of the first dose of study treatment.
- Presence of ≥ CTCAE grade 2 toxicity (except alopecia, peripheral neuropathy and ototoxicity, which are excluded if ≥ CTCAE grade 3) due to prior therapy.
- Use of hematopoietic colony stimulating growth factors </= 3 weeks prior to first dose

Additional exclusion criteria for PDR001/LCL161
- Patients requiring medications metabolized through CYP3A4/5 and have a narrow therapeutic index or medications that are CYP3A4 substrates that cause QT prolongation
- Patients requiring treatment with strong CYP2C8 inhibitors

Additional exclusion criteria for PDR001/Everolimus
- Patients requiring treatment with moderate CYP3A4 inhibitors
- Patients requiring treatment with a strong CYP3A4 inhibitor or inducer

Additional exclusion criteria for PDR001/Panobinostat-
- Patient who received DAC inhibitors
- Patient needing valproic acid during the study or within 5 days prior to first dose
- Patients requiring medications that are sensitive CYP2D6 substrates areCYP2D6 substrates with a narrow therapeutic index or are anti-arrhythmic drugs/drugs with QT-prolongation risks
- Patients requiring a strong inhibitor or inducer of CYP3A4
- Clinically significant, uncontrolled heart disease and/or recent cardiac event within 6 months prior to study
- Unresolved diarrhea ≥ CTCAE grade 2 or a medical condition associated with chronic diarrhea
- Taking medications with QT prolongation risk or interval or inducing Torsade de pointes

Additional exclusion criteria for PDR001/QBM076-

- Patients requiring medications that are strong inducers or strong inhibitors of CYP3A4
- Patients requiring medications with narrow therapeutic index CYP3A4 substrates
- Women using any form of hormonal contraception (oral, injected, implanted, transdermal) will be excluded (unless they are willing to switch to another effective form of contraception under their physician's guidance)

Additional exclusion criteria for PDR001/HDM201-
- Prior treatment with compounds with the same mode of action as proposed for HDM201, i.e. an inhibition of the interaction of TP53 with HDM2, e.g. RG7112 or CGM097
- Patients who require the following treatments moderate to strong CYP3A4 inhibitors; any substrates of CYP3A4/5 with a narrow therapeutic index
- Moderate to strong CYP3A4 inducers
- Patients having out of range values for:
Absolute neutrophil count (ANC) <1500/µL; Platelets < 100 000/µL

Participant Flow Table

Treatment Period 1

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 100 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 100 mg (RDE) RCC	PDR001 + QBM07 6 75 mg CRC	PDR001 + QBM07 6 150 mg CRC	PDR001 + QBM07 6 75 mg NSCLC	PDR001 + QBM07 6 150 mg NSCLC	PDR001 + QBM07 6 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW	Total
Arm/Group	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg every	PDR001 400 mg	PDR001 400 mg every	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg	PDR001 400 mg	

Description	every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)	
Started	7	10	27	35	36	32	5	24	11	7	2	1	1	9	25	33	27	6	298
Completed	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed	7	10	27	35	36	32	5	24	11	7	2	1	1	9	25	33	27	6	298
Adverse Event	0	1	1	0	2	2	1	0	0	1	0	0	1	2	3	0	1	0	15

Progressive Disease	6	8	22	33	34	28	3	14	8	6	2	0	0	4	21	28	23	5	245
Subject/guardian decision	1	0	1	0	0	1	0	3	1	0	0	0	0	1	1	1	0	1	11
Death	0	1	2	2	0	1	1	1	0	0	0	1	0	0	0	3	3	0	15
Physician Decision	0	0	1	0	0	0	0	6	2	0	0	0	0	0	0	1	0	0	10
Study terminated by sponsor	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	2

Treatment Period 2

	PDR001 + LBH589 10 mg TIW 1wk on/1 wk off	**PDR001 + LBH589 10 mg TIW 2wk on/1 wk off**	**PDR001 + RAD001 5 mg QW NSCLC**	**PDR001 + RAD001 5 mg QW TNBC**	**PDR001 + RAD001 5 mg QW CRC**	**PDR001 + HDM201 60 mg (RDE) CRC**	**PDR001 + HDM201 100 mg CRC**	**PDR001 + HDM201 60 mg (RDE) RCC**	**PDR001 + QBM076 75 mg CRC**	**PDR001 + QBM076 150 mg CRC**	**PDR001 + QBM076 75 mg NSCLC**	**PDR001 + QBM076 150 mg NSCLC**	**PDR001 + QBM076 75 mg TNBC**	**PDR001 + LCL161 300 mg QW**	**PDR001 + LCL161 600 mg QW NSCLC**	**PDR001 + LCL161 600 mg QW TNBC**	**PDR001 + LCL161 600 mg QW CRC**	**PDR001 + LCL161 900 mg QW**	**Total**
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks (Q4W) in	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks (Q4W) in	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks	PDR001 400 mg every 4 weeks	

	in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	(Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	(Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	(Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	(Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	(Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	(Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	(Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	(Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	(Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	(Q4W) in combination with LCL161 300 mg once per week (QW)	(Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	(Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	(Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	(Q4W) in combination with LCL161 900 mg once per week (QW)	
Started	0	1	5	2	4	2	1	4	2	0	0	0	0	0	5	1	0	0	27
Completed	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed	0	1	5	2	4	2	1	4	2	0	0	0	0	0	5	1	0	0	27
Adverse Event	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	2
Progressive Disease	0	1	3	2	3	2	1	2	1	0	0	0	0	0	3	1	0	0	19
Unknown	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2

Physician Decision	0	0	0	0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	3
Study terminated by sponsor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1

Baseline Characteristics

	PDR001 + LBH589 10 mg TIW 1wk on/1 wk off	**PDR001 + LBH589 10 mg TIW 2wk on/1 wk off**	**PDR001 + RAD001 5 mg QW NSCLC**	**PDR001 + RAD001 5 mg QW TNBC**	**PDR001 + RAD001 5 mg QW CRC**	**PDR001 + HDM201 60 mg (RDE) CRC**	**PDR001 + HDM201 100 mg CRC**	**PDR001 + HDM201 60 mg (RDE) RCC**	**PDR001 + QBM076 75 mg CRC**	**PDR001 + QBM076 150 mg CRC**	**PDR001 + QBM076 75 mg NSCLC**	**PDR001 + QBM076 150 mg NSCLC**	**PDR001 + QBM076 75 mg TNBC**	**PDR001 + LCL161 300 mg QW**	**PDR001 + LCL161 600 mg QW NSCLC**	**PDR001 + LCL161 600 mg QW TNBC**	**PDR001 + LCL161 600 mg QW CRC**	**PDR001 + LCL161 900 mg QW**	**Total**
Arm/ Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinosta	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinosta	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommende	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommende	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once	

	t 10 mg three times a week (TIW) 1 week on/1 week off	t 10 mg three times a week (TIW) 2 weeks on/1 week off	per week (QW) in non-small cell lung cancer (NSCLC)	per week (QW) in triple-negative breast cancer (TNBC)	per week (QW) in colorectal cancer (CRC)	d dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	d dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	per week (QW)	per week (QW) in non-small cell lung cancer (NSCLC)	per week (QW) in triple-negative breast cancer (TNBC)	per week (QW) in colorectal cancer (CRC)	per week (QW)	
Number of Participants [units: participants]	7	10	27	35	36	32	5	24	11	7	2	1	1	9	25	33	27	6	298
Age Continuous (units: years) Mean ± Standard Deviation																			
	57.4 ±8.54	60.4 ±4.65	64.4 ±10.54	51.0 ±11.97	54.8 ±11.68	63.8± 10.66	60.8 ±9.98	61.5± 9.70	64.7 ±10.60	53.6 ±12.41	60.0 ±8.49	59.0	56.0	59.0 ±12.13	62.1 ±10.68	49.2 ±10.95	57.0 ±12.29	50.7 ±15.73	57.7 ±12.02
Sex: Female, Male (units: participants) Count of Participants (Not Applicable)																			
Female	3	4	11	35	14	9	2	2	6	2	0	1	1	4	8	33	10	3	148
Male	4	6	16	0	22	23	3	22	5	5	2	0	0	5	17	0	17	3	150

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

Caucasian	4	4	8	26	26	26	4	4	8	2	0	0	1	3	11	22	20	4	173
Asian	3	3	19	6	8	2	0	16	1	3	2	1	0	5	14	9	5	2	99
Unknown	0	1	0	2	1	0	1	1	1	1	0	0	0	1	0	0	0	0	9
Black	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	1	0	3
Native American	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Other	0	2	0	0	0	4	0	3	1	1	0	0	0	0	0	1	1	0	13

Primary Outcome Result(s)

Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period

(Time Frame: From first dose of study treatment up to 30 days after last dose in each treatment period. The median duration of exposure to study treatment ranged between 8 and 9.15 weeks in Treatment Period 1 and between 5 and 42.05 weeks in Treatment Period 2)

PDR001 + LBH589 10 mg TIW 1wk on/1	PDR001 + LBH589 10 mg TIW 2wk on/1	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW	PDR001 + LCL161 600 mg QW	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW

	wk off	wk off													NSC LC	TNB C		
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Participants Analyzed [units: participants]	7	10	27	35	36	32	5	24	11	7	2	1	1	10	25	32	27	6
Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period (units: participants) Count of Participants (Not Applicable)																		
AEs – All grades	7 (100%)	10 (100%)	26 (96.3%)	35 (100%)	35 (97.22%)	31 (96.88%)	5 (100%)	23 (95.83%)	11 (100%)	7 (100%)	2 (100%)	1 (100%)	1 (100%)	10 (100%)	24 (96%)	31 (96.88%)	27 (100%)	6 (100%)

AEs – Grade ≥3	5 (71.43%)	8 (80%)	16 (59.26%)	16 (45.71%)	18 (50%)	11 (34.38%)	4 (80%)	15 (62.5%)	6 (54.55%)	7 (100%)	2 (100%)	1 (100%)	1 (100%)	5 (50%)	12 (48%)	19 (59.38%)	11 (40.74%)	4 (66.67%)
Treatment-related AEs – All grades	6 (85.71%)	6 (60%)	19 (70.37%)	20 (57.14%)	30 (83.33%)	25 (78.13%)	4 (80%)	19 (79.17%)	9 (81.82%)	4 (57.14%)	1 (50%)	1 (100%)	1 (100%)	9 (90%)	16 (64%)	24 (75%)	23 (85.19%)	6 (100%)
Treatment-related AEs – Grade ≥3	1 (14.29%)	3 (30%)	1 (3.7%)	3 (8.57%)	8 (22.22%)	5 (15.63%)	3 (60%)	9 (37.5%)	2 (18.18%)	3 (42.86%)	1 (50%)	0 (%)	0 (%)	0 (%)	3 (12%)	5 (15.63%)	4 (14.81%)	3 (50%)
SAEs – All grades	4 (57.14%)	6 (60%)	12 (44.44%)	14 (40%)	14 (38.89%)	6 (18.75%)	2 (40%)	8 (33.33%)	4 (36.36%)	5 (71.43%)	1 (50%)	1 (100%)	1 (100%)	4 (40%)	12 (48%)	12 (37.5%)	8 (29.63%)	2 (33.33%)
SAEs – Grade ≥3	4 (57.14%)	5 (50%)	10 (37.04%)	13 (37.14%)	12 (33.33%)	5 (15.63%)	1 (20%)	8 (33.33%)	2 (18.18%)	5 (71.43%)	1 (50%)	1 (100%)	1 (100%)	4 (40%)	8 (32%)	11 (34.38%)	7 (25.93%)	1 (16.67%)
Treatment-related SAEs – All grades	0 (%)	1 (10%)	1 (3.7%)	0 (%)	4 (11.11%)	2 (6.25%)	0 (%)	3 (12.5%)	0 (%)	2 (28.57%)	0 (%)	0 (%)	0 (%)	0 (%)	3 (12%)	3 (9.38%)	2 (7.41%)	0 (%)
Treatment-related SAEs – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	4 (11.11%)	1 (3.13%)	0 (%)	2 (8.33%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4%)	2 (6.25%)	2 (7.41%)	0 (%)
Fatal SAEs – All grades	0 (%)	0 (%)	1 (3.7%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (3.7%)	0 (%)
Fatal SAEs – Grade ≥3	0 (%)	0 (%)	1 (3.7%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (3.7%)	0 (%)
AEs leading to discontinuation – All grades	0 (%)	1 (10%)	1 (3.7%)	0 (%)	3 (8.33%)	2 (6.25%)	1 (20%)	0 (%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	1 (100%)	1 (10%)	4 (16%)	0 (%)	1 (3.7%)	0 (%)

AEs leading to discontinuation – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	2 (5.56%)	1 (3.13%)	0 (%)	0 (%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	1 (100%)	1 (10%)	3 (12%)	0 (%)	1 (3.7%)	0 (%)
Treatment-related AEs leading to discontinuation – All grades	0 (%)	0 (%)	1 (3.7%)	0 (%)	1 (2.78%)	2 (6.25%)	1 (20%)	0 (%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)	3 (12%)	0 (%)	1 (3.7%)	0 (%)
Treatment-related AEs leading to discontinuation – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	1 (2.78%)	1 (3.13%)	0 (%)	0 (%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4%)	0 (%)	1 (3.7%)	0 (%)
AEs leading to dose adjustment/interruption – All grades	4 (57.14%)	4 (40%)	6 (22.22%)	9 (25.71%)	12 (33.33%)	8 (25%)	3 (60%)	7 (29.17%)	2 (18.18%)	5 (71.43%)	2 (100%)	1 (100%)	0 (%)	4 (40%)	7 (28%)	9 (28.13%)	8 (29.63%)	4 (66.67%)
AEs leading to dose adjustment/interruption – Grade ≥3	2 (28.57%)	3 (30%)	4 (14.81%)	5 (14.29%)	8 (22.22%)	5 (15.63%)	2 (40%)	6 (25%)	2 (18.18%)	4 (57.14%)	2 (100%)	1 (100%)	0 (%)	4 (40%)	3 (12%)	5 (15.63%)	5 (18.52%)	2 (33.33%)
AEs requiring additional therapy – All grades	6 (85.71%)	9 (90%)	24 (88.89%)	32 (91.43%)	33 (91.67%)	25 (78.13%)	4 (80%)	23 (95.83%)	10 (90.91%)	7 (100%)	2 (100%)	1 (100%)	1 (100%)	9 (90%)	24 (96%)	29 (90.63%)	23 (85.19%)	6 (100%)
AEs requiring additional therapy – Grade ≥3	4 (57.14%)	5 (50%)	14 (51.85%)	14 (40%)	12 (33.33%)	8 (25%)	1 (20%)	11 (45.83%)	3 (27.27%)	7 (100%)	2 (100%)	1 (100%)	1 (100%)	5 (50%)	12 (48%)	15 (46.88%)	7 (25.93%)	4 (66.67%)

