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Sponsor

Novartis Pharmaceuticals

Generic Drug Name

MAK683

Trial Indication(s)

Advanced malignancies

- Diffuse large B-cell lymphoma (DLBCL)
- Nasopharyngeal carcinoma (NPC)
- Gastric cancer (GC)
- Ovarian clear cell carcinoma (OCCC)
- Castration-resistant Prostate cancer (PC)
- Sarcoma

Protocol Number

CMAK683X2101

Protocol Title

A phase I/II, multicenter, open-label study of MAK683 in adult patients with advanced malignancies

Clinical Trial Phase

Phase 1

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Phase of Drug Development

Phase I

Study Start/End Dates

Study Start Date: October 03, 2016 (Actual)
Primary Completion Date: October 09, 2024 (Actual)
Study Completion Date: October 09, 2024 (Actual)

Reason for Termination (If applicable)

The decision of early termination was made due to business reasons, and was not based on any safety or tolerability concerns for MAK683

Study Design/Methodology

This study was a phase I/II, multi-center, open-label study starting with a phase I dose escalation part followed by a phase II part in adult participants with advanced malignancies. Oral MAK683 was administered per protocol on a continuous (daily) schedule until participant experienced unacceptable toxicity, progressive disease and/or treatment was discontinued at the discretion of the investigator or participant or withdrawal of consent. One cycle was defined as 28 days.

As per protocol amendment 05, phase II part of the study was not conducted, due to the decision to halt patient enrollment, effective 08-Nov-2022.

Centers

16 centers in 10 countries/subdivisions: Canada(1), Singapore(1), Japan(2), Hong Kong(1), United States(3), France(1), Spain(1), Germany(2), Italy(2), China(2)

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Objectives:

The primary objective for phase I of this study was to characterize safety and tolerability and determine the MTD and/or RP2D of MAK683

Phase I secondary objectives were:

- To characterize the anti-tumor activity of MAK683
- To characterize the PK profile of MAK683
- To characterize the pharmacodynamic effect of MAK683

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

Manually enter: Oral capsules of MAK683 of 10, 20, 40,80,120,160 ,240 ,300 ,500 ,800 mg once daily (QD) or 60, 80, 120, 150, 300, 450 mg twice daily (BID) dosing schedule.

Statistical Methods

Dose limiting toxicities (DLTs) were listed, and their incidence was summarized by primary system organ class and preferred term (CTCAE version 4.03). Listings and summaries were based on the Dose Determining Set.

Tolerability of study treatment was assessed by summarizing the number of dose interruptions and dose reductions by treatment group/disease group. Reasons for dose interruption and dose reductions were listed by patient and treatment group/disease group and summarized by treatment group/disease group. Cumulative dose, dose intensity and relative dose intensity of study treatment were also used to assess tolerability.

AEs were summarized by number and percentage of patients having at least one AE. A patient with multiple occurrences of an AE was counted only once in the respective AE category. A patient with multiple CTCAE grades for the same preferred term was summarized under the maximum CTCAE grade recorded for the event.

Evaluation of anti-tumor activity was based on investigator assessment of overall lesion response according to Cheson et al 2014 for participants with lymphoma, PCWG2 for participants with PC, and RECIST v1.1 for participants with other solid tumors. The variables used to evaluate anti-tumor activity were BOR, ORR, DOR and PFS using the FAS.

Derived MAK683 PK parameters were summarized with the descriptive statistics, arithmetic and geometric mean, median, standard deviation, arithmetic CV, geometric CV, minimum and maximum. Only median values and ranges were given for Tmax. Missing data were not imputed.

H3K27 trimethylation assessments were summarized using descriptive statistics

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

1.Eastern Cooperative Oncology Group (ECOG): 0 to 2

2.Relapsed or refractory diffuse large B cell lymphoma with measurable disease as determined by Non-Hodgkin's Lymphoma Cheson response criteria (2014)

3.Advanced or recurrent/metastatic solid tumor, including nasopharyngeal carcinoma, castration-resistant prostate cancer, gastric cancer, ovarian clear cell carcinoma and sarcoma, with measurable disease as determined by RECIST 1.1.

Exclusion Criteria:

1.Other malignant diseases than the ones being treated in this study

2.Severe and/or uncontrolled medical conditions that in the investigator's opinion could affect the safety of individual or impair the assessment of study result.

3.B-cell lymphoma patients who have received prior allogeneic stem cell transplant

4.Patient have received anti-cancer therapies within defined time frames prior to the first dose of study treatment

5.Symptomatic central nervous system (CNS) involvement which are neurologically unstable or requiring increasing doses of steroids

to control.

6.Patient having out of range laboratory values defined as:

1) Insufficient bone marrow function at screening:

•Platelets ≤ 50,000/mm3

•Hemoglobin (Hgb) ≤ 80 g/L

•Absolute neutrophil count (ANC) ≤ 1000/mm3

2) Insufficient hepatic and renal function at screening:

• ALP, ALT, and AST > 3 x ULN (>5 x ULN if subject has liver metastases)

• Total bilirubin >1.5 x ULN

• Serum creatinine > 1.5 x ULN and/or creatinine clearance ≤ 50 mL/min

Participant Flow Table

Overall Study

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID	Total
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily	
Started	4	7	3	8	8	5	6	4	18	4	8	11	11	8	30	4	139