Number of participants with shifts from baseline to the worst post-baseline hematology abnormalities based on CTC grades

(Time Frame: From baseline (predose) up to 30 days after last dose of study treatment in each treatment period. The median duration of exposure to study treatment ranged between 8 and 9.15 weeks in Treatment Period 1 and between 5 and 42.05 weeks in Treatment Period 2)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Participants Analyz	7	10	27	35	36	32	5	24	11	7	2	1	1	10	25	32	27	6

ed [units: participants]																		
Number of participants with shifts from baseline to the worst post-baseline hematology abnormalities based on CTC grades (units: participants) Count of Participants (Not Applicable)																		
Hemoglobin (decrease) – All grades	6 (85.71 %)	8 (80%)	26 (96.3 %)	28 (80%)	32 (88.89%)	29 (90.63 %)	4 (80%)	23 (95.83 %)	9 (81.82%)	6 (85.71%)	2 (100 %)	1 (100 %)	1 (100 %)	6 (60%)	17 (68%)	23 (71.88%)	26 (96.3 %)	5 (83.33%)
Hemoglobin (decrease) – Grade ≥3	1 (14.29 %)	0 (%)	1 (3.7%)	2 (5.71 %)	3 (8.33 %)	1 (3.13%)	1 (20%)	5 (20.83 %)	0 (%)	1 (14.29%)	0 (%)	1 (100 %)	0 (%)	1 (10%)	0 (%)	1 (3.13 %)	1 (3.7%)	0 (%)
Leukocytes (decrease) – All grades	1 (14.29 %)	0 (%)	2 (7.41 %)	7 (20%)	4 (11.11%)	7 (21.88 %)	3 (60%)	8 (33.33 %)	3 (27.27%)	2 (28.57%)	0 (%)	0 (%)	1 (100 %)	1 (10%)	4 (16%)	10 (31.25%)	0 (%)	2 (33.33%)
Leukocytes (decrease) – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4.17%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Lymphocytes (increase) – All grades	0 (%)	0 (%)	5 (18.52%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (9.09 %)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Lymphocytes (increase) – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Lymphocytes (decrease) – All grades	4 (57.14 %)	6 (60%)	0 (%)	22 (62.86%)	20 (55.56%)	20 (62.5%)	2 (40%)	4 (16.67 %)	6 (54.55%)	2 (28.57%)	0 (%)	0 (%)	1 (100 %)	2 (20%)	9 (36%)	14 (43.75%)	12 (44.44%)	3 (50%)
Lymphocytes (decrease) – Grade ≥3	1 (14.29 %)	0 (%)	0 (%)	5 (14.29%)	8 (22.22%)	2 (6.25%)	0 (%)	0 (%)	0 (%)	2 (28.57%)	0 (%)	0 (%)	1 (100 %)	0 (%)	0 (%)	2 (6.25 %)	3 (11.11%)	1 (16.67%)
Neutrophils (decrease) – All grades	1 (14.29 %)	0 (%)	0 (%)	0 (%)	1 (2.78 %)	2 (6.25%)	2 (40%)	0 (%)	2 (18.18%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	3 (9.38 %)	0 (%)	0 (%)
Neutrophils (decrease) – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (40%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Platelets (decrease – All grades	2 (28.57 %)	4 (40%)	2 (7.41 %)	6 (17.14%)	4 (11.11%)	11 (34.38 %)	4 (80%)	12 (50%)	3 (27.27%)	1 (14.29%)	0 (%)	1 (100 %)	0 (%)	1 (10%)	1 (4%)	2 (6.25 %)	3 (11.11%)	0 (%)
Platelets (decrea	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (6.25%)	1 (20%)	4 (16.67 %)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4%)	0 (%)	0 (%)	0 (%)

se) – Grade ≥3

Number of participants with shifts from baseline to the worst post-baseline biochemistry abnormalities based on CTC grades

(Time Frame: From baseline (predose) up to 30 days after last dose in each treatment period. The median duration of exposure to study treatment ranged between 8 and 9.15 weeks in Treatment Period 1 and between 5 and 42.05 weeks in Treatment Period 2)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)

Number of Participants Analyzed [units: participants]	7	10	27	35	36	32	5	24	11	7	2	1	1	10	25	32	27	6
Number of participants with shifts from baseline to the worst post-baseline biochemistry abnormalities based on CTC grades (units: participants) Count of Participants (Not Applicable)																		
Alanine Aminotransferase (increase) – All grades	4 (57.14 %)	1 (10%)	7 (25.93%)	14 (40%)	20 (55.56%)	9 (28.13 %)	0 (%)	5 (20.83 %)	5 (45.45%)	3 (42.86%)	1 (50%)	0 (%)	0 (%)	2 (20%)	7 (28%)	7 (21.88%)	10 (37.04%)	4 (66.67%)
Alanine Aminotransferase (increase) – Grade ≥3	2 (28.57 %)	0 (%)	0 (%)	1 (2.86 %)	4 (11.11%)	2 (6.25%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (50%)	0 (%)	0 (%)	1 (10%)	0 (%)	0 (%)	1 (3.7%)	1 (16.67%)
Albumin (decrease) – All grades	4 (57.14 %)	5 (50%)	13 (48.15%)	18 (51.43%)	16 (44.44%)	14 (43.75 %)	1 (20%)	18 (75%)	5 (45.45%)	5 (71.43%)	1 (50%)	1 (100 %)	1 (100 %)	3 (30%)	8 (32%)	11 (34.38%)	12 (44.44%)	3 (50%)
Albumin (decrease) – Grade ≥3	0 (%)	1 (10%)	0 (%)	0 (%)	1 (2.78 %)	0 (%)	0 (%)	0 (%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	1 (10%)	0 (%)	0 (%)	1 (3.7%)	0 (%)
Alkaline Phosphatase (increase) – All grades	7 (100 %)	7 (70%)	13 (48.15%)	18 (51.43%)	29 (80.56%)	26 (81.25 %)	1 (20%)	15 (62.5%)	7 (63.64%)	6 (85.71%)	2 (100 %)	1 (100 %)	1 (100 %)	5 (50%)	11 (44%)	13 (40.63%)	24 (88.89%)	5 (83.33%)

Alkaline Phosphatase (increase) – Grade ≥3	2 (28.57 %)	2 (20%)	1 (3.7%)	2 (5.71 %)	7 (19.4 4%)	2 (6.25%)	0 (%)	1 (4.17%)	4 (36.3 6%)	3 (42.8 6%)	0 (%)	0 (%)	0 (%)	2 (20%)	0 (%)	3 (9.38 %)	3 (11.1 1%)	2 (33.3 3%)
Amylase (increase) – All grades	0 (%)	1 (10%)	7 (25.9 3%)	3 (8.57 %)	9 (25%)	4 (12.5%)	1 (20%)	9 (37.5%)	4 (36.3 6%)	1 (14.2 9%)	0 (%)	0 (%)	0 (%)	1 (10%)	10 (40%)	4 (12.5 %)	4 (14.8 1%)	2 (33.3 3%)
Amylase (increase) – Grade ≥3	0 (%)	0 (%)	2 (7.41 %)	0 (%)	2 (5.56 %)	1 (3.13%)	0 (%)	1 (4.17%)	1 (9.09 %)	1 (14.2 9%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (6.25 %)	0 (%)	0 (%)
Aspartate Aminotransferase (increase) – All grades	6 (85.71 %)	5 (50%)	11 (40.7 4%)	23 (65.7 1%)	24 (66.6 7%)	17 (53.13 %)	1 (20%)	6 (25%)	8 (72.7 3%)	5 (71.4 3%)	1 (50%)	0 (%)	1 (100 %)	6 (60%)	4 (16%)	12 (37.5 %)	17 (62.9 6%)	5 (83.3 3%)
Aspartate Aminotransferase (increase) – Grade ≥3	3 (42.86 %)	1 (10%)	1 (3.7%)	2 (5.71 %)	4 (11.1 1%)	1 (3.13%)	0 (%)	0 (%)	1 (9.09 %)	1 (14.2 9%)	1 (50%)	0 (%)	0 (%)	3 (30%)	0 (%)	4 (12.5 %)	1 (3.7%)	2 (33.3 3%)
Bilirubin (increase) – All grades	3 (42.86 %)	4 (40%)	0 (%)	2 (5.71 %)	9 (25%)	4 (12.5%)	0 (%)	2 (8.33%)	3 (27.2 7%)	4 (57.1 4%)	0 (%)	1 (100 %)	0 (%)	3 (30%)	1 (4%)	2 (6.25 %)	5 (18.5 2%)	3 (50%)
Bilirubin (increase) – Grade ≥3	2 (28.57 %)	1 (10%)	0 (%)	1 (2.86 %)	4 (11.1 1%)	0 (%)	0 (%)	0 (%)	2 (18.1 8%)	1 (14.2 9%)	0 (%)	0 (%)	0 (%)	1 (10%)	0 (%)	0 (%)	2 (7.41 %)	1 (16.6 7%)
Creatinine (increase)	1 (14.29 %)	1 (10%)	6 (22.2 2%)	5 (14.2 9%)	5 (13.8 9%)	7 (21.88 %)	1 (20%)	8 (33.33 %)	4 (36.3 6%)	1 (14.2 9%)	0 (%)	0 (%)	0 (%)	3 (30%)	2 (8%)	4 (12.5 %)	4 (14.8 1%)	1 (16.6 7%)

– All grades																		
Creatinine (increase) – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Glucose (increase) – All grades	3 (42.86 %)	4 (40%)	15 (55.5 6%)	8 (22.8 6%)	12 (33.3 3%)	14 (43.75 %)	3 (60%)	11 (45.83 %)	5 (45.4 5%)	2 (28.5 7%)	2 (100 %)	1 (100 %)	1 (100 %)	6 (60%)	11 (44%)	6 (18.7 5%)	8 (29.6 3%)	2 (33.3 3%)
Glucose (increase) – Grade ≥3	0 (%)	2 (20%)	1 (3.7%)	0 (%)	1 (2.78 %)	0 (%)	0 (%)	0 (%)	0 (%)	1 (14.2 9%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4%)	0 (%)	1 (3.7%)	0 (%)
Glucose (decrease) – All grades	0 (%)	0 (%)	0 (%)	1 (2.86 %)	1 (2.78 %)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4%)	1 (3.13 %)	2 (7.41 %)	0 (%)
Glucose (decrease) – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Lipase (increase) – All grades	3 (42.86 %)	0 (%)	7 (25.9 3%)	4 (11.4 3%)	11 (30.5 6%)	9 (28.13 %)	1 (20%)	8 (33.33 %)	5 (45.4 5%)	3 (42.8 6%)	0 (%)	0 (%)	0 (%)	1 (10%)	8 (32%)	4 (12.5 %)	3 (11.1 1%)	1 (16.6 7%)
Lipase (increase) – Grade ≥3	1 (14.29 %)	0 (%)	2 (7.41 %)	0 (%)	5 (13.8 9%)	1 (3.13%)	0 (%)	3 (12.5%)	3 (27.2 7%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4%)	4 (12.5 %)	1 (3.7%)	0 (%)
Magnesium (increase) – All grades	0 (%)	0 (%)	1 (3.7%)	2 (5.71 %)	2 (5.56 %)	2 (6.25%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4%)	1 (3.13 %)	0 (%)	0 (%)

Magnesium (increase) – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (6.25%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Magnesium (decrease) – All grades	3 (42.86%)	3 (30%)	6 (22.22%)	11 (31.43%)	7 (19.44%)	9 (28.13%)	0 (%)	3 (12.5%)	1 (9.09%)	2 (28.57%)	1 (50%)	1 (100%)	0 (%)	4 (40%)	6 (24%)	9 (28.13%)	4 (14.81%)	0 (%)
Magnesium (decrease) – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Phosphate (decrease) – All grades	2 (28.57%)	3 (30%)	4 (14.81%)	10 (28.57%)	9 (25%)	10 (31.25%)	2 (40%)	5 (20.83%)	4 (36.36%)	3 (42.86%)	1 (50%)	0 (%)	0 (%)	0 (%)	5 (20%)	4 (12.5%)	5 (18.52%)	2 (33.33%)
Phosphate (decrease) – Grade ≥3	0 (%)	1 (10%)	0 (%)	0 (%)	1 (2.78%)	1 (3.13%)	0 (%)	2 (8.33%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (3.13%)	1 (3.7%)	0 (%)
Potassium (increase) – All grades	1 (14.29%)	2 (20%)	2 (7.41%)	3 (8.57%)	6 (16.67%)	4 (12.5%)	1 (20%)	6 (25%)	2 (18.18%)	2 (28.57%)	0 (%)	0 (%)	0 (%)	0 (%)	3 (12%)	1 (3.13%)	4 (14.81%)	0 (%)
Potassium (increase) – Grade ≥3	0 (%)	0 (%)	1 (3.7%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4%)	0 (%)	0 (%)	0 (%)

Potassium (decrease) – All grades	2 (28.57 %)	3 (30%)	4 (14.81%)	6 (17.14%)	5 (13.89%)	5 (15.63 %)	1 (20%)	0 (%)	2 (18.18%)	2 (28.57%)	0 (%)	1 (100 %)	0 (%)	2 (20%)	4 (16%)	3 (9.38 %)	2 (7.41 %)	1 (16.67%)
Potassium (decrease) – Grade ≥3	0 (%)	0 (%)	0 (%)	1 (2.86 %)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Serum calcium corrected (increase) – All grades	1 (14.29 %)	0 (%)	3 (11.11%)	6 (17.14%)	4 (11.11%)	4 (12.5%)	0 (%)	12 (50%)	2 (18.18%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	2 (20%)	5 (20%)	3 (9.38 %)	3 (11.11%)	1 (16.67%)
Serum calcium corrected (increase) – Grade ≥3	0 (%)	0 (%)	1 (3.7%)	0 (%)	0 (%)	0 (%)	0 (%)	3 (12.5%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (3.13 %)	0 (%)	0 (%)
Serum calcium corrected (decrease) – All grades	0 (%)	0 (%)	2 (7.41 %)	2 (5.71 %)	3 (8.33 %)	6 (18.75 %)	1 (20%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (10%)	3 (12%)	3 (9.38 %)	1 (3.7%)	1 (16.67%)
Serum calcium corrected (decrease) – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Serum creatine kinase (increase)	2 (28.57 %)	4 (40%)	2 (7.41 %)	6 (17.14%)	10 (27.78%)	4 (12.5%)	2 (40%)	2 (8.33%)	4 (36.36%)	4 (57.14%)	0 (%)	0 (%)	1 (100 %)	1 (10%)	2 (8%)	5 (15.63%)	11 (40.74%)	4 (66.67%)

– All grades																		
Serum creatine kinase(increase) – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	1 (2.78 %)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (3.13 %)	0 (%)	1 (16.67%)
Sodium (increase) – All grades	0 (%)	0 (%)	0 (%)	0 (%)	1 (2.78 %)	1 (3.13%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4%)	2 (6.25 %)	2 (7.41 %)	0 (%)
Sodium (increase) – Grade ≥3	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Sodium (decrease) – All grades	4 (57.14 %)	7 (70%)	15 (55.56%)	10 (28.57%)	19 (52.78%)	14 (43.75 %)	3 (60%)	11 (45.83 %)	7 (63.64%)	4 (57.14%)	2 (100 %)	1 (100 %)	1 (100 %)	7 (70%)	9 (36%)	12 (37.5 %)	11 (40.74%)	4 (66.67%)
Sodium (decrease) – Grade ≥3	3 (42.86 %)	3 (30%)	1 (3.7%)	1 (2.86 %)	4 (11.11%)	3 (9.38%)	0 (%)	1 (4.17%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (20%)	3 (12%)	1 (3.13 %)	2 (7.41 %)	0 (%)
Uric acid (urate) (increased) – All grades	0 (%)	1 (10%)	4 (14.81%)	11 (31.43%)	9 (25%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	4 (40%)	4 (16%)	12 (37.5 %)	9 (33.33%)	2 (33.33%)
Urate (increased) – Grade ≥3	0 (%)	0 (%)	1 (3.7%)	2 (5.71 %)	3 (8.33 %)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (20%)	0 (%)	2 (6.25 %)	3 (11.11%)	1 (16.67%)

Number of participants with notable changes from baseline in vital sign values

(Time Frame: From baseline (predose) up to 30 days after last dose of study treatment in each treatment period. The median duration of exposure to study treatment ranged between 8 and 9.15 weeks in Treatment Period 1 and between 5 and 42.05 weeks in Treatment Period 2)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Participants Analyzed [units: participants]	7	10	27	35	36	32	5	24	11	7	2	1	1	10	25	32	27	6

Number of participants with notable changes from baseline in vital sign values
(units: participants)
Count of Participants (Not Applicable)

Systemic blood pressure (increase)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Systemic blood pressure (decrease)	0 (%)	0 (%)	0 (%)	5 (14.29%)	1 (2.78%)	2 (6.25%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (10%)	0 (%)	1 (3.13%)	1 (3.7%)	0 (%)
Diastolic blood pressure (increase)	0 (%)	0 (%)	1 (3.7%)	1 (2.86%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Diastolic blood pressure (decrease)	0 (%)	0 (%)	0 (%)	2 (5.71%)	1 (2.78%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	1 (10%)	1 (4%)	0 (%)	0 (%)	0 (%)
Pulse rate (increase)	3 (42.86%)	5 (50%)	6 (22.22%)	8 (22.86%)	10 (27.78%)	5 (15.63%)	0 (%)	3 (12.5%)	1 (9.09%)	3 (42.86%)	1 (50%)	0 (%)	0 (%)	3 (30%)	5 (20%)	10 (31.25%)	4 (14.81%)	2 (33.33%)
Pulse rate (decrease)	0 (%)	1 (10%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (9.09%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (3.7%)	0 (%)

Weight (increase)	1 (14.29 %)	0 (%)	1 (3.7%)	1 (2.86 %)	0 (%)	1 (3.13%)	0 (%)	2 (8.33%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (10%)	0 (%)	0 (%)	0 (%)	1 (16.6 7%)
Weight (decrease)	1 (14.29 %)	1 (10%)	6 (22.2 2%)	5 (14.2 9%)	4 (11.1 1%)	1 (3.13%)	0 (%)	2 (8.33%)	3 (27.2 7%)	1 (14.2 9%)	0 (%)	0 (%)	0 (%)	1 (10%)	5 (20%)	1 (3.13 %)	1 (3.7%)	0 (%)
Temperature (increase)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Number of participants with Dose-Limiting Toxicities (DLTs) (Dose escalation only)

(Time Frame: 56 days)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcino	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)

			cancer (NSCLC)	breast cancer (TNBC)	cancer (CRC)	cancer (CRC)	cancer (CRC)	ma (RCC)	colorectal cancer (CRC)	colorectal cancer (CRC)	non-small cell lung cancer (NSCLC)	non-small cell lung cancer (NSCLC)	triple-negative breast cancer (TNBC)		cancer (NSCLC)	breast cancer (TNBC)	cancer (CRC)	
Number of Participants Analyzed [units: participants]	5	3	0	0	5	8	4	1	8	4	2	0	1	7	1	1	3	4
Number of participants with Dose-Limiting Toxicities (DLTs) (Dose escalation only) (units: participants) Count of Participants (Not Applicable)																		
	1 (20%)	1 (33.33%)	(NaN%)	(NaN%)	0 (%)	1 (12.5%)	3 (75%)	0 (%)	0 (%)	1 (25%)	0 (%)	(NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (50%)

Number of participants with dose reductions or interruptions of PDR001

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment ranged between 8 and 9.15 weeks in Treatment Period 1 and between 5 and 42.05 weeks in Treatment Period 2)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	**PDR001 + LBH589 10 mg TIW 2wk on/1wk off**	**PDR001 + RAD001 5 mg QW NSCLC**	**PDR001 + RAD001 5 mg QW TNBC**	**PDR001 + RAD001 5 mg QW CRC**	**PDR001 + HDM201 60 mg (RDE) CRC**	**PDR001 + HDM201 100 mg CRC**	**PDR001 + HDM201 60 mg (RDE) RCC**	**PDR001 + QBM076 75 mg CRC**	**PDR001 + QBM076 150 mg CRC**	**PDR001 + QBM076 75 mg NSCLC**	**PDR001 + QBM076 150 mg NSCLC**	**PDR001 + QBM076 75 mg TNBC**	**PDR001 + LCL161 300 mg QW**	**PDR001 + LCL161 600 mg QW NSCLC**	**PDR001 + LCL161 600 mg QW TNBC**	**PDR001 + LCL161 600 mg QW CRC**	**PDR001 + LCL161 900 mg QW**
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in	PDR001 400 mg every 4 weeks (Q4W) in	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W) in combina	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W) in combina	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)	PDR001 400 mg every 4 weeks (Q4W)

	combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	tion with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	tion with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	in combination with LCL161 300 mg once per week (QW)	in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	in combination with LCL161 900 mg once per week (QW)
Number of Participants Analyzed [units: participants]	7	10	27	35	36	32	5	24	11	7	2	1	1	10	25	32	27	6
Number of participants with dose reductions or interruptions of PDR001 (units: participants) Count of Participants (Not Applicable)																		
With at least one dose reduction or interruption	0 (%)	1 (10%)	4 (14.81%)	0 (%)	1 (2.78%)	4 (12.5%)	1 (20%)	5 (20.83%)	2 (18.18%)	2 (28.57%)	0 (%)	0 (%)	0 (%)	1 (10%)	3 (12%)	1 (3.13%)	1 (3.7%)	0 (%)

With only one dose reduction or interruption	0 (%)	0 (%)	3 (11.11%)	0 (%)	1 (2.78%)	4 (12.5%)	1 (20%)	5 (20.83%)	2 (18.18%)	2 (28.57%)	0 (%)	0 (%)	0 (%)	1 (10%)	2 (8%)	1 (3.13%)	1 (3.7%)	0 (%)
With two dose reductions or interruptions	0 (%)	1 (10%)	1 (3.7%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4%)	0 (%)	0 (%)	0 (%)
With more than two dose reductions or interruptions	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Number of participants with dose reductions or interruptions of panobinostat

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment was 8 weeks in Treatment Period 1 and 5 weeks in Treatment Period 2)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off

Number of Participants Analyzed [units: participants]	7	10
Number of participants with dose reductions or interruptions of panobinostat (units: participants) Count of Participants (Not Applicable)		
With at least one dose reduction or interruption	2 (28.57%)	6 (60%)
With only one dose reduction or interruption	2 (28.57%)	4 (40%)
With two dose reductions or interruptions	0 (%)	0 (%)
With more than two dose reductions or interruptions	0 (%)	2 (20%)

Number of participants with dose reductions or interruptions of everolimus

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment was 9.15 weeks in Treatment Period 1 and 9 weeks in Treatment Period 2)

	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)
Number of Participants Analyzed [units: participants]	27	35	36

Number of participants with dose reductions or interruptions of everolimus (units: participants) Count of Participants (Not Applicable)			
With at least one dose reduction or interruption	6 (22.22%)	3 (8.57%)	4 (11.11%)
With only one dose reduction or interruption	4 (14.81%)	2 (5.71%)	3 (8.33%)
With two dose reductions or interruptions	2 (7.41%)	1 (2.86%)	1 (2.78%)
With more than two dose reductions or interruptions	0 (%)	0 (%)	0 (%)

Number of participants with dose reductions or interruptions of HDM201

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment was 9 weeks in Treatment Period 1 and 8.15 weeks in Treatment Period 2)

	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)
Number of Participants Analyzed [units: participants]	32	5	24

Number of participants with dose reductions or interruptions of HDM201 (units: participants) Count of Participants (Not Applicable)

With at least one dose reduction or interruption	5 (15.63%)	1 (20%)	4 (16.67%)
With only one dose reduction or interruption	4 (12.5%)	0 (%)	2 (8.33%)
With two dose reductions or interruptions	1 (3.13%)	0 (%)	2 (8.33%)
With more than two dose reductions or interruptions	0 (%)	1 (20%)	0 (%)

Number of participants with dose reductions or interruptions of QBM076

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment was 8 weeks in Treatment Period 1 and 42.05 weeks in Treatment Period 2)

	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	11	7	2	1	1
Number of participants with dose reductions or interruptions of QBM076 (units: participants) Count of Participants (Not Applicable)					
With at least one dose reduction or interruption	2 (18.18%)	3 (42.86%)	2 (100%)	1 (100%)	0 (%)

With only one dose reduction or interruption	1 (9.09%)	3 (42.86%)	2 (100%)	1 (100%)	0 (%)
With two dose reductions or interruptions	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
With more than two dose reductions or interruptions	1 (9.09%)	0 (%)	0 (%)	0 (%)	0 (%)

Number of participants with dose reductions or interruptions of LCL161

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment was 8.65 weeks in Treatment Period 1 and 7.3 weeks in Treatment Period 2)

	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Participants Analyzed [units: participants]	10	25	32	27	6
Number of participants with dose reductions or interruptions of LCL161 (units: participants) Count of Participants (Not Applicable)					
With at least one dose reduction or interruption	1 (10%)	8 (32%)	5 (15.63%)	7 (25.93%)	3 (50%)
With only one dose reduction or interruption	1 (10%)	3 (12%)	3 (9.38%)	6 (22.22%)	1 (16.67%)

With two dose reductions or interruptions	0 (%)	4 (16%)	1 (3.13%)	0 (%)	2 (33.33%)
With more than two dose reductions or interruptions	0 (%)	1 (4%)	1 (3.13%)	1 (3.7%)	0 (%)

Relative dose intensity of PDR001

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment ranged between 8 and 9.15 weeks in Treatment Period 1 and between 5 and 42.05 weeks in Treatment Period 2)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	**PDR001 + LBH589 10 mg TIW 2wk on/1wk off**	**PDR001 + RAD001 5 mg QW NSCLC**	**PDR001 + RAD001 5 mg QW TNBC**	**PDR001 + RAD001 5 mg QW CRC**	**PDR001 + HDM201 60 mg (RDE) CRC**	**PDR001 + HDM201 100 mg CRC**	**PDR001 + HDM201 60 mg (RDE) RCC**	**PDR001 + QBM076 75 mg CRC**	**PDR001 + QBM076 150 mg CRC**	**PDR001 + QBM076 75 mg NSCLC**	**PDR001 + QBM076 150 mg NSCLC**	**PDR001 + QBM076 75 mg TNBC**	**PDR001 + LCL161 300 mg QW**	**PDR001 + LCL161 600 mg QW NSCLC**	**PDR001 + LCL161 600 mg QW TNBC**	**PDR001 + LCL161 600 mg QW CRC**	**PDR001 + LCL161 900 mg QW**
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negat	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in color	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)

	on/1 week off	on/1 week off	cell lung cancer (NSCLC)	ive breast cancer (TNBC)	cancer (CRC)	cycle in colorectal cancer (CRC)	in color ectal cancer (CRC)	cycle in renal cell carcinoma (RCC)	week off in color ectal cancer (CRC)	week off in color ectal cancer (CRC)	week off in non-small cell lung cancer (NSCLC)	week off in non-small cell lung cancer (NSCLC)	week off in triple-negative breast cancer (TNBC)		small cell lung cancer (NSCLC)	negative breast cancer (TNBC)	ectal cancer (CRC)	
Number of Participants Analyzed [units: participants]	7	10	27	35	36	32	5	24	11	7	2	1	1	10	25	32	27	6
Relative dose intensity of PDR001 (units: percentage of dose intensity) Median (Full Range)																		
Treatment Period 1 (n=7,10,27,35,36,32,5,24,11,7,2,1,1,10,25,32,27,6)	100.00 (66.67 to 100)	100.00 (66.67 to 100)	100.00 (57.14 to 100)	100.00 (66.67 to 100)	100.00 (66.67 to 100)	100.00 (60 to 100)	100.00 (85.71 to 100)	85.71 (26.92 to 100)	100.00 (83.33 to 100)	100.00 (66.67 to 100)	100.00 (100 to 100)	100.00 (100 to 100)	100.00 (100 to 100)	100.00 (75 to 100)	100.00 (66.67 to 100)	100.00 (66.67 to 100)	100.00 (66.67 to 100)	100.00 (100 to 100)
Treatment Period 2 (n=0,1,5,2,4,2,1,4,2,0,0,0,0,0,5,1,0,0)		100.00 (100 to 100)	100.00 (80 to 100)	100.00 (100 to 100)	100.00 (100 to 100)	100.00 (100 to 100)	100.00 (100 to 100)	91.67 (66.67 to 100)	96.67 (93.33 to 100)						100.00 (66.67 to 100)	100.00 (100 to 100)		