Completed*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed*	4	7	3	8	8	5	6	4	18	4	8	11	11	8	30	4	139
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Progressive Disease	3	5	3	8	7	4	4	4	14	4	4	9	7	7	22	2	107
Physician Decision	1	1	0	0	1	0	1	0	0	0	2	1	1	0	1	1	10
Adverse Event	0	0	0	0	0	0	0	0	1	0	2	0	0	0	4	1	8
Subject / Guardian Decision	0	1	0	0	0	0	0	0	2	0	0	0	2	0	2	0	7
Death	0	0	0	0	0	0	1	0	1	0	0	1	0	1	1	0	5
Lost to Follow-up	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1

*Completed/Not completed refers to the participants that completed or discontinued from study treatment and the respective reasons for treatment discontinuation

Baseline Characteristics

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID	Total
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily	
Number of Participants [units: participants]	4	7	3	8	8	5	6	4	18	4	8	11	11	8	30	4	139
Baseline Analysis Population Description																	
Age, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)																	
18 - <65 years	4	4	1	3	4	4	4	1	15	2	4	6	9	5	22	1	89
65 - <85	0	3	2	4	4	1	2	3	3	2	4	5	2	3	8	3	49
≥ 85	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1
Sex: Female, Male (units: participants)																	

Analysis Population Type: Participants
Count of Participants (Not Applicable)

Female	0	4	1	3	4	1	2	1	8	2	1	7	4	1	6	3	48
Male	4	3	2	5	4	4	4	3	10	2	7	4	7	7	24	1	91

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

Asian	2	3	2	3	4	1	0	0	6	1	1	1	3	3	5	1	36
Black	0	0	0	0	1	0	0	0	0	0	1	0	0	0	1	0	3
Caucasian	2	2	0	4	1	4	5	1	8	2	1	5	5	5	15	2	62
Other	0	0	1	1	2	0	1	3	3	0	5	5	2	0	3	0	26
Unknown	0	2	0	0	0	0	0	0	1	1	0	0	1	0	6	1	12

Study Specific Characteristic
Disease classification
(units: participants)
Description: DLBCL - Diffuse large B-cell lymphoma. Solid tumors - including Nasopharyngeal carcinoma, gastric cancer, prostate cancer, ovarian cancer, sarcoma
Analysis Population Type: Participants
Count of Participants (Not Applicable)

DLBCL	1	3	1	3	4	0	2	2	1	1	5	5	1	1	1	0	31
Solid tumors	3	4	2	5	4	5	4	2	17	3	3	6	10	7	29	4	108

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Primary Outcome Result(s)

Incidence of dose limiting toxicities (DLTs)

Description	Number of participants with DLTS. A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value assessed as unrelated to disease, disease progression, inter-current illness, or concomitant medications that occurs within the first 28 days of continuous treatment with MAK683 and meets any of the protocol specified criteria.
Time Frame	First cycle of treatment (28 days)
Analysis Population Description	The dose-determining analysis set (DDS) includes all patients from the Safety Set (SS) who met the minimum exposure criterion and had sufficient safety evaluations, or experienced a DLT during the first 28 days of dosing. The SS comprises all patients who received at least one dose of MAK683.

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	3	7	3	7	7	3	6	4	15	4	8	8	9	8	26	4
Incidence of dose limiting toxicit	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**

ies (DLTs) (units: partici pants)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)	Appli cable)
	0 (%)	0 (%)	0 (%)	0 (%)	1 (14.29 %)	0 (%)	1 (16.67 %)	0 (%)	1 (6.67%)	2 (50%)	1 (12.5%)	2 (25%)	1 (11.11 %)	1 (12.5%)	2 (7.69%)	3 (75%)

Incidence of Adverse Events (AEs) and Serious Adverse Events (SAEs)

Description	Number of participants with AEs and SAEs, including changes in laboratory values, vital signs and ECGs qualifying and reported as AEs.
Time Frame	From first dose of study treatment until 30 days after last dose up to approximately 5.4 years
Analysis Population Description	The Safety Set (SS) comprises all patients who received at least one dose of MAK683.

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	4	7	3	8	8	5	6	4	18	4	8	11	11	8	30	4

Incidence of Adverse Events (AEs) and Serious Adverse Events (SAEs) (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
AEs	4 (100%)	7 (100%)	3 (100%)	8 (100%)	8 (100%)	5 (100%)	6 (100%)	4 (100%)	18 (100%)	4 (100%)	8 (100%)	11 (100%)	11 (100%)	8 (100%)	29 (96.67%)	4 (100%)
Treatment related AEs	4 (100%)	4 (57.14%)	3 (100%)	3 (37.5%)	4 (50%)	2 (40%)	2 (33.33%)	3 (75%)	14 (77.78%)	4 (100%)	8 (100%)	5 (45.45%)	9 (81.82%)	7 (87.5%)	22 (73.33%)	4 (100%)
SAEs	2 (50%)	3 (42.86%)	1 (33.33%)	4 (50%)	3 (37.5%)	3 (60%)	4 (66.67%)	2 (50%)	6 (33.33%)	2 (50%)	4 (50%)	8 (72.73%)	6 (54.55%)	2 (25%)	15 (50%)	3 (75%)
Treatment related SAEs	0 (%)	0 (%)	0 (%)	0 (%)	1 (12.5%)	0 (%)	0 (%)	1 (25%)	1 (5.56%)	2 (50%)	3 (37.5%)	2 (18.18%)	2 (18.18%)	1 (12.5%)	3 (10%)	3 (75%)
Fatal SAEs	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	3 (50%)	0 (%)	1 (5.56%)	0 (%)	1 (12.5%)	2 (18.18%)	0 (%)	1 (12.5%)	1 (3.33%)	1 (25%)
AEs requiring	4 (100%)	7 (100%)	2 (66.67%)	7 (87.5%)	6 (75%)	4 (80%)	6 (100%)	3 (75%)	16 (88.89%)	4 (100%)	7 (87.5%)	11 (100%)	10 (90.91%)	7 (87.5%)	25 (83.33%)	4 (100%)

additional therapy

Incidence of dose interruptions and dose reductions

Description	Tolerability measured by the number of subjects who have interruptions or reductions of study treatment
Time Frame	From first dose of study treatment until last dose up to approximately 5.3 years (average 57 days)
Analysis Population Description	The Safety Set (SS) comprises all patients who received at least one dose of MAK683.