Relative dose intensity of panobinostat

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment was 8 weeks in Treatment Period 1 and 5 weeks in Treatment Period 2)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three

	times a week (TIW) 1 week on/1 week off	times a week (TIW) 2 weeks on/1 week off
Number of Participants Analyzed [units: participants]	7	10
Relative dose intensity of panobinostat (units: percentage of dose intensity) Median (Full Range)		
Treatment Period 1 (n=7,10)	100.00 (66.67 to 100)	83.33 (47.92 to 108.33)
Treatment Period 2 (n=0,1)		66.67 (66.67 to 66.67)

Relative dose intensity of everolimus

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment was 9.15 weeks in Treatment Period 1 and 9 weeks in Treatment Period 2)

	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)
Number of Participants Analyzed [units: participants]	27	35	36
Relative dose intensity of everolimus (units: percentage of dose intensity) Median (Full Range)			
Treatment Period 1 (n=27,35,36)	100.00 (63.64 to 100)	100.00 (50 to 116.67)	100.00 (50 to 100)

Treatment Period 2 (n=5,2,4)	100.00 (88.89 to 103.13)	100.00 (100 to 100)	90.00 (66.67 to 100)

Relative dose intensity of HDM201

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment was 9 weeks in Treatment Period 1 and 8.15 weeks in Treatment Period 2)

	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)
Number of Participants Analyzed [units: participants]	32	5	24
Relative dose intensity of HDM201 (units: percentage of dose intensity) Median (Full Range)			
Treatment Period 1 (n=32,5,24)	100.00 (50 to 100)	75.00 (60.83 to 83.33)	100.00 (26.92 to 100)
Treatment Period 2 (n=2,1,4)	91.67 (83.33 to 100)	91.67 (91.67 to 91.67)	100.00 (75 to 100)

Relative dose intensity of QBM076

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment was 8 weeks in Treatment Period 1 and 42.05 weeks in Treatment Period 2)

PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC

Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	11	7	2	1	1
Relative dose intensity of QBM076 (units: percentage of dose intensity) Median (Full Range)					
Treatment Period 1 (n=11,7,2,1,1)	57.50 (27.78 to 100)	51.22 (14.13 to 100)	59.15 (48.51 to 69.79)	47.44 (47.44 to 47.44)	59.57 (59.57 to 59.57)
Treatment Period 2 (n=2,0,0,0,0)	53.81 (52.99 to 54.63)				

Relative dose intensity of LCL161

(Time Frame: From first dose of study treatment up to last dose in each treatment period. The median duration of exposure to study treatment was 8.65 weeks in Treatment Period 1 and 7.3 weeks in Treatment Period 2)

	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Participants Analyzed [units: participants]	10	25	32	27	6

Relative dose intensity of LCL161 (units: percentage of dose intensity) Median (Full Range)					
Treatment Period 1 (n=10,25,32,27,6)	100.00 (50 to 100)	100.00 (61.9 to 100)	100.00 (55.56 to 120)	100.00 (66.67 to 100)	93.59 (62.5 to 100)
Treatment Period 2 (n=0,5,1,0,0)		88.89 (75 to 100)	100.00 (100 to 100)		

Secondary Outcome Result(s)

Number of participants with changes from baseline in ECG parameters in the combination arm of PDR001 and panobinostat

(Time Frame: Treatment Period 1: Cycle 1 (Days 1, 8, 15 and 22), Cycle 2 and 3 (Days 1 and 15) and Cycle 4 to 6 (Day 1). Treatment Period 2: Cycle 1 (Days 1, 8, 15 and 22) and Cycle 2 (Day 1). The duration of one treatment cycle is 28 days.)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	**PDR001 + LBH589 10 mg TIW 2wk on/1wk off**
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off
Number of Participants Analyzed [units: participants]	7	10
Number of participants with changes from baseline in ECG parameters in the combination arm of PDR001 and panobinostat (units: participants) Count of Participants (Not Applicable)		
QTcF: Increase > 30 to ≤ 60 milliseconds (ms) (n=7,10)	1 (14.29%)	3 (30%)
QTcF: Increase > 60 ms (n=7,10)	0 (%)	0 (%)

QTcF: New > 450 to ≤ 480 ms (n=7,10)	0 (%)	2 (20%)
QTcF: New > 480 to ≤ 500 ms (n=7,10)	0 (%)	0 (%)
QTcF: New > 500 ms (n=7,10)	0 (%)	0 (%)
QTcB: Increase > 30 to ≤ 60 ms (n=0,2)	(NaN%)	1 (50%)
QTcB: Increase > 60 ms (n=0,2)	(Na N%)	0 (%)
QTcB: New > 450 to ≤ 480 ms (n=0,2)	(NaN%)	2 (100%)
QTcB: New > 480 to ≤ 500 ms (n=0,2)	(NaN%)	1 (50%)
QTcB: New > 500 ms (n=0,2)	(NaN%)	0 (%)
QT: Increase > 30 to ≤ 60 ms (n=7,10)	3 (42.86%)	1 (10%)
QT: Increase > 60 ms (n=7,10)	0 (%)	0 (%)
QT: New > 450 to ≤ 480 ms (n=7,10)	0 (%)	0 (%)
QT: New > 480 to ≤ 500 ms (n=7,10)	0 (%)	0 (%)
QT: New > 500 ms (n=7,10)	0 (%)	0 (%)
PR: Increase >25% and PR > 200 ms (n=7,9)	0 (%)	0 (%)
QRS: Increase > 25% and QRS > 120 ms (n=7,10)	0 (%)	0 (%)

Best Overall Response (BOR) per RECIST v1.1

(Time Frame: From start of treatment until end of treatment in Treatment period 1, with a median duration ranging between 8 and 9.15 weeks. Treatment period 1 included up to 6 treatment cycles (1 cycle=28 days).)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Participants Analyzed	7	10	27	35	36	32	5	24	11	7	2	1	1	9	25	33	27	6

[units: participants]																		
Best Overall Response (BOR) per RECIST v1.1 (units: participants) Count of Participants (Not Applicable)																		
Complete Response (CR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Partial Response (PR)	0 (%)	0 (%)	3 (11.11%)	1 (2.86%)	1 (2.78%)	0 (%)	1 (20%)	4 (16.67%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (11.11%)	1 (4%)	0 (%)	0 (%)	0 (%)
Stable disease (SD)	0 (%)	1 (10%)	8 (29.63%)	5 (14.29%)	11 (30.56%)	10 (31.25%)	0 (%)	10 (41.67%)	4 (36.36%)	1 (14.29%)	1 (50%)	0 (%)	0 (%)	4 (44.44%)	11 (44%)	3 (9.09%)	1 (3.7%)	0 (%)
Progressive disease (PD)	6 (85.71%)	7 (70%)	13 (48.15%)	24 (68.57%)	21 (58.33%)	17 (53.13%)	4 (80%)	7 (29.17%)	5 (45.45%)	5 (71.43%)	1 (50%)	0 (%)	0 (%)	4 (44.44%)	12 (48%)	22 (66.67%)	22 (81.48%)	5 (83.33%)
Unknown (UNK)	1 (14.29%)	2 (20%)	3 (11.11%)	5 (14.29%)	3 (8.33%)	5 (15.63%)	0 (%)	3 (12.5%)	2 (18.18%)	1 (14.29%)	0 (%)	1 (100%)	1 (100%)	0 (%)	1 (4%)	8 (24.24%)	4 (14.81%)	1 (16.67%)

Best Overall Response (BOR) per irRC

(Time Frame: From start of treatment until end of treatment in Treatment period 1, with a median duration ranging between 8 and 9.15 weeks. Treatment period 1 included up to 6 treatment cycles (1 cycle=28 days).)

PDR001 + LBH589 10 mg TIW 1wk on/1wk off	**PDR001 + LBH589 10 mg TIW 2wk on/1wk off**	**PDR001 + RAD001 5 mg QW NSCLC**	**PDR001 + RAD001 5 mg QW TNBC**	**PDR001 + RAD001 5 mg QW CRC**	**PDR001 + HDM201 60 mg (RDE) CRC**	**PDR001 + HDM201 100 mg CRC**	**PDR001 + HDM201 60 mg (RDE) RCC**	**PDR001 + QBM076 75 mg CRC**	**PDR001 + QBM076 150 mg CRC**	**PDR001 + QBM076 75 mg NSCLC**	**PDR001 + QBM076 150 mg NSCLC**	**PDR001 + QBM076 75 mg TNBC**	**PDR001 + LCL161 300 mg QW**	**PDR001 + LCL161 600 mg QW NSCLC**	**PDR001 + LCL161 600 mg QW TNBC**	**PDR001 + LCL161 600 mg QW CRC**	**PDR001 + LCL161 900 mg QW**

Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Participants Analyzed [units: participants]	7	10	27	35	36	32	5	24	11	7	2	1	1	9	25	33	27	6
Best Overall Response (BOR) per irRC (units: participants) Count of Participants (Not Applicable)																		
Complete Response (irCR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Partial response (irPR)	0 (%)	0 (%)	4 (14.81%)	1 (2.86%)	1 (2.78%)	0 (%)	1 (20%)	4 (16.67%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (11.11%)	1 (4%)	0 (%)	0 (%)	0 (%)
Stable disease (irSD)	1 (14.29%)	1 (10%)	10 (37.04%)	6 (17.14%)	13 (36.11%)	8 (25%)	0 (%)	10 (41.67%)	6 (54.55%)	1 (14.29%)	1 (50%)	0 (%)	0 (%)	4 (44.44%)	13 (52%)	4 (12.12%)	4 (14.81%)	0 (%)
Confirmed progressive disease (ir(cPD))	0 (%)	0 (%)	2 (7.41%)	4 (11.43%)	9 (25%)	3 (9.38%)	0 (%)	2 (8.33%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (8%)	5 (15.15%)	6 (22.22%)	2 (33.33%)
Unconfirmed progressive disease (ir(uPD))	5 (71.43%)	6 (60%)	8 (29.63%)	19 (54.29%)	10 (27.78%)	16 (50%)	4 (80%)	5 (20.83%)	3 (27.27%)	5 (71.43%)	1 (50%)	0 (%)	0 (%)	4 (44.44%)	8 (32%)	16 (48.48%)	14 (51.85%)	3 (50%)
Unknown (irUNK)	1 (14.29%)	2 (20%)	3 (11.11%)	5 (14.29%)	3 (8.33%)	5 (15.63%)	0 (%)	3 (12.5%)	2 (18.18%)	1 (14.29%)	0 (%)	1 (100%)	1 (100%)	0 (%)	1 (4%)	8 (24.24%)	3 (11.11%)	1 (16.67%)
Non-CR/Non-PD (irNCRNPD)	0 (%)	1 (10%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

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

(Time Frame: From start of treatment to first documented progression or death due to any cause in Treatment period 1, with a median duration ranging between 8 and 9.15 weeks. Treatment period 1 included up to 6 treatment cycles (1 cycle=28 days).)

PDR001 + LBH589 10	PDR001 + LBH589 10	PDR001 + RAD001 5	PDR001 + RAD001 5	PDR001 + RAD001 5	PDR001 + HDM201 60	PDR001 + HDM201	PDR001 + HDM201 60	PDR001 + QBM076	PDR001 + QBM076	PDR001 + QBM076	PDR001 + QBM076	PDR001 + QBM076	PDR001 + LCL161	PDR001 + LCL161	PDR001 + LCL161	PDR001 + LCL161	PDR001 + LCL161

	mg TIW 1wk on/1wk off	mg TIW 2wk on/1wk off	mg QW NSCLC	mg QW TNBC	mg QW CRC	mg (RDE) CRC	100 mg CRC	mg (RDE) RCC	75 mg CRC	150 mg CRC	75 mg NSCLC	150 mg NSCLC	75 mg TNBC	300 mg QW	600 mg QW NSCLC	600 mg QW TNBC	600 mg QW CRC	900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Participants Analyzed [units: participants]	7	10	27	35	36	32	5	24	11	7	2	1	1	9	25	33	27	6

Progression-Free Survival (PFS) per RECIST v1.1
(units: months)
Median (Full Range)

	1.7 (0.5 to 2.0)	1.6 (0.4 to 1.8)	1.9 (1.8 to 4.7)	1.7 (1.6 to 1.8)	1.9 (1.8 to 2.6)	1.9 (1.7 to 2.9)	1.8 (1.4 to NA)[1]	3.6 (1.8 to 7.2)	1.9 (1.3 to 3.5)	1.6 (1.3 to 2.0)	NA (1.7 to NA)[1]	2.0 (NA to NA)[1]	2.5 (NA to NA)[1]	3.5 (1.2 to NA)[1]	2.7 (1.7 to 3.7)	1.7 (1.1 to 1.8)	1.8 (1.6 to 1.8)	1.8 (1.0 to 1.8)

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

Progression-Free Survival (PFS) per irRC

(Time Frame: From start of treatment to first documented progression or death due to any cause in Treatment period 1, with a median duration ranging between 8 and 9.15 weeks. Treatment period 1 included up to 6 treatment cycles (1 cycle=28 days).)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 1 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 1 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 1 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 1 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 1 900 mg once per week (QW)

											(NSCLC)	(NSCLC)	(TNBC)					
Number of Participants Analyzed [units: participants]	7	10	27	35	36	32	5	24	11	7	2	1	1	9	25	33	27	6
Progression-Free Survival (PFS) per irRC (units: months) Median (Full Range)																		
	1.7 (0.5 to 2.0)	1.6 (0.4 to 1.8)	4.7 (1.8 to 5.5)	1.7 (1.6 to 1.8)	1.9 (1.8 to 3.5)	1.9 (1.7 to 2.8)	1.8 (1.4 to NA)[1]	3.6 (1.8 to 7.2)	3.5 (1.3 to 5.1)	1.6 (1.3 to 2.0)	NA (1.7 to NA)[1]	2.0 (NA to NA)[1]	2.5 (NA to NA)[1]	3.5 (1.2 to NA)[1]	3.5 (1.8 to 3.7)	1.7 (1.1 to 1.8)	1.8 (1.6 to 1.9)	1.8 (1.0 to 1.8)

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

Treatment Free Survival (TFS)

(Time Frame: From last exposure to study drug in treatment period 1 up to progression or death due to progression)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	**PDR001 + LBH589 10 mg TIW 2wk on/1wk off**	**PDR001 + RAD001 5 mg QW NSCLC**	**PDR001 + RAD001 5 mg QW TNBC**	**PDR001 + RAD001 5 mg QW CRC**	**PDR001 + HDM201 60 mg (RDE) CRC**	**PDR001 + HDM201 100 mg CRC**	**PDR001 + HDM201 60 mg (RDE) RCC**	**PDR001 + QBM076 75 mg CRC**	**PDR001 + QBM076 150 mg CRC**	**PDR001 + QBM076 75 mg NSCLC**	**PDR001 + QBM076 150 mg NSCLC**	**PDR001 + QBM076 75 mg TNBC**	**PDR001 + LCL161 300 mg QW**	**PDR001 + LCL161 600 mg QW NSCLC**	**PDR001 + LCL161 600 mg QW TNBC**	**PDR001 + LCL161 600 mg QW CRC**	**PDR001 + LCL161 900 mg QW**
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM20	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM20	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combi	PDR001 400 mg every 4 weeks (Q4W) in combi

	with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	nation with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	nation with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	nation with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	1 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	nation with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	1 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	nation with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	nation with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	nation with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	nation with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	nation with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	nation with LCL161 300 mg once per week (QW)	nation with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	nation with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	nation with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	nation with LCL161 900 mg once per week (QW)
Number of Participants Analyzed [units: participants]	0	0	3	3	0	1	1	6	0	0	0	0	0	3	5	1	0	0
Treatment Free Survival (TFS) (units: months) Median (Full Range)			2.0 (1.7 to 3.7)	7.3 (5.7 to 9.0)		5.3 (NA to NA)[1]	6.3 (NA to NA)[1]	NA (1.7 to NA)[1]						NA (1.6 to NA)[1]	1.6 (1.1 to 5.8)	3.5 (NA to NA)[1]		

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

Maximum observed serum concentration (Cmax) of PDR001

(Time Frame: pre-dose, 1, 168, 336, 504 and 648 hours post infusion on Treatment Period 1 Cycle 1 Day 1. The last sample corresponds to the pre-dose of Cycle 2 Day 1.)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/ Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Participant	7	8	21	27	29	25	4	19	10	5	2	1	1	9	23	17	21	2

s Analyzed [units: participants]

Maximum observed serum concentration (Cmax) of PDR001 (units: µg/mL) Geometric Mean (Geometric Coefficient of Variation)																		
Treatment period 1 C1D1	133 (21.1 %)	95.7 (39.4 %)	108 (27.9 %)	124 (26.8 %)	116 (29.0 %)	88.1 (38.7 %)	87.3 (22.8 %)	84.0 (27.4 %)	89.7 (32.9 %)	85.3 (20.3 %)	108 (22.3 %)	117	105	119 (45.8 %)	109 (35.6 %)	120 (23.9 %)	85.9 (37.2 %)	139 (12.8 %)

Time to reach maximum serum concentration (Tmax) of PDR001

(Time Frame: pre-dose, 1, 168, 336, 504 and 648 hours post infusion on Treatment Period 1 Cycle 1 Day 1 (C1D1). The last sample corresponds to the pre-dose of Cycle 2 Day 1.)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900

	three times a week (TIW) 1 week on/1 week off	three times a week (TIW) 2 weeks on/1 week off	mg once per week (QW) in non-small cell lung cancer (NSCLC)	mg once per week (QW) in triple-negative breast cancer (TNBC)	mg once per week (QW) in colorectal cancer (CRC)	expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	mg once per week (QW)	mg once per week (QW) in non-small cell lung cancer (NSCLC)	mg once per week (QW) in triple-negative breast cancer (TNBC)	mg once per week (QW) in colorectal cancer (CRC)	mg once per week (QW)
Number of Participants Analyzed [units: participants]	7	8	21	27	29	25	4	19	10	5	2	1	1	9	23	17	21	2
Time to reach maximum serum concentration (Tmax) of PDR001 (units: hours) Median (Full Range)																		
Treatment period 1 C1D1	1.50 (1.48 to 1.57)	1.56 (1.50 to 1.75)	1.50 (1.42 to 1.67)	1.52 (1.08 to 1.98)	1.57 (0.00 to 669)	1.53 (0.500 to 3.15)	1.52 (1.50 to 1.75)	1.50 (1.00 to 1.60)	1.53 (1.50 to 1.67)	1.53 (1.52 to 1.62)	1.49 (1.48 to 1.50)	1.45 (1.45 to 1.45)	1.62 (1.62 to 1.62)	1.50 (1.43 to 1.88)	1.50 (1.42 to 1.83)	1.55 (1.42 to 2.50)	1.55 (1.02 to 2.00)	1.52 (1.45 to 1.58)

Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of PDR001

(Time Frame: pre-dose, 1, 168, 336, 504 and 648 hours post infusion on Treatment Period 1 Cycle 1 Day 1. The last sample corresponds to the pre-dose of Cycle 2 Day 1.)

PDR001 + LBH589 10 mg	PDR001 + LBH589 10 mg	PDR001 + RAD001 5 mg	PDR001 + RAD001 5 mg	PDR001 + RAD001 5 mg	PDR001 + HDM201 60 mg	PDR001 + HDM201 100	PDR001 + HDM201 60 mg	PDR001 + QBM076 75	PDR001 + QBM076 150	PDR001 + QBM076 75 mg	PDR1001 + QBM0	PDR1001 + QBM0	PDR001 + LCL161 300	PDR001 + LCL161 600	PDR001 + LCL161 600	PDR001 + LCL161 600	PDR001 + LCL161 900

	TIW 1wk on/1wk off	TIW 2wk on/1wk off	QW NSCLC	QW TNBC	QW CRC	(RDE) CRC	mg CRC	(RDE) RCC	mg CRC	mg CRC	NSCLC	76 150 mg NSCLC	76 75 mg TNBC	mg QW	mg QW NSCLC	mg QW TNBC	mg QW CRC	mg QW
Arm/ Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Parti	7	8	21	27	29	25	4	19	10	5	2	1	1	9	23	17	21	2

cipants Analyzed [units: participants]																		
Area under the serum concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of PDR001 (units: h*µg/mL) Geometric Mean (Geometric Coefficient of Variation)																		
Treatment period 1 C1D1	2890 (25.4%)	2640 (40.8%)	4190 (33.6%)	5070 (25.1%)	4320 (41.4%)	3310 (40.7%)	2790 (22.8%)	3290 (27.2%)	2430 (32.6%)	2220 (18.6%)	2700 (34.2%)	25500	25000	3080 (50.2%)	4370 (30.6%)	4820 (28.6%)	3250 (30.9%)	3540 (16.1%)

Pre-dose trough concentration (Ctrough) of PDR001

(Time Frame: pre-dose, 1, 168, 336, 504 and 648 hours post infusion on Treatment Period 1 Cycle 1 Day 1. The last sample corresponds to the pre-dose of Cycle 2 Day 1.)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4	PDR001 400 mg every 4 weeks (Q4	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4W) in combination	PDR001 400 mg every 4 weeks (Q4

	with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	with LCL161 300 mg once per week (QW)	with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	W) in combination with LCL161 900 mg once per week (QW)
Number of Participants Analyzed [units: participants]	5	6	21	28	30	28	5	20	9	3	2	1	1	7	23	17	23	1
Pre-dose trough concentration (Ctrough) of PDR001 (units: µg/mL) Geometric Mean (Geometric Coefficient of Variation)																		
Treatment period	16.6 (37.8 %)	12.3 (64.8 %)	21.1 (65.1 %)	27.9 (39.3 %)	25.8 (63.0 %)	19.5 (73.1 %)	13.4 (44.4 %)	20.1 (70.9 %)	20.1 (42.8 %)	14.2 (13.8 %)	19.2 (65.4 %)	9.65	14.6	21.4 (61.3 %)	21.6 (59.0 %)	22.9 (46.4 %)	16.7 (46.6 %)	24.3

1
C1D1

Maximum observed plasma concentration (Cmax) of panobinostat

(Time Frame: pre-dose, 0.25, 0.5, 1, 3, 6 and 168 hours post-dose on Treatment Period 1 Cycle 1 Day 1 (C1D1))

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off
Number of Participants Analyzed [units: participants]	7	10
Maximum observed plasma concentration (Cmax) of panobinostat (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)		
Treatment period 1 C1D1	7.38 (36.2%)	6.06 (50.1%)

Time to reach maximum plasma concentration (Tmax) of panobinostat

(Time Frame: pre-dose, 0.25, 0.5, 1, 3, 6 and 168 hours post-dose on Treatment Period 1 Cycle 1 Day 1 (C1D1))

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off
Number of Participants Analyzed [units: participants]	7	10

Time to reach maximum plasma concentration (Tmax) of panobinostat (units: hours) Median (Full Range)		
Treatment period 1 C1D1	5.50 (1.00 to 5.87)	1.54 (0.917 to 3.25)

Maximum observed blood concentration (Cmax) of everolimus

(Time Frame: pre-dose, 1, 2, 6 and 168 hours post-dose on Treatment Period 1 Cycle 1 Day 1 (C1D1))

	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)
Number of Participants Analyzed [units: participants]	1	2	4
Maximum observed blood concentration (Cmax) of everolimus (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)			
Treatment period 1 C1D1	32.2	17.0 (8.3%)	29.8 (92.9%)

Time to reach maximum blood concentration (Tmax) of everolimus

(Time Frame: pre-dose, 1, 2, 6 and 168 hours post-dose on Treatment Period 1 Cycle 1 Day 1 (C1D1))

	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with	PDR001 400 mg every 4 weeks (Q4W) in combination with	PDR001 400 mg every 4 weeks (Q4W) in combination with

	everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	everolimus 5 mg once per week (QW) in colorectal cancer (CRC)
Number of Participants Analyzed [units: participants]	1	2	4
Time to reach maximum blood concentration (Tmax) of everolimus (units: hours) Median (Full Range)			
Treatment period 1 C1D1	2.50 (2.50 to 2.50)	1.99 (1.98 to 2.00)	1.04 (0.917 to 2.17)

Maximum observed plasma concentration (Cmax) of HDM201

(Time Frame: pre-dose, 1, 2, 4 and 8 hours post-dose on Treatment Period 1 Cycle 1 Day 8 (C1D8))

	PDR001 + HDM201 60 mg (RDE) CRC	**PDR001 + HDM201 100 mg CRC**	**PDR001 + HDM201 60 mg (RDE) RCC**
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)
Number of Participants Analyzed [units: participants]	25	5	20
Maximum observed plasma concentration (Cmax) of HDM201 (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)			

Treatment period 1 C1D8	612 (37.2%)	792 (29.1%)	647 (37.1%)

Time to reach maximum plasma concentration (Tmax) of HDM201

(Time Frame: pre-dose, 1, 2, 4 and 8 hours post-dose on Treatment Period 1 Cycle 1 Day 8 (C1D8))

	PDR001 + HDM201 60 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)
Number of Participants Analyzed [units: participants]	25	5	20
Time to reach maximum plasma concentration (Tmax) of HDM201 (units: hours) Median (Full Range)			
Treatment period 1 C1D8	2.92 (1.00 to 8.63)	2.00 (1.97 to 7.67)	2.01 (1.00 to 7.83)

Maximum observed plasma concentration (Cmax) of QBM076

(Time Frame: pre-dose, 0.5, 1, 2, 4 and 6 hours post-dose on Treatment Period 1 Cycle 1 Day 1 (C1D1))

	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week

	on/2 week off in colorectal cancer (CRC)	week on/2 week off in colorectal cancer (CRC)	on/2 week off in non-small cell lung cancer (NSCLC)	week on/2 week off in non-small cell lung cancer (NSCLC)	on/2 week off in triple-negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	11	6	2	1	1
Maximum observed plasma concentration (Cmax) of QBM076 (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)					
Treatment period 1 C1D1	706 (148.6%)	4610 (27.7%)	185 (101.0%)	6.46	545

Time to reach maximum plasma concentration (Tmax) of QBM076

(Time Frame: pre-dose, 0.5, 1, 2, 4 and 6 hours post-dose on Treatment Period 1 Cycle 1 Day 1 (C1D1))

	PDR001 + QBM076 75 mg CRC	**PDR001 + QBM076 150 mg CRC**	**PDR001 + QBM076 75 mg NSCLC**	**PDR001 + QBM076 150 mg NSCLC**	**PDR001 + QBM076 75 mg TNBC**
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	11	6	2	1	1
Time to reach maximum plasma concentration (Tmax) of QBM076 (units: hours) Median (Full Range)					
Treatment period 1 C1D1	2.00 (0.500 to 5.50)	1.98 (0.950 to 2.02)	3.89 (3.78 to 4.00)	5.58 (5.58 to 5.58)	2.08 (2.08 to 2.08)

Maximum observed plasma concentration (Cmax) of LCL161

(Time Frame: pre-dose, 1, 3, 4 and 6 hours post-dose on Treatment Period 1 Cycle 1 Day 1 (C1D1))

	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Participants Analyzed [units: participants]	6	0	1	3	3
Maximum observed plasma concentration (Cmax) of LCL161 (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)					
Treatment period 1 C1D1	1000 (48.8%)		1660	2410 (87.8%)	3910 (89.9%)

Time to reach maximum plasma concentration (Tmax) of LCL161

(Time Frame: pre-dose, 1, 3, 4 and 6 hours post-dose on Treatment Period 1 Cycle 1 Day 1 (C1D1))

	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)
Number of Participants	6	0	1	3	3

Analyzed [units: participants]					
Time to reach maximum plasma concentration (Tmax) of LCL161 (units: hours) Median (Full Range)					
Treatment period 1 C1D1	1.77 (0.950 to 4.00)		3.98 (3.98 to 3.98)	1.00 (1.00 to 1.02)	2.58 (1.00 to 2.70)

Number of participants with anti-drug antibodies (ADA) against PDR001

(Time Frame: Baseline (before first dose) and post-baseline (assessed throughout the treatment up to Cycle 6 in treatment period 1 and 2). The duration of each treatment cycle was 28 days.)