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	4	7	3	8	8	5	6	4	18	4	8	11	11	8	30	4
Incidence of dose interru	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**

ptions and dose reductions (units: participants)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)	(Not Applicable)
at least one dose reduction or interruption	2 (50%)	3 (42.86%)	1 (33.33%)	6 (75%)	4 (50%)	3 (60%)	3 (50%)	3 (75%)	12 (66.67%)	4 (100%)	7 (87.5%)	10 (90.91%)	6 (54.55%)	4 (50%)	19 (63.33%)	4 (100%)
at least one dose reduction	0 (%)	0 (%)	0 (%)	0 (%)	1 (12.5%)	0 (%)	1 (16.67%)	1 (25%)	3 (16.67%)	3 (75%)	1 (12.5%)	1 (9.09%)	2 (18.18%)	2 (25%)	6 (20%)	1 (25%)
at least one dose interruption	2 (50%)	3 (42.86%)	1 (33.33%)	6 (75%)	4 (50%)	3 (60%)	3 (50%)	3 (75%)	12 (66.67%)	4 (100%)	7 (87.5%)	10 (90.91%)	5 (45.45%)	4 (50%)	19 (63.33%)	4 (100%)

Dose intensity

Description	Tolerability was measured by the dose of study drug. Dose intensity is defined as the ratio of actual dose received and actual duration of exposure.
Time Frame	From first dose of study treatment until last dose up to approximately 5.3 years (average 57 days)
Analysis Population Description	The Safety Set (SS) comprises all patients who received at least one dose of MAK683.

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	4	7	3	8	8	5	6	4	18	4	8	11	11	8	30	4
Dose intensity (units: mg/day)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
	9.9 ± 0.12	21.1 ± 3.01	39.9 ± 0.16	76.1 ± 7.61	106.7 ± 23.10	154.8 ± 11.58	223.2 ± 35.79	269.4 ± 53.05	442.5 ± 99.40	485.1 ± 180.32	107.6 ± 17.42	150.0 ± 25.94	224.5 ± 44.96	278.4 ± 35.20	523.4 ± 121.93	723.3 ± 213.85

Relative Dose intensity

Description	Tolerability was measured by the dose of study drug. Relative dose intensity is defined as the ratio of dose intensity to planned dose intensity multiplied by 100
Time Frame	From first dose of study treatment until last dose up to approximately 5.3 years (average 57 days)
Analysis Population Description	The Safety Set (SS) comprises all patients who received at least one dose of MAK683.

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	4	7	3	8	8	5	6	4	18	4	8	11	11	8	30	4
Relative Dose intensity (units: percentage)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
	100.0 (98 to 100)	100.0 (100 to 140)	100.0 (99 to 100)	100.0 (78 to 104)	100.0 (46 to 100)	100.0 (84 to 100)	100.0 (63 to 100)	97.9 (63 to 100)	99.7 (31 to 100)	62.7 (34 to 83)	96.6 (58 to 100)	98.5 (45 to 100)	100.0 (38 to 103)	99.4 (73 to 100)	100.0 (31 to 100)	84.7 (52 to 100)

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Secondary Outcome Result(s)

Overall Response Rate (ORR) - DLBCL

Description	Overall response rate (ORR) is the proportion of patients with a best overall response of CR or PR. Efficacy was based on local investigator assessment, as defined in Cheson 2014.
Time Frame	From first dose of study treatment until 30 days after last dose up to approximately 5.4 years
Analysis Population Description	Participants in the Full Analysis Set (FAS) with Diffuse large B-cell lymphoma. The FAS comprises all patients who received at least one dose of MAK683.

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	1	3	1	3	4	0	2	2	1	1	5	5	1	1	1	0
Overall Response Rate (ORR) -	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**

DLBCL (units: Percentage of participants)																
	0.0 (0.0 to 95.0)	33.3 (1.7 to 86.5)	0.0 (0.0 to 95.0)	0.0 (0.0 to 63.2)	0.0 (0.0 to 52.7)	0.0 (0.0 to 77.6)	0.0 (0.0 to 77.6)	0.0 (0.0 to 95.0)	0.0 (0.0 to 95.0)	40.0 (7.6 to 81.1)	20.0 (1.0 to 65.7)	0.0 (0.0 to 95.0)	0.0 (0.0 to 95.0)	0.0 (0.0 to 95.0)		

Overall Response Rate (ORR) - SOLID TUMORS

Description	Overall response rate (ORR) is the proportion of patients with a best overall response of CR or PR. Efficacy was based on based on local investigator assessment, as defined in Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.
Time Frame	From first dose of study treatment until 30 days after last dose up to approximately 5.4 years
Analysis Population Description	Participants in the Full Analysis Set (FAS) with solid tumors. The FAS comprises all patients who received at least one dose of MAK683.

	10 mg QD	**20 mg QD**	**40 mg QD**	**80 mg QD**	**120 mg QD**	**160 mg QD**	**240 mg QD**	**300 mg QD**	**500 mg QD**	**800 mg QD**	**60 mg BID**	**80 mg BID**	**120 mg BID**	**150 mg BID**	**300 mg BID**	**450 mg BID**
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed	3	4	2	5	4	5	4	2	17	3	3	6	10	7	29	4

[units: participants]																
Overall Response Rate (ORR) - SOLID TUMORS (units: Percentage of participants)	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**
	0 (0.0 to 63.2)	0 (0.0 to 52.7)	0 (0.0 to 77.6)	0 (0.0 to 45.1)	0 (0.0 to 52.7)	0 (0.0 to 45.1)	0 (0.0 to 52.7)	0 (0.0 to 77.6)	5.9 (0.3 to 25.0)	0 (0.0 to 63.2)	0 (0.0 to 63.2)	0 (0.0 to 39.3)	20.0 (3.7 to 50.7)	0 (0.0 to 34.8)	0 (0.0 to 9.8)	0 (0.0 to 52.7)

Best Overall Response (BOR) - DLBCL

Description	The best overall response is the best response recorded from the start of the treatment until disease progression/recurrence. Efficacy was based on local investigator assessment, as defined in Cheson 2014.
Time Frame	From first dose of study treatment until 30 days after last dose up to approximately 5.4 years
Analysis Population Description	Participants in the Full Analysis Set (FAS) with Diffuse large B-cell lymphoma. The FAS comprises all patients who received at least one dose of MAK683.

	10 mg QD	**20 mg QD**	**40 mg QD**	**80 mg QD**	**120 mg QD**	**160 mg QD**	**240 mg QD**	**300 mg QD**	**500 mg QD**	**800 mg QD**	**60 mg BID**	**80 mg BID**	**120 mg BID**	**150 mg BID**	**300 mg BID**	**450 mg BID**
Arm/Group	MAK683 10	MAK683 20	MAK683 40	MAK683 80	MAK683	MAK683	MAK683	MAK683	MAK683	MAK683	MAK683 60	MAK683 80	MAK683	MAK683	MAK683	MAK683

Description	mg orally once daily	mg orally once daily	mg orally once daily	mg orally once daily	120 mg orally once daily	160 mg orally once daily	240 mg orally once daily	300 mg orally once daily	500 mg orally once daily	800 mg orally once daily	mg orally twice daily	mg orally twice daily	120 mg orally twice daily	150 mg orally twice daily	300 mg orally twice daily	450 mg orally twice daily
Number of Participants Analyzed [units: participants]	1	3	1	3	4	0	2	2	1	1	5	5	1	1	1	0
Best Overall Response (BOR) - DLBCL (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Complete Response (CR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (40%)	0 (%)	0 (%)	0 (%)	0 (%)	(NaN%)
Partial Response (PR)	0 (%)	1 (33.33%)	0 (%)	0 (%)	0 (%)	0 (NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (20%)	0 (%)	0 (%)	0 (%)	(NaN%)
Stable Disease (SD)	0 (%)	0 (%)	1 (100%)	0 (%)	1 (25%)	0 (NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (20%)	0 (%)	0 (%)	1 (100%)	1 (100%)	(NaN%)

Progressive Disease (PD)	1 (100%)	2 (66.67 %)	0 (%)	2 (66.67 %)	2 (50%)	0 (NaN%)	2 (100%)	2 (100%)	1 (100%)	1 (100%)	1 (20%)	3 (60%)	1 (100%)	0 (%)	0 (%)	(NaN%)
Unknown (UNK)	0 (%)	0 (%)	0 (%)	1 (33.33 %)	1 (25%)	0 (NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (20%)	1 (20%)	0 (%)	0 (%)	0 (%)	(NaN%)

Best Overall Response (BOR) - SOLID TUMORS

Description	The best overall response is the best response recorded from the start of the treatment until disease progression/recurrence. Efficacy was based on based on local investigator assessment, as defined in Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.
Time Frame	From first dose of study treatment until 30 days after last dose up to approximately 5.4 years
Analysis Population Description	Participants in the Full Analysis Set (FAS) with solid tumors. The FAS comprises all patients who received at least one dose of MAK683.

	10 mg QD	**20 mg QD**	**40 mg QD**	**80 mg QD**	**120 mg QD**	**160 mg QD**	**240 mg QD**	**300 mg QD**	**500 mg QD**	**800 mg QD**	**60 mg BID**	**80 mg BID**	**120 mg BID**	**150 mg BID**	**300 mg BID**	**450 mg BID**
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units:	3	4	2	5	4	5	4	2	17	3	3	6	10	7	29	4

participants]																
Best Overall Response (BOR) - SOLID TUMORS (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Partial Response (PR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (5.88%)	0 (%)	0 (%)	0 (%)	2 (20%)	0 (%)	0 (%)	0 (%)
Stable Disease (SD)	0 (%)	1 (25%)	1 (50%)	3 (60%)	0 (%)	1 (20%)	1 (25%)	0 (%)	9 (52.94%)	1 (33.33%)	3 (100%)	1 (16.67%)	2 (20%)	5 (71.43%)	10 (34.48%)	1 (25%)
Progressive Disease (PD)	1 (33.33%)	2 (50%)	1 (50%)	1 (20%)	4 (100%)	3 (60%)	2 (50%)	2 (100%)	4 (23.53%)	2 (66.67%)	0 (%)	2 (33.33%)	5 (50%)	2 (28.57%)	16 (55.17%)	1 (25%)
Unknown (UNK)	2 (66.67%)	1 (25%)	0 (%)	1 (20%)	0 (%)	1 (20%)	1 (25%)	0 (%)	3 (17.65%)	0 (%)	0 (%)	3 (50%)	1 (10%)	0 (%)	3 (10.34%)	2 (50%)

Duration of overall response (DOR) - DLBCL

Description	The time between the date of first documented response (CR or PR) and the date of first documented progression or death. Duration of response was to be estimated using the Kaplan-Meier method.
Time Frame	From first time of CR/PR to date of death, treatment failure or relapse, up to approximately 5.4 years.