	PDR001 + LBH589 10 mg TIW 1wk on/1wk off	PDR001 + LBH589 10 mg TIW 2wk on/1wk off	PDR001 + RAD001 5 mg QW NSCLC	PDR001 + RAD001 5 mg QW TNBC	PDR001 + RAD001 5 mg QW CRC	PDR001 + HDM201 160 mg (RDE) CRC	PDR001 + HDM201 100 mg CRC	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC	PDR001 + QBM076 150 mg CRC	PDR001 + QBM076 75 mg NSCLC	PDR001 + QBM076 150 mg NSCLC	PDR001 + QBM076 75 mg TNBC	PDR001 + LCL161 300 mg QW	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC	PDR001 + LCL161 600 mg QW CRC	PDR001 + LCL161 900 mg QW
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)

			(NSCLC)	(TNBC)					cancer (CRC)	cancer (CRC)	lung cancer (NSCLC)	lung cancer (NSCLC)	breast cancer (TNBC)		(NSCLC)	(TNBC)		
Number of Participants Analyzed [units: participants]	1	2	3	2	6	32	5	24	11	7	2	1	1	1	6	3	9	1
Number of participants with anti-drug antibodies (ADA) against PDR001 (units: participants) Count of Participants (Not Applicable)																		
	1 (100%)	2 (100%)	3 (100%)	2 (100%)	6 (100%)	4 (12.5%)	1 (20%)	4 (16.67%)	0 (%)	1 (14.29%)	1 (50%)	0 (%)	0 (%)	1 (100%)	6 (100%)	3 (100%)	9 (100%)	1 (100%)

Safety Results

All-Cause Mortality

PDR001 + LBH589 10 mg TIW 1wk on/1 wk	PDR001 + LBH589 10 mg TIW 2wk on/1 wk off	PDR001 + RAD001 5 mg QW NSCLC N = 27	PDR001 + RAD001 5 mg QW TNBC N = 35	PDR001 + RAD001 5 mg QW CRC N = 36	PDR001 + HDM201 60 mg (RDE) CRC N = 32	PDR001 + HDM201 100 mg CRC N = 5	PDR001 + HDM201 60 mg (RDE) RCC	PDR001 + QBM076 75 mg CRC N = 11	PDR001 + QBM076 150 mg CRC N = 7	PDR001 + QBM076 75 mg NSCLC N = 1	PDR001 + QBM076 150 mg NSCLC N = 1	PDR001 + QBM076 75 mg TNBC N = 1	PDR001 + LCL161 300 mg QW N = 10	PDR001 + LCL161 600 mg QW NSCLC	PDR001 + LCL161 600 mg QW TNBC N = 32	PDR001 + LCL161 600 mg QW CRC N = 27	PDR001 + LCL161 900 mg QW N = 6	All participants N = 298

	off N = 7	N = 10						N = 24				N = 2				N = 25				
Arm/ Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)	All participants in the study
Total participants affected	3 (42.86 %)	7 (70.00 %)	11 (40.74 %)	16 (45.71 %)	17 (47.22 %)	11 (34.38 %)	2 (40.00 %)	7 (29.17%)	7 (63.64 %)	6 (85.71 %)	0 (0.00 %)	1 (100.00 %)	1 (100.00 %)	4 (40.00 %)	4 (16.00 %)	14 (43.75 %)	14 (51.85 %)	2 (33.33 %)	127 (42.62 %)

Serious Adverse Events by System Organ Class

Time Frame	From first dose of study treatment up to 150 days after last dose in each treatment period. The median duration of exposure to study treatment ranged between 8 and 9.15 weeks in Treatment Period 1 and between 5 and 42.05 weeks in Treatment Period 2.
Additional Description	Any sign or symptom that occurs during the study treatment plus 150 days after last dose in each treatment period.
Source Vocabulary for Table Default	MedDRA (25.0)
Assessment Type for Table Default	Systematic Assessment

	PDR001 + LBH589 10 mg TIW 1wk on/1 wk off N = 7	PDR001 + LBH589 10 mg TIW 2wk on/1 wk off N = 10	PDR001 + RAD001 5 mg QW NSC LC N = 27	PDR001 + RAD001 5 mg QW TNBC N = 35	PDR001 + RAD001 5 mg QW CRC N = 36	PDR001 + HDM201 60 mg (RDE) CRC N = 32	PDR001 + HDM201 100 mg CRC N = 5	PDR001 + HDM201 60 mg (RDE) RCC N = 24	PDR001 + QBM076 75 mg CRC N = 11	PDR001 + QBM076 150 mg CRC N = 7	PDR001 + QBM076 75 mg NSC LC N = 2	PDR001 + QBM076 150 mg NSC LC N = 1	PDR001 + QBM076 75 mg TNBC N = 1	PDR001 + LCL161 300 mg QW N = 10	PDR001 + LCL161 600 mg QW NSC LC N = 25	PDR001 + LCL161 600 mg QW TNBC N = 32	PDR001 + LCL161 600 mg QW CRC N = 27	PDR001 + LCL161 900 mg QW N = 6	All participants N = 298
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once	All participants in the study

	times a week (TIW) 1 week on/1 week off	times a week (TIW) 2 weeks on/1 week off	(QW) in non-small cell lung cancer (NSCLC)	(QW) in triple-negative breast cancer (TNBC)	(QW) in colorectal cancer (CRC)	dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	Day 1 and Day 8 every cycle in colorectal cancer (CRC)	dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	(BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	2 week on/2 week off in triple-negative breast cancer (TNBC)	per week (QW)	(QW) in non-small cell lung cancer (NSCLC)	(QW) in triple-negative breast cancer (TNBC)	per week (QW) in colorectal cancer (CRC)	per week (QW)	
Total participants affected	6 (85.71 %)	8 (80.00 %)	13 (48.15 %)	13 (37.14 %)	15 (41.67 %)	7 (21.88 %)	2 (40.00 %)	9 (37.50 %)	4 (36.36 %)	5 (71.43 %)	1 (50.00 %)	1 (100.00 %)	1 (100.00 %)	6 (60.00 %)	12 (48.00 %)	13 (40.63 %)	8 (29.63 %)	2 (33.33 %)	126 (42.28 %)
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%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Haematotoxicity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	1 (0.34%)
Neutropenia	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Pancytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Cardiac disorders																			
Atrial fibrillation	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	2 (0.67%)

Cardiac tamponade	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Pericardial effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Supraventricular 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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	2 (0.67%)
Endocrine disorders																			
Adrenal insufficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Eye disorders																			
Keratitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Photophobia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Gastrointestinal disorders																			
Abdominal pain	0 (0.00%)	2 (2 0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	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%)	4 (1.34%)

Abdominal pain lower	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Abdominal pain upper	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Constipation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Diarrhoea	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Gastric ulcer	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Gastrointestinal haemorrhage	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Ileus	0 (0.00%)	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 (14.29%)	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 (0.34%)
Intestinal obstruction	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	2 (0.67%)
Nausea	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Obstruction gastric	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Pancreatitis	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)

Proctalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Rectal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Small intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Vomiting	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	2 (5.56%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.34%)
General disorders and administration site conditions																			
Asthenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Breakthrough pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Fatigue	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
General physical health deterioration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	1 (16.67%)	2 (0.67%)

Malaise	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Multiple organ dysfunction syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Non-cardiac chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Pyrexia	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	1 (2.78%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (2.35%)
Hepatobiliary disorders																			
Autoimmune hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Bile duct stenosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	1 (0.34%)
Cholangitis	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Cholecystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Cholestasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Hyperbilirubinaemia	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Hypertransaminasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Jaundice cholestatic	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Infections and infestations																			
Abdominal 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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Abdominal infection	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%)	1 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	3 (1.01%)
Abdominal sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Acute 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%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
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%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Device related infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Diverticulitis	0 (0.00%)	1 (1 0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Enterobacter infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Erysipelas	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (1 0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Febrile infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Gastroenteritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Lower 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%)	0 (0.00%)	2 (8.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Nosocomial infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Peritonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (1 0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Pneumonia	0 (0.00%)	1 (1 0.00 %)	3 (11.11%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (1 4.29 %)	0 (0.00%)	1 (10 0.00 %)	0 (0.00%)	0 (0.00%)	4 (16.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	13 (4.36%)
Pneumonia aspiration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Pyelonephritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Sepsis	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Septic shock	0 (0.00%)	2 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Urinary tract infection	2 (28.57%)	0 (0.00%)	0 (0.00%)	2 (5.71%)	1 (2.78%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	8 (2.68%)
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%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Injury, poisoning and procedural complications																			
Femur fracture	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Hip fracture	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 (9.09%)	0 (0.00%)	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 (0.34%)
Humerus fracture	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Wrist fracture	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 (9.09%)	0 (0.00%)	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 (0.34%)
Investigations																			

Alanine aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Aspartate aminotransferase increased	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Blood bilirubin increased	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (2.86%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.34%)
Blood creatinine increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Electrocardiogram QT prolonged	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Metabolism and nutrition disorders																			
Acidosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Dehydration	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)

Electrolyte imbalance	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Failure to thrive	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Hyperglycaemia	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	2 (0.67%)
Hyperkalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Hypokalaemia	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Hypophosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Musculoskeletal and connective tissue disorders																			
Arthralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
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%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)

Bone pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Muscular weakness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Myalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Pain in extremity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)																			
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%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Nervous system disorders																			
Cerebral infarction	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Cerebrovascular accident	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Dizziness postural	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)	1 (0.34%)

Encephalopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Headache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Hydrocephalus	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Intracranial pressure increased	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Neuralgia	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Spinal cord compression	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (12.50%)	0 (0.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (2.01%)
Status epilepticus	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Product issues																			
Device malfunction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Psychiatric disorders																			

Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Delirium	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Mental status changes	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Renal and urinary disorders																			
Acute kidney injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.34%)
Hydronephrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	3 (1.01%)
Urinary tract 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%)	1 (9.09%)	0 (0.00%)	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 (0.34%)
Respiratory, thoracic and mediastinal disorders																			
Acute respiratory 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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (0.34%)

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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (0.34%)
Dyspnoea	0 (0.00%)	2 (20.00%)	2 (7.41%)	1 (2.86%)	1 (2.78%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.25%)	2 (7.41%)	0 (0.00%)	12 (4.03%)
Epistaxis	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Haemoptysis	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	1 (0.34%)
Pleural effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.71%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	5 (1.68%)
Pneumonitis	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	0 (0.00%)	4 (1.34%)
Pneumothorax	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Pulmonary embolism	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Respiratory failure	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	4 (1.34%)

Skin and subcutaneous tissue disorders																			
Rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Vascular disorders																			
Hypotension	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Thrombosis	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Other Adverse Events by System Organ Class

Time Frame	From first dose of study treatment up to 150 days after last dose in each treatment period. The median duration of exposure to study treatment ranged between 8 and 9.15 weeks in Treatment Period 1 and between 5 and 42.05 weeks in Treatment Period 2.
Additional Description	Any sign or symptom that occurs during the study treatment plus 150 days after last dose in each treatment period.
Source Vocabulary for Table Default	MedDRA (25.0)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	0%

	PDR 001 + LBH 589 10 mg TIW 1wk on/1 wk off N = 7	PDR 001 + LBH 589 10 mg TIW 2wk on/1 wk off N = 10	PDR 001 + RAD 001 5 mg QW NSC LC N = 27	PDR001 + RAD001 5 mg QW TNBC N = 35	PDR 001 + RAD 001 5 mg QW CRC N = 36	PDR 001 + HDM 201 60 mg (RDE) CRC N = 32	PDR 001 + HDM 201 100 mg CRC N = 5	PDR 001 + HDM 201 60 mg (RDE) RCC N = 24	PDR001 + QBM 076 75 mg CRC N = 11	PDR 001 + QBM 076 150 mg CRC N = 7	PDR 001 + QBM 076 75 mg NSC LC N = 2	PDR 001 + QBM 076 150 mg NSC LC N = 1	PDR 001 + QBM 076 75 mg TNBC N = 1	PDR001 + LCL1 61 300 mg QW N = 10	PDR 001 + LCL1 61 600 mg QW NSC LC N = 25	PDR 001 + LCL1 61 600 mg QW TNBC N = 32	PDR001 + LCL1 61 600 mg QW CRC N = 27	PDR 001 + LCL1 61 900 mg QW N = 6	All participants N = 298
Arm/Group Description	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 1 week on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with panobinostat 10 mg three times a week (TIW) 2 weeks on/1 week off	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with everolimus 5 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 100 mg on Day 1 and Day 8 every cycle in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with HDM201 60 mg (recommended dose for expansion) on Day 1 and Day 8 every cycle in renal cell carcinoma (RCC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 150 mg twice daily (BID) 2 week on/2 week off in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with QBM076 75 mg twice daily (BID) 2 week on/2 week off in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 300 mg once per week (QW)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in non-small cell lung cancer (NSCLC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in triple-negative breast cancer (TNBC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 600 mg once per week (QW) in colorectal cancer (CRC)	PDR001 400 mg every 4 weeks (Q4W) in combination with LCL161 900 mg once per week (QW)	All participants in the study

Total participants affected	7 (100.0%)	9 (90.00%)	26 (96.30%)	35 (100.0%)	35 (97.22%)	31 (96.88%)	5 (100.0%)	23 (95.83%)	11 (100.0%)	7 (100.0%)	2 (100.0%)	1 (100.0%)	1 (100.0%)	10 (100.0%)	24 (96.00%)	30 (93.75%)	27 (100.0%)	6 (100.0%)	290 (97.32%)
Blood and lymphatic system disorders																			
Anaemia	2 (28.57%)	3 (30.00%)	1 (3.70%)	8 (22.86%)	5 (13.89%)	9 (28.13%)	3 (60.00%)	7 (29.17%)	1 (9.09%)	3 (42.86%)	1 (50.00%)	1 (100.0%)	0 (0.00%)	2 (20.00%)	1 (4.00%)	5 (15.63%)	4 (14.81%)	1 (16.67%)	57 (19.13%)
Leukocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	3 (1.01%)
Leukopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Lymphadenopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Monocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	2 (40.00%)	1 (4.17%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	7 (2.35%)
Polycythaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)

Thrombocytopenia	0 (0.00%)	2 (20.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	1 (20.00%)	3 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	9 (3.02%)
Cardiac disorders																			
Angina pectoris	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Atrial fibrillation	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Atrial flutter	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	2 (0.67%)
Bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Extrasystoles	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Palpitations	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Pericardial effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
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%)	1 (9.09%)	0 (0.00%)	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 (0.34%)
Sinus tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	2 (0.67%)