Analysis Population Description: DLBCL participants in the Full Analysis Set (FAS) with an available value for the outcome measure. The FAS comprises all patients who received at least one dose of MAK683.

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	0	1	0	0	0	0	0	0	0	0	2	1	0	0	0	0
Duration of overall response (DOR) - DLBCL (units: months)	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**

				3.7 (NA to NA)[1]							NA (NA to NA)[1]	3.1 (NA to NA)[1]				

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

Duration of overall response (DOR) - SOLID TUMORS

Description	The time between the date of first documented response (CR or PR) and the date of first documented progression or death. Duration of response was to be estimated using the Kaplan-Meier method.
Time Frame	From first time of CR/PR to date of death, treatment failure or relapse, up to approximately 5.4 years.
Analysis Population Description	Solid tumor participants in the Full Analysis Set (FAS) with an available value for the outcome measure. The FAS comprises all patients who received at least one dose of MAK683.

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	0	0	0	0	0	0	0	0	1	0	0	0	2	0	0	0
Duration of overall	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**	**Median (90%**

response (DOR) - SOLID TUMORS (units: months)	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**	**Confidence Interval)**
									28.5 (NA to NA)[1]				NA (NA to NA)[1]			

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

Progression-free survival (PFS) - DLBCL

Description	Progression-free survival (PFS) is defined as the time from the date of start of treatment to the date of event defined as the first documented progression or death due to any cause
Time Frame	From first dose of study treatment to date of death, treatment failure or relapse, up to approximately 5.4 years
Analysis Population Description	DLBCL participants in the Full Analysis Set (FAS) with an available value for the outcome measure. The FAS comprises all patients who received at least one dose of MAK683.

	10 mg QD	**20 mg QD**	**40 mg QD**	**80 mg QD**	**120 mg QD**	**160 mg QD**	**240 mg QD**	**300 mg QD**	**500 mg QD**	**800 mg QD**	**60 mg BID**	**80 mg BID**	**120 mg BID**	**150 mg BID**	**300 mg BID**	**450 mg BID**
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of	1	3	1	3	4	0	2	2	1	1	5	5	1	1	1	0

Participants Analyzed [units: participants]																
Progression-free survival (PFS) - DLBCL (units: months)	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**
	2.4 (NA to NA)[1]	1.1 (1.0 to NA)[1]	8.4 (NA to NA)[1]	0.9 (0.8 to NA)[1]	1.8 (1.8 to NA)[1]		2.0 (1.8 to NA)[1]	1.9 (1.8 to NA)[1]	0.9 (NA to NA)[1]	2.8 (NA to NA)[1]	7.5 (1.1 to NA)[1]	1.1 (0.6 to NA)[1]	0.9 (NA to NA)[1]	5.5 (NA to NA)[1]	4.1 (NA to NA)[1]	

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

Progression-free survival (PFS) - SOLID TUMORS

Description	Progression-free survival (PFS) is defined as the time from the date of start of treatment to the date of event defined as the first documented progression or death due to any cause.
Time Frame	From first dose of study treatment to date of death, treatment failure or relapse, up to approximately 5.4 years
Analysis Population Description	Solid tumor participants in the Full Analysis Set (FAS) with an available value for the outcome measure. The FAS comprises all patients who received at least one dose of MAK683.

	10 mg QD	**20 mg QD**	**40 mg QD**	**80 mg QD**	**120 mg QD**	**160 mg QD**	**240 mg QD**	**300 mg QD**	**500 mg QD**	**800 mg QD**	**60 mg BID**	**80 mg BID**	**120 mg BID**	**150 mg BID**	**300 mg BID**	**450 mg BID**
Arm/Group	MAK683 10	MAK683 20	MAK683 40	MAK683 80	MAK683	MAK683	MAK683	MAK683	MAK683	MAK683	MAK683 60	MAK683 80	MAK683	MAK683	MAK683	MAK683

Description	mg orally once daily	mg orally once daily	mg orally once daily	mg orally once daily	120 mg orally once daily	160 mg orally once daily	240 mg orally once daily	300 mg orally once daily	500 mg orally once daily	800 mg orally once daily	mg orally twice daily	mg orally twice daily	120 mg orally twice daily	150 mg orally twice daily	300 mg orally twice daily	450 mg orally twice daily
Number of Participants Analyzed [units: participants]	3	4	2	5	4	5	4	2	17	3	3	6	10	7	29	4
Progression-free survival (PFS) - SOLID TUMORS (units: months)	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**
	1.6 (1.6 to NA)[1]	1.8 (1.7 to NA)[1]	2.7 (1.9 to NA)[1]	3.9 (1.2 to NA)[1]	1.7 (1.7 to NA)[1]	1.9 (1.8 to NA)[1]	1.1 (1.0 to NA)[1]	1.8 (1.7 to NA)[1]	3.6 (1.8 to 7.5)	2.0 (1.8 to NA)[1]	10.5 (7.4 to NA)[1]	1.8 (0.2 to NA)[1]	1.6 (0.8 to NA)[1]	3.7 (1.0 to 5.6)	1.9 (1.7 to 2.1)	1.7 (1.6 to NA)[1]

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

Peak Plasma Concentration (Cmax) of MAK683

Description	The maximum (peak) observed plasma, drug concentration after study drug administration (mass x volume-1)
Time Frame	Cycle 1 day 1 and day 8 and Cycle 2 day 1: Pre-dose, 0.5, 1, 2, 3, 4, 6, 8 hours post-dose. 24 hour post-dose is collected for QD arms and a 12hour post-dose for BID arms.

Analysis Population Description: The pharmacokinetic analysis set (PAS) includes all patients who provide an evaluable PK profile.

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	4	7	3	8	8	5	6	4	15	4	7	9	10	8	26	3
Peak Plasma Concentration (Cmax) of MAK683 (units: ng/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Cycle 1 day 1	70.9 ± 43.30	176 ± 108.00	337 ± 157.00	871 ± 548.00	659 ± 573.00	1380 ± 792.00	1920 ± 1690.00	3310 ± 949.00	3330 ± 2020.00	9470 ± 4250.00	518 ± 221.00	496 ± 411.00	973 ± 645.00	823 ± 514.00	1490 ± 1620	2880 ± 2280.00

Cycle 1 day 8	67.4 ± 43.90	143 ± 87.60	333 ± 118.00	743 ± 516.00	943 ± 643.00	1560 ± 1330.00	1150 ± 861.00	3450 ± 1170.00	3120 ± 1940.00	10500 ± 3820.00	502 ± 224.00	622 ± 402.00	999 ± 579.00	1260 ± 851.00	2200 ± 1900.00	3400 ± 3220.00
Cycle 2 day 1	71.4 ± 12.40	175 ± 54.30	239 ± 147.00	788 ± 355.00	995 ± 558.00	1620 ± 1150.00	1530 ± 755.00	2080 ± 1150.0	2380 ± 1810.00	4890 ± 127.00	669 ± 220.00	691 ± 324.00	575 ± 569.00	1340 ± 807.00	1510 ± 1380.00	

Area Under the Plasma Concentration (AUClast) Time Curve of MAK683

Description	The AUC from time zero to the last measurable concentration sampling time (tlast) (mass x time x volume-1)
Time Frame	Cycle 1 day 1 and day 8 and Cycle 2 day 1: Pre-dose, 0.5, 1, 2, 3, 4, 6, 8 hours post-dose. 24 hour post-dose is collected for QD arms and a 12hour post-dose for BID arms.
Analysis Population Description	The pharmacokinetic analysis set (PAS) includes all patients who provide an evaluable PK profile.

	10 mg QD	**20 mg QD**	**40 mg QD**	**80 mg QD**	**120 mg QD**	**160 mg QD**	**240 mg QD**	**300 mg QD**	**500 mg QD**	**800 mg QD**	**60 mg BID**	**80 mg BID**	**120 mg BID**	**150 mg BID**	**300 mg BID**	**450 mg BID**
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units:	4	7	3	8	8	5	6	4	15	4	7	9	10	8	26	3

participants]																
Area Under the Plasma Concentration (AUClast) Time Curve of MAK683 (units: hours*ng/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Cycle 1 day 1	326 ± 160.00	646 ± 254.00	2000 ± 977.00	3620 ± 1610.00	3700 ± 2670.00	5570 ± 2340.00	10100 ± 7080.00	13300 ± 5720.00	16300 ± 9570.00	52300 ± 33700.00	1520 ± 651.00	1650 ± 1310.00	3040 ± 1990.00	2630 ± 1760.00	4340 ± 4670.00	8720 ± 7370.00
Cycle 1 day 8	362 ± 79.10	583 ± 269.00	2130 ± 1200.00	4700 ± 2260.00	4390 ± 2160.00	6330 ± 3170.00	8440 ± 7270.00	19600 ± 10200.00	19400 ± 11800.00	77400 ± 43700.00	1830 ± 76700	2760 ± 2010.00	4360 ± 2210.00	4080 ± 1910.00	9700 ± 8860.00	20400 ± 20800.00
Cycle 2 day 1	480 ± 102.00	796 ± 188.00	1560 ± 894.00	3900 ± 1190.00	5590 ± 3360.00	7960 ± 4530.00	9870 ± 3680.00	12300 ± 6900.00	14800 ± 10500.00	20200 ± 4690.00	2180 ± 841.00	2370 ± 1070.00	2130 ± 1850.00	3950 ± 1920.00	5200 ± 4050.00	

Area Under the Plasma Concentration (AUCinf) Time Curve of MAK683

Description	The AUC from time zero to infinity (mass x time x volume-1).
Time Frame	Cycle 1 day 1 and day 8 and Cycle 2 day 1: Pre-dose, 0.5, 1, 2, 3, 4, 6, 8 hours post-dose. 24 hour post-dose is collected for QD arms and a 12hour post-dose for BID arms.
Analysis Population Description	Participants in the pharmacokinetic analysis set (PAS) with an available measure for the endpoint. The PAS includes all patients who provide an evaluable PK profile.