Tachycardia	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	1 (3.70%)	0 (0.00%)	6 (2.01%)
Ventricular extrasystoles	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Ear and labyrinth disorders																			
Cerumen impaction	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Ear discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Ear pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Hypoacusis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Tinnitus	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Vertigo	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Endocrine disorders																			
Autoimmune	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

hypothyroidism																		
Hyperthyroidism	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	7 (2.35%)
Hypothyroidism	0 (0.00%)	1 (10.00%)	0 (0.00%)	2 (5.71%)	2 (5.56%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	1 (4.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	11 (3.69%)
Thyroid 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%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Eye disorders																		
Altered visual depth perception	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
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%)	1 (10.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Diplopia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Dry eye	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.56%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	1 (4.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	7 (2.35%)
Erythema of eyelid	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 (9.09%)	0 (0.00%)	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 (0.34%)
Eye pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Eyelid ptosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Lacrimation increased	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Miosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Ocular 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%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Ocular hyperaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Swelling of eyelid	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Vision blurred	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	4 (1.34%)
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%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Gastrointestinal disorders																			
Abdominal discomfort	0 (0.00%)	1 (10.00%)	1 (3.70%)	0 (0.00%)	3 (8.33%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	10 (3.36%)
Abdominal	1 (14.29%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	6 (16.67%)	3 (9.38%)	1 (20.00%)	2 (8.33%)	1 (9.09%)	1 (14.29%)	1 (50.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)	2 (8.00%)	0 (0.00%)	1 (3.70%)	1 (16.67%)	22 (7.38%)

distension																		
Abdominal pain	2 (28.57%)	3 (30.00%)	1 (3.70%)	1 (2.86%)	12 (33.33%)	7 (21.88%)	1 (20.00%)	1 (4.17%)	3 (27.27%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (3.13%)	2 (7.41%)	2 (33.33%)	39 (13.09%)
Abdominal pain lower	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Abdominal pain upper	1 (14.29%)	3 (30.00%)	1 (3.70%)	1 (2.86%)	6 (16.67%)	0 (0.00%)	1 (20.00%)	1 (4.17%)	0 (0.00%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (3.13%)	2 (7.41%)	1 (16.67%)	21 (7.05%)
Abdominal tenderness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Ascites	1 (14.29%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	7 (2.35%)
Constipation	2 (28.57%)	2 (20.00%)	6 (22.22%)	7 (20.00%)	9 (25.00%)	7 (21.88%)	0 (0.00%)	3 (12.50%)	5 (45.45%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	1 (100.00%)	2 (20.00%)	3 (12.00%)	6 (18.75%)	5 (18.52%)	1 (16.67%)	60 (20.13%)
Diarrhoea	3 (42.86%)	2 (20.00%)	4 (14.81%)	6 (17.14%)	8 (22.22%)	4 (12.50%)	1 (20.00%)	3 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)	3 (12.00%)	1 (3.13%)	6 (22.22%)	2 (33.33%)	44 (14.77%)
Dry mouth	0 (0.00%)	1 (10.00%)	1 (3.70%)	2 (5.71%)	2 (5.56%)	5 (15.63%)	0 (0.00%)	1 (4.17%)	1 (9.09%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	2 (6.25%)	3 (11.11%)	0 (0.00%)	20 (6.71%)
Dyspepsia	0 (0.00%)	2 (20.00%)	1 (3.70%)	0 (0.00%)	2 (5.56%)	2 (6.25%)	1 (20.00%)	1 (4.17%)	1 (9.09%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	14 (4.70%)
Dysphagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.34%)

Epigastric discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	1 (0.34%)
Flatulence	0 (0.00%)	1 (10.00%)	0 (0.00%)	2 (5.71%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	6 (2.01%)
Frequent bowel movements	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Gastric haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Gastritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Gastrointestinal sounds abnormal	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Gastrooesophageal reflux disease	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	1 (3.70%)	4 (1.34%)
Gingival pain	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)

Haematochezia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Ileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
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%)	1 (14.29%)	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 (0.34%)
Lip dry	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
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%)	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 (3.70%)	0 (0.00%)	1 (0.34%)
Lip swelling	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Lip ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Melaena	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	3 (1.01%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (0.34%)
Nausea	3 (42.86%)	2 (20.00%)	4 (14.81%)	13 (37.14%)	6 (16.67%)	18 (56.25%)	4 (80.00%)	15 (62.50%)	6 (54.55%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	7 (28.00%)	10 (31.25%)	6 (22.22%)	3 (50.00%)	101 (33.89%)

Oesophageal compression	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Oral dysaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Oral pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Pancreatitis	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Paraesthesia oral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Proctalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Proctitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Rectal discharge	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Stomatitis	1 (14.29%)	0 (0.00%)	3 (11.11%)	3 (8.57%)	3 (8.33%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	3 (9.38%)	1 (3.70%)	0 (0.00%)	19 (6.38%)
Tongue 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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Toothache	1 (14.29%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	5 (1.68%)

Vomiting	0 (0.00%)	2 (20.00%)	2 (7.41%)	13 (37.14%)	9 (25.00%)	9 (28.13%)	1 (20.00%)	6 (25.00%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	3 (12.00%)	8 (25.00%)	6 (22.22%)	4 (66.67%)	66 (22.15%)
General disorders and administration site conditions																			
Asthenia	3 (42.86%)	1 (10.00%)	2 (7.41%)	6 (17.14%)	6 (16.67%)	7 (21.88%)	2 (40.00%)	0 (0.00%)	1 (9.09%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (16.00%)	3 (9.38%)	2 (7.41%)	0 (0.00%)	38 (12.75%)
Axillary pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Breakthrough pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Catheter site erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Catheter site pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Chest discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Chills	0 (0.00%)	0 (0.00%)	2 (7.41%)	0 (0.00%)	2 (5.56%)	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 (10.00%)	2 (8.00%)	2 (6.25%)	1 (3.70%)	0 (0.00%)	10 (3.36%)
Early satiety	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Facial pain	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Fatigue	0 (0.00%)	4 (40.00%)	5 (18.52%)	10 (28.57%)	18 (50.00%)	10 (31.25%)	1 (20.00%)	9 (37.50%)	6 (54.55%)	2 (28.57%)	0 (0.00%)	1 (100.00%)	1 (100.00%)	4 (40.00%)	1 (4.00%)	8 (25.00%)	10 (37.04%)	1 (16.67%)	91 (30.54%)
Gait disturbance	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	4 (1.34%)
General physical health deterioration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Generalised oedema	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Influenza like illness	0 (0.00%)	0 (0.00%)	3 (11.11%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.00%)	2 (6.25%)	2 (7.41%)	0 (0.00%)	10 (3.36%)
Injection site reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Localised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Malaise	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (3.13%)	0 (0.00%)	1 (4.17%)	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 (3.70%)	0 (0.00%)	4 (1.34%)
Mass	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Mucosal inflammation	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Non-cardiac chest pain	0 (0.00%)	1 (10.00%)	0 (0.00%)	2 (5.71%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	7 (2.35%)
Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Oedema peripheral	0 (0.00%)	2 (20.00%)	3 (11.11%)	7 (20.00%)	7 (19.44%)	3 (9.38%)	2 (40.00%)	2 (8.33%)	3 (27.27%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	1 (100.0%)	1 (10.00%)	2 (8.00%)	1 (3.13%)	2 (7.41%)	2 (33.33%)	40 (13.42%)
Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Pyrexia	2 (28.57%)	7 (70.00%)	2 (7.41%)	6 (17.14%)	8 (22.22%)	4 (12.50%)	0 (0.00%)	4 (16.67%)	0 (0.00%)	3 (42.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (30.00%)	4 (16.00%)	7 (21.88%)	6 (22.22%)	2 (33.33%)	58 (19.46%)
Temperature intolerance	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Temperature regulation disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Hepatobiliary disorders																			
Bile duct stenosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	1 (0.34%)
Biliary obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Cholangitis	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Cholestasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (0.34%)
Hepatic pain	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)	1 (0.34%)
Hyperbilirubinaemia	1 (14.29%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (16.67%)	8 (2.68%)
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%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	3 (1.01%)
Ocular icterus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)	2 (0.67%)
Portal hypertension	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Immune system disorders																			
Cytokine release 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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	2 (0.67%)

Seasonal allergy	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Infections and infestations																			
Abdominal 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%)	1 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	2 (0.67%)
Abscess	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Bacteraemia	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Bronchiolitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Candida infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Cellulitis	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Conjunctivitis	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Cystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Device related infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Eye infection viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Fungal skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Gingivitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Hepatitis viral	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Herpes virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Herpes zoster	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	3 (1.01%)
Infected skin ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Laryngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Lower respiratory tract infection	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)

Mucosal 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%)	1 (14.29%)	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 (0.34%)
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 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	0 (0.00%)	4 (1.34%)
Ophthalmic herpes zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Oral candidiasis	1 (14.29%)	1 (10.00%)	0 (0.00%)	1 (2.86%)	3 (8.33%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	10 (3.36%)
Oral herpes	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Otitis externa	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Otitis media chronic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Paronychia	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Pneumonia	0 (0.00%)	1 (10.00%)	2 (7.41%)	1 (2.86%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.00%)	2 (6.25%)	1 (3.70%)	0 (0.00%)	12 (4.03%)
Pyelonephritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Rash pustular	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Rectal 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%)	1 (14.29%)	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 (0.34%)
Respiratory syncytial 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%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Respiratory tract infection	1 (14.29%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	1 (2.78%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (1.68%)
Rhinitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Skin infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Suspected COVID-19	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Tooth infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (2.78%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (12.00%)	1 (3.13%)	1 (3.70%)	0 (0.00%)	9 (3.02%)
Urinary tract infection	0 (0.00%)	1 (10.00%)	2 (7.41%)	3 (8.57%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	11 (3.69%)
Viral upper respirat	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)

ory tract infection																		
Wound infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Injury, poisoning and procedural complications																		
Anaemia postoperative	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	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 (0.34%)
Ankle fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Contusion	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Fall	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	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%)	3 (1.01%)
Gastrointestinal stoma 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%)	1 (9.09%)	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 (0.34%)
Infusion related reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Ligament sprain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)

Postoperative wound complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Procedural pain	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	0 (0.00%)	5 (1.68%)
Rib fracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	1 (0.34%)
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%)	1 (14.29%)	0 (0.00%)	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 (0.34%)
Upper limb fracture	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 (9.09%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Wound complication	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.34%)
Wound haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Investigations																				
Activated partial thromboplastin time prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Alanine aminotransferase increased	2 (28.57%)	1 (10.00%)	2 (7.41%)	3 (8.57%)	8 (22.22%)	4 (12.50%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	2 (8.00%)	4 (12.50%)	0 (0.00%)	2 (33.33%)	31 (10.40%)
Ammonia increased	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Amylase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	2 (5.56%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	2 (18.18%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	8 (2.68%)
Aspartate aminotransferase increased	3 (42.86%)	3 (30.00%)	3 (11.11%)	5 (14.29%)	8 (22.22%)	4 (12.50%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	2 (28.57%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	2 (8.00%)	6 (18.75%)	4 (14.81%)	3 (50.00%)	47 (15.77%)
Blood albumin decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Blood alkaline phosphatase increased	2 (28.57%)	5 (50.00%)	0 (0.00%)	3 (8.57%)	4 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (42.86%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	1 (4.00%)	2 (6.25%)	4 (14.81%)	0 (0.00%)	27 (9.06%)
Blood bicarbonate decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Blood bicarbonate 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%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Blood bilirubin increased	0 (0.00%)	3 (30.00%)	0 (0.00%)	1 (2.86%)	6 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	3 (42.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	1 (3.70%)	2 (33.33%)	18 (6.04%)
Blood calcium increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Blood cholesterol increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Blood creatine phosphokinase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.71%)	2 (5.56%)	1 (3.13%)	1 (20.00%)	1 (4.17%)	1 (9.09%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	2 (7.41%)	2 (33.33%)	14 (4.70%)
Blood creatinine increased	1 (14.29%)	0 (0.00%)	0 (0.00%)	3 (8.57%)	3 (8.33%)	1 (3.13%)	0 (0.00%)	1 (4.17%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	3 (11.11%)	0 (0.00%)	14 (4.70%)
Blood glucose increased	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Blood lactate dehydrogenase	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 (9.09%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	3 (1.01%)

increased																		
Blood phosphorus decreased	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Blood pressure increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Blood thyroid stimulating hormone increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	0 (0.00%)	4 (1.34%)
Blood urea increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Blood uric acid increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Body temperature 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%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	1 (3.70%)	0 (0.00%)	2 (0.67%)
Breath sounds abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Electrocardiogram QT interval abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Electrocardiogram ST segment depression	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Eosinophil count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Eosinophil count increased	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.34%)
Gamma-glutamyltransferase increased	0 (0.00%)	2 (20.00%)	0 (0.00%)	0 (0.00%)	3 (8.33%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	2 (18.18%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	2 (8.00%)	1 (3.13%)	1 (3.70%)	0 (0.00%)	16 (5.37%)
Globulins increased	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Glucose urine present	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Hepatic enzyme	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	1 (0.34%)

increased																		
International normalised ratio increased	1 (14.29%)	1 (10.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (1.68%)
Lipase increased	1 (14.29%)	1 (10.00%)	0 (0.00%)	2 (5.71%)	5 (13.89%)	0 (0.00%)	0 (0.00%)	3 (12.50%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	16 (5.37%)
Lymphocyte count decreased	1 (14.29%)	0 (0.00%)	0 (0.00%)	3 (8.57%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	9 (3.02%)
Monocyte count 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%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Neutrophil count decreased	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.34%)
Platelet count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (18.75%)	2 (40.00%)	3 (12.50%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	13 (4.36%)
Protein total increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
SARS-CoV-2 test negative	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)

Troponin I increased	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Urine output decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Vitamin D decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Weight decreased	1 (14.29%)	1 (10.00%)	3 (11.11%)	3 (8.57%)	4 (11.11%)	3 (9.38%)	1 (20.00%)	2 (8.33%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	1 (4.00%)	3 (9.38%)	2 (7.41%)	2 (33.33%)	28 (9.40%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (0.34%)
White blood cell count decreased	1 (14.29%)	0 (0.00%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.34%)
White blood cell count increased	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Metabolism and nutrition disorders																			

Acidosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Alkalosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	1 (0.34%)
Decreased appetite	4 (57.14%)	5 (50.00%)	7 (25.93%)	8 (22.86%)	8 (22.22%)	7 (21.88%)	0 (0.00%)	8 (33.33%)	6 (54.55%)	3 (42.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	4 (16.00%)	4 (12.50%)	6 (22.22%)	4 (66.67%)	76 (25.50%)
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.25%)	1 (3.70%)	0 (0.00%)	5 (1.68%)
Diabetes mellitus	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 (9.09%)	0 (0.00%)	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 (0.34%)
Food craving	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
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%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Hypercalcaemia	0 (0.00%)	1 (10.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (20.83%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	9 (3.02%)
Hyperglycaemia	1 (14.29%)	3 (30.00%)	1 (3.70%)	3 (8.57%)	3 (8.33%)	4 (12.50%)	1 (20.00%)	1 (4.17%)	3 (27.27%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (16.67%)	24 (8.05%)
Hyperkalaemia	0 (0.00%)	2 (20.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (3.13%)	2 (7.41%)	0 (0.00%)	9 (3.02%)
Hyperlipidaemia	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)