	10 mg QD	20 mg QD	40 mg QD	80 mg QD	120 mg QD	160 mg QD	240 mg QD	300 mg QD	500 mg QD	800 mg QD	60 mg BID	80 mg BID	120 mg BID	150 mg BID	300 mg BID	450 mg BID
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	3	6	3	8	7	5	6	4	14	4	6	7	7	8	14	2
Area Under the Plasma Concentration (AUCinf) Time Curve of MAK683 (units: hours*ng/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Cycle 1 day 1	417 ± 79.60	733 ± 184.00	2060 ± 1030.00	3700 ± 1670.00	3280 ± 2450.00	5750 ± 2210.00	10700 ± 7940.00	13600 ± 6030.00	16500 ± 9980.00	53800 ± 35900	1820 ± 708.00	2330 ± 1670.00	4330 ± 2310.00	3760 ± 1700.00	6910 ± 4040.00	15100 ± 4220.00
Cycle 1 day 8	398 ± 62.00	684 ± 144.00	2200 ± 1260	4620 ±	4660 ±	6030 ±	7740 ±	20600 ±	19900 ±	71000 ±	2290 ±	2500 ±	4390 ±	4440 ±	10800 ±	35100 ±

				2160.00	2350.00	3720.00	6420.00	11700.00	12100.00	47000.00	569.00	1190.00	2900.00	2040.00	4380.00	21000.00
Cycle 2 day 1	430 ± 24.80	721 ± 14.10	1640 ± 909.00	4020 ± 1310.00	5710 ± 3490.00	8090 ± 4520.00	10200 ± 4720.00	12600 ± 7150.00	15100 ± 10800.00	20900 ± 5250.00	1330 ± 86.40	3110 ± 923.00	3650	4560	7880 ± 5090.00	

Time to Peak Plasma Concentration (Tmax) of MAK683

Description	The time to reach maximum (peak) plasma drug concentration after study drug administration (time)
Time Frame	Cycle 1 day 1 and day 8 and Cycle 2 day 1: Pre-dose, 0.5, 1, 2, 3, 4, 6, 8 hours post-dose. 24 hour post-dose is collected for QD arms and a 12hour post-dose for BID arms.
Analysis Population Description	The pharmacokinetic analysis set (PAS) includes all patients who provide an evaluable PK profile.

	10 mg QD	**20 mg QD**	**40 mg QD**	**80 mg QD**	**120 mg QD**	**160 mg QD**	**240 mg QD**	**300 mg QD**	**500 mg QD**	**800 mg QD**	**60 mg BID**	**80 mg BID**	**120 mg BID**	**150 mg BID**	**300 mg BID**	**450 mg BID**
Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	4	7	3	8	8	5	6	4	15	4	7	9	10	8	26	3
Time to Peak	**Median**	**Median**	**Median**	**Median**	**Median**	**Median**	**Median**	**Median**	**Median**	**Median**	**Median**	**Median**	**Median**	**Median**	**Median**	**Median**

Plasma Concentration (Tmax) of MAK683 (units: hours)	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**	**(Full Range)**
Cycle 1 day 1	1.07 (0.917 to 7.03)	2.08 (0.5 to 3)	1.05 (0.983 to 3)	1 (0.5 to 3.03)	1.05 (0.567 to 8.05)	1 (0.583 to 2)	3.23 (1 to 6.17)	1 (0.567 to 1.02)	2 (0.983 to 3.85)	1.52 (0.817 to 2.17)	1 (0.617 to 4)	1.08 (0.5 to 4)	1.08 (0.5 to 2.03)	1.82 (0.9 to 2.08)	2.08 (0.5 to 8.02)	1.17 (0.417 to 8.02)
Cycle 1 day 8	1.6 (1 to 5.5)	1.08 (0.467 to 2.02)	2 (2 to 2.03)	0.975 (0.5 to 7)	1 (0.583 to 5.97)	1.08 (0.583 to 1.93)	4.08 (0.5 to 6.08)	2 (0.5 to 2.15)	2.13 (0.75 to 4.05)	1.33 (0.95 to 1.98)	1.05 (0.5 to 2)	2 (0.517 to 3.5)	1.12 (0 to 6)	1.05 (0.4 to 2.8)	1.99 (0 to 7.92)	1.08 (0.5 to 2.92)
cycle 2 day 1	2.15 (2 to 5.45)	1 (0.5 to 7.77)	2.97 (1 to 3)	1.03 (0.5 to 3.03)	2.03 (0.417 to 3)	1.08 (1.08 to 2)	2 (0.583 to 3.93)	2.07 (1.03 to 3.92)	1.98 (0.833 to 3.83)	0.867 (0.583 to 1.15)	1 (0 to 2.03)	1.18 (0.833 to 4)	1.95 (1.12 to 2.98)	1.07 (0.4 to 2)	2.08 (0 to 6.05)	

Change from baseline H3K27 tri methylation level in PBMC

Description	Best percent change from baseline for H3K12 trimethylation in peripheral blood mononuclear cell (PBMC). Where "Best percent change from baseline" is defined as maximum reduction from baseline at any on-treatment time point. Different cell populations were evaluated
Time Frame	Cycle 1 Day 1,8 and 15, Cycle 2 Day 1, Cycle 3 Day 1
Analysis Population Description	Participants in the Full Analysis Set (FAS) with >300mg QD and all BID doses with an available value for the outcome measure at baseline and postbaseline. The FAS comprises all patients who received at least one dose of MAK683.

	500 mg QD	**800 mg QD**	**60 mg BID**	**80 mg BID**	**120 mg BID**	**150 mg BID**	**300 mg BID**	**450 mg BID**
Arm/Group Description	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	sdb	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily

Number of Participants Analyzed [units: participants]	8	3	2	3	4	6	16	2
Change from baseline H3K27 tri methylation level in PBMC (units: Percent change in H3K27 trimethylation)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
CD19+ population	-57.6 ± 29.36	-58 ± 22.27	-88.6 ± 3.68	-38	-63.9 ± 23.33	-66.1 ± 22.84	-46.1 ± 25.08	-16.3
CD3+ population	-61.5 ± 37.42	-34.4	-31.9	-88.7	-44 ± 46.46	-26.8 ± 24.28	-50.4 ± 28.50	
HLADR+CD14+ population	-87 ± 9.35	-80.9 ± 27.22	-78.3 ± 2.19	-89.8 ± 16.43	-84.4 ± 10.67	-77.7 ± 24.19	-79.7 ± 17.69	-84.3 ± 13.15

Other Pre-Specified Outcome Result(s)

No data identified.

Post-Hoc Outcome Result(s)

All collected deaths

Description	On-treatment deaths were collected from first dose of study treatment to 30 days after last dose. Post- treatment and disease progression FU deaths were collected from 31 days after last dose until end of study. All deaths refer to the sum of pre-treatment deaths, on-treatment, post-treatment safety FU deaths, and disease progression FU deaths.
Time Frame	On-treatment deaths: up to approximately 5.4 years. Post-treatment safety FU and disease progression FU deaths: up to 5.4 years
Analysis Population Description	The Safety Set (SS) comprises all patients who received at least one dose of MAK683.

10 mg QD	**20 mg QD**	**40 mg QD**	**80 mg QD**	**120 mg QD**	**160 mg QD**	**240 mg QD**	**300 mg QD**	**500 mg QD**	**800 mg QD**	**60 mg BID**	**80 mg BID**	**120 mg BID**	**150 mg BID**	**300 mg BID**	**450 mg BID**

Arm/Group Description	MAK683 10 mg orally once daily	MAK683 20 mg orally once daily	MAK683 40 mg orally once daily	MAK683 80 mg orally once daily	MAK683 120 mg orally once daily	MAK683 160 mg orally once daily	MAK683 240 mg orally once daily	MAK683 300 mg orally once daily	MAK683 500 mg orally once daily	MAK683 800 mg orally once daily	MAK683 60 mg orally twice daily	MAK683 80 mg orally twice daily	MAK683 120 mg orally twice daily	MAK683 150 mg orally twice daily	MAK683 300 mg orally twice daily	MAK683 450 mg orally twice daily
Number of Participants Analyzed [units: participants]	4	7	3	8	8	5	6	4	18	4	8	11	11	8	30	4
All collected deaths (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
On treatment deaths	0 (%)	1 (14.29 %)	0 (%)	0 (%)	0 (%)	0 (%)	3 (50%)	0 (%)	1 (5.56%)	0 (%)	0 (%)	3 (27.27 %)	1 (9.09%)	1 (12.5%)	2 (6.67%)	0 (%)
Post-treatment death	3 (75%)	1 (14.29 %)	0 (%)	1 (12.5%)	2 (25%)	0 (%)	0 (%)	1 (25%)	1 (5.56%)	0 (%)	1 (12.5%)	3 (27.27 %)	2 (18.18 %)	1 (12.5%)	7 (23.33 %)	2 (50%)
Total deaths	3 (75%)	2 (28.57 %)	0 (%)	1 (12.5%)	2 (25%)	0 (%)	3 (50%)	1 (25%)	2 (11.11 %)	0 (%)	1 (12.5%)	6 (54.55 %)	3 (27.27 %)	2 (25%)	9 (30%)	2 (50%)

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Safety Results

Time Frame	On treatment Adverse events and deaths : from first dose of study treatment until 30 days after last treatment up to maximum duration of 5.4 years
Source Vocabulary for Table Default	MedDRA (27.1)
Collection Approach for Table Default	Systematic Assessment

All-Cause Mortality

	Phase I 10 mg QD fasted N = 4	**Phase I 20 mg QD fasted N = 7**	**Phase I 40 mg QD fasted N = 3**	**Phase I 80 mg QD fasted N = 8**	**Phase I 120 mg QD fasted N = 8**	**Phase I 160 mg QD fasted N = 5**	**Phase I 240 mg QD fasted N = 6**	**Phase I 300 mg QD fasted N = 4**	**Phase I 500 mg QD fasted N = 18**	**Phase I 800 mg QD fasted N = 4**	**Phase I 60 mg BID fasted N = 8**	**Phase I 80 mg BID fasted N = 11**	**Phase I 120 mg BID fasted N = 11**	**Phase I 150 mg BID fasted N = 8**	**Phase I 300 mg BID fasted N = 30**	**Phase I 450 mg BID fasted N = 4**
Arm/Group Description	Phase I 10 mg QD fasted	Phase I 20 mg QD fasted	Phase I 40 mg QD fasted	Phase I 80 mg QD fasted	Phase I 120 mg QD fasted	Phase I 160 mg QD fasted	Phase I 240 mg QD fasted	Phase I 300 mg QD fasted	Phase I 500 mg QD fasted	Phase I 800 mg QD fasted	Phase I 60 mg BID fasted	Phase I 80 mg BID fasted	Phase I 120 mg BID fasted	Phase I 150 mg BID fasted	Phase I 300 mg BID fasted	Phase I 450 mg BID fasted
Total Number Affected	0	1	0	0	0	0	3	0	1	0	0	3	1	1	2	0
Total Number At Risk	4	7	3	8	8	5	6	4	18	4	8	11	11	8	30	4

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Serious Adverse Events

Time Frame	On treatment Adverse events and deaths : from first dose of study treatment until 30 days after last treatment up to maximum duration of 5.4 years
Source Vocabulary for Table Default	MedDRA (27.1)
Collection Approach for Table Default	Systematic Assessment

	Phase I 10 mg QD fasted