Hyperna traemia	0 (0. 00%)	1 (1 0.00 %)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	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 (0. 34%)
Hypertri glycerid aemia	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	2 (5. 56%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	2 (0. 67%)
Hyperuri caemia	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	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 (10 .00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	1 (0. 34%)
Hypoalb uminae mia	1 (1 4.29 %)	4 (4 0.00 %)	0 (0. 00%)	2 (5. 71%)	3 (8. 33%)	3 (9. 38%)	0 (0. 00%)	1 (4. 17%)	1 (9. 09%)	2 (2 8.57 %)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	2 (20 .00%)	1 (4. 00%)	0 (0. 00%)	2 (7. 41%)	1 (1 6.67 %)	23 (7 .72%)
Hypocal caemia	1 (1 4.29 %)	2 (2 0.00 %)	0 (0. 00%)	1 (2. 86%)	2 (5. 56%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	6 (2. 01%)
Hypogly caemia	0 (0. 00%)	2 (2 0.00 %)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	1 (3. 13%)	0 (0. 00%)	0 (0. 00%)	1 (9. 09%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	4 (1. 34%)
Hypokal aemia	0 (0. 00%)	3 (3 0.00 %)	0 (0. 00%)	1 (2. 86%)	1 (2. 78%)	4 (1 2.50 %)	0 (0. 00%)	0 (0. 00%)	1 (9. 09%)	2 (2 8.57 %)	0 (0. 00%)	1 (1 00.0 0%)	0 (0. 00%)	1 (10 .00%)	0 (0. 00%)	1 (3. 13%)	0 (0. 00%)	0 (0. 00%)	15 (5 .03%)
Hypoma gnesae mia	0 (0. 00%)	2 (2 0.00 %)	0 (0. 00%)	1 (2. 86%)	0 (0. 00%)	1 (3. 13%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	1 (5 0.00 %)	1 (1 00.0 0%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	2 (7. 41%)	0 (0. 00%)	8 (2. 68%)
Hyponat raemia	2 (2 8.57 %)	5 (5 0.00 %)	1 (3. 70%)	3 (8. 57%)	4 (1 1.11 %)	2 (6. 25%)	0 (0. 00%)	0 (0. 00%)	3 (27 .27%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	1 (10 .00%)	4 (1 6.00 %)	1 (3. 13%)	3 (11 .11%)	1 (1 6.67 %)	30 (1 0.07 %)
Hypoph agia	0 (0. 00%)	0 (0. 00%)	1 (3. 70%)	0 (0. 00%)	0 (0. 00%)	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 (10 .00%)	0 (0. 00%)	1 (3. 13%)	0 (0. 00%)	0 (0. 00%)	3 (1. 01%)
Hypoph osphata emia	1 (1 4.29 %)	2 (2 0.00 %)	1 (3. 70%)	2 (5. 71%)	3 (8. 33%)	1 (3. 13%)	0 (0. 00%)	0 (0. 00%)	1 (9. 09%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	1 (4. 00%)	1 (3. 13%)	0 (0. 00%)	1 (1 6.67 %)	14 (4 .70%)

Lactic acidosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	1 (0.34%)
Vitamin D deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	3 (1.01%)
Musculoskeletal and connective tissue disorders																				
Arthralgia	0 (0.00%)	1 (10.00%)	5 (18.52%)	3 (8.57%)	6 (16.67%)	3 (9.38%)	0 (0.00%)	4 (16.67%)	1 (9.09%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	2 (8.00%)	4 (12.50%)	2 (7.41%)	2 (33.33%)	36 (12.08%)
Arthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Back pain	0 (0.00%)	2 (20.00%)	2 (7.41%)	6 (17.14%)	4 (11.11%)	1 (3.13%)	0 (0.00%)	5 (20.83%)	0 (0.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	2 (8.00%)	4 (12.50%)	2 (7.41%)	1 (16.67%)	31 (10.40%)
Bone pain	0 (0.00%)	1 (10.00%)	2 (7.41%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	1 (3.70%)	0 (0.00%)	8 (2.68%)
Bone 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%)	1 (14.29%)	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 (0.34%)
Flank pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	6 (2.01%)
Fracture pain	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)

Greater trochanteric pain syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Groin pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)	2 (0.67%)
Joint stiffness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Muscle spasms	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.25%)	1 (3.70%)	0 (0.00%)	7 (2.35%)
Muscular weakness	0 (0.00%)	1 (10.00%)	1 (3.70%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (3.13%)	1 (3.70%)	0 (0.00%)	8 (2.68%)
Musculoskeletal chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (8.57%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	1 (16.67%)	6 (2.01%)
Musculoskeletal disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Musculoskeletal pain	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Musculoskeletal stiffness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Myalgia	0 (0.00%)	1 (10.00%)	1 (3.70%)	2 (5.71%)	3 (8.33%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.00%)	3 (9.38%)	2 (7.41%)	2 (33.33%)	19 (6.38%)

Neck pain	0 (0.00%)	1 (10.00%)	1 (3.70%)	4 (11.43%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	12 (4.03%)
Osteoarthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Osteoporosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Pain in extremity	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	3 (8.33%)	4 (12.50%)	1 (20.00%)	1 (4.17%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (3.13%)	0 (0.00%)	1 (16.67%)	14 (4.70%)
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%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Pubic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)																			
Fibroma	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 (9.09%)	0 (0.00%)	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 (0.34%)
Haemangioma of skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Infected neoplasm	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Neoplasm	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Tumour associated fever	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Tumour pain	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.0%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (1.68%)
Nervous system disorders																			
Ataxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Aura	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Cerebral infarction	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Cognitive disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Depressed level of consciousness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Disturbance in attention	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)	1 (0.34%)
Dizziness	2 (28.57%)	0 (0.00%)	2 (7.41%)	3 (8.57%)	2 (5.56%)	0 (0.00%)	1 (20.00%)	2 (8.33%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	1 (4.00%)	2 (6.25%)	0 (0.00%)	1 (16.67%)	19 (6.38%)

Dizziness postural	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
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%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Dysgeusia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	1 (2 0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	1 (16.67%)	4 (1.34%)
Headache	0 (0.00%)	2 (20.00%)	1 (3.70%)	9 (25.71%)	3 (8.33%)	3 (9.38%)	1 (2 0.00%)	2 (8.33%)	1 (9.09%)	4 (57.14%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.00%)	3 (9.38%)	2 (7.41%)	0 (0.00%)	34 (11.41%)
Hypoaesthesia	0 (0.00%)	0 (0.00%)	1 (3.70%)	3 (8.57%)	0 (0.00%)	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 (10.00%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	7 (2.35%)
Lethargy	1 (14.29%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.34%)
Memory impairment	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Migraine	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Myoclonus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Neuropathy peripheral	1 (14.29%)	1 (10.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (2.35%)
Paraesthesia	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (5.71%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	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 (3.13%)	1 (3.70%)	0 (0.00%)	6 (2.01%)

Paraplegia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Peripheral sensory neuropathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Post herpetic 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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (0.34%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Spinal cord compression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Taste disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	2 (5.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Tension headache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
VIth nerve paralysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Vocal cord 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%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Psychiatric disorders																				
Anxiety	0 (0.00%)	2 (20.00%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	1 (3.13%)	1 (3.70%)	1 (16.67%)	8 (2.68%)
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%)	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 (3.70%)	0 (0.00%)	1 (0.34%)
Delirium	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Depressed mood	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Depression	1 (14.29%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (2.35%)
Disorientation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Hallucination	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Insomnia	1 (14.29%)	0 (0.00%)	3 (11.11%)	3 (8.57%)	1 (2.78%)	1 (3.13%)	0 (0.00%)	1 (4.17%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (12.00%)	0 (0.00%)	2 (7.41%)	2 (33.33%)	20 (6.71%)
Mental status changes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Panic attack	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Restlessness	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Renal and urinary disorders																		
Acute kidney injury	1 (14.29%)	2 (20.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	8 (2.68%)
Azotaemia	1 (14.29%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
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%)	1 (10.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	2 (0.67%)
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (3.13%)	0 (0.00%)	5 (1.68%)
Haematuria	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Micturition urgency	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
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%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Pollakiuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.34%)

Renal failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Renal 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%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Renal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Urinary hesitation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Urinary incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Urinary retention	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	4 (1.34%)
Urinary tract 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%)	1 (9.09%)	0 (0.00%)	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 (0.34%)
Urinary tract pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Reproductive system and breast disorders																			
Breast 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%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)

Breast mass	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Breast pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	4 (1.34%)
Heavy menstrual 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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.34%)
Intermenstrual bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Pelvic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Scrotal 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%)	1 (9.09%)	0 (0.00%)	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 (0.34%)
Testicular pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Vaginal 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%)	1 (14.29%)	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 (0.34%)
Respiratory, thoracic and mediastinal disorders																			
Acute respirat	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)

ory failure																			
Broncho spasm	0 (0. 00%)	0 (0. 00%)	1 (3. 70%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	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 (0. 34%)
Catarrh	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	1 (2. 86%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	2 (8. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	3 (1. 01%)
Cough	0 (0. 00%)	1 (1 0.00 %)	7 (2 5.93 %)	5 (14 .29%)	11 (30.5 6%)	2 (6. 25%)	0 (0. 00%)	5 (2 0.83 %)	3 (27 .27%)	3 (4 2.86 %)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	1 (10 .00%)	3 (1 2.00 %)	5 (1 5.63 %)	6 (22 .22%)	1 (1 6.67 %)	53 (1 7.79 %)
Dyspho nia	0 (0. 00%)	0 (0. 00%)	1 (3. 70%)	1 (2. 86%)	1 (2. 78%)	1 (3. 13%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	3 (4 2.86 %)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	1 (4. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	8 (2. 68%)
Dyspno ea	0 (0. 00%)	2 (2 0.00 %)	1 (3. 70%)	8 (22 .86%)	5 (1 3.89 %)	5 (1 5.63 %)	1 (2 0.00 %)	2 (8. 33%)	4 (36 .36%)	1 (1 4.29 %)	0 (0. 00%)	1 (1 00.0 0%)	0 (0. 00%)	1 (10 .00%)	4 (1 6.00 %)	8 (2 5.00 %)	4 (14 .81%)	1 (1 6.67 %)	48 (1 6.11 %)
Dyspno ea at rest	0 (0. 00%)	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 (1 4.29 %)	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 (0. 34%)
Dyspno ea exertion al	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	1 (2. 86%)	2 (5. 56%)	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 (10 .00%)	2 (8. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	6 (2. 01%)
Epistaxi s	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	2 (5. 71%)	0 (0. 00%)	0 (0. 00%)	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 (4. 00%)	0 (0. 00%)	1 (3. 70%)	0 (0. 00%)	4 (1. 34%)
Haemop tysis	0 (0. 00%)	2 (2 0.00 %)	2 (7. 41%)	1 (2. 86%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	1 (4. 17%)	1 (9. 09%)	0 (0. 00%)	0 (0. 00%)	1 (1 00.0 0%)	0 (0. 00%)	0 (0. 00%)	1 (4. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	9 (3. 02%)
Hiccups	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	2 (5. 56%)	2 (6. 25%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	0 (0. 00%)	4 (1. 34%)

Hypoxia	0 (0.00%)	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 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Laryngeal oedema	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Lung infiltration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Nasal congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Oropharyngeal pain	1 (14.29%)	0 (0.00%)	0 (0.00%)	3 (8.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	1 (3.70%)	0 (0.00%)	6 (2.01%)
Pleural effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (11.43%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.00%)	4 (12.50%)	0 (0.00%)	0 (0.00%)	11 (3.69%)
Pleuritic pain	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Pneumonitis	0 (0.00%)	0 (0.00%)	2 (7.41%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (2.01%)
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%)	1 (9.09%)	0 (0.00%)	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 (0.34%)
Productive cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	2 (6.25%)	0 (0.00%)	2 (8.33%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (16.00%)	2 (6.25%)	1 (3.70%)	0 (0.00%)	14 (4.70%)
Pulmonary embolism	0 (0.00%)	1 (10.00%)	1 (3.70%)	1 (2.86%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (1.68%)

Rhinorrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (3.13%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	3 (12.00%)	0 (0.00%)	0 (0.00%)	7 (2.35%)
Sinus 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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Sinus pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Tachypnoea	0 (0.00%)	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 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (0.67%)
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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Wheezing	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (8.57%)	1 (2.78%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (1.68%)
Skin and subcutaneous tissue disorders																		
Acne	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 (9.09%)	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 (0.34%)
Alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Cold sweat	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Decubitus ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Dermatitis acneiform	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 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	2 (0.67%)
Dry skin	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	0 (0.00%)	6 (2.01%)
Ecchymosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	1 (3.70%)	0 (0.00%)	5 (1.68%)
Erythema nodosum	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Hyperhidrosis	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Nail disorder	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Night sweats	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	1 (3.70%)	1 (16.67%)	4 (1.34%)
Pruritus	0 (0.00%)	2 (20.00%)	3 (11.11%)	3 (8.57%)	5 (13.89%)	1 (3.13%)	0 (0.00%)	5 (20.83%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	3 (12.00%)	5 (15.63%)	6 (22.22%)	1 (16.67%)	37 (12.42%)
Psoriasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Rash	0 (0.00%)	1 (10.00%)	7 (25.93%)	2 (5.71%)	3 (8.33%)	0 (0.00%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (20.00%)	4 (16.00%)	7 (21.88%)	3 (11.11%)	0 (0.00%)	31 (10.40%)
Rash erythematous	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Rash macular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Rash maculo-papular	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	0 (0.00%)	4 (1.34%)
Rash pruritic	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	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%)	3 (1.01%)
Seborrhoeic dermatitis	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Skin hypopigmentation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	1 (0.34%)
Skin irritation	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Skin lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	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 (4.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)
Skin lesion inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)

Skin ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.70%)	0 (0.00%)	1 (0.34%)
Urticaria	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	5 (1.68%)
Vitiligo	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (0.34%)
Vascular disorders																			
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	1 (3.70%)	0 (0.00%)	3 (1.01%)
Flushing	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	2 (0.67%)
Haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.67%)
Hot flush	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	1 (2.78%)	0 (0.00%)	0 (0.00%)	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 (3.13%)	0 (0.00%)	0 (0.00%)	4 (1.34%)
Hypertension	0 (0.00%)	0 (0.00%)	2 (7.41%)	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	2 (18.18%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	8 (2.68%)
Hypotension	1 (14.29%)	2 (20.00%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (2.01%)
Lymphoedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	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 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.01%)

Conclusion:

The evaluated combinations of PDR001 with LBH589, LCL161 and RAD001, while being generally well tolerated, did not identify a combination treatment with efficacy clearly superior to that of single agent PDR001. This study also sought to explore whether ~6 months of treatment with PDR001 in combination would be sufficient to induce a durable clinical benefit. There were too few subjects with clinical response to assess this question, but two patients with NSCLC treated with PDR001 + LCL161 remained well until study completion after the initial six cycles of treatment, suggesting that for some subjects, six months of treatment might be sufficient to provide durable clinical benefit.

Date of Clinical Trial Report

14-Nov-2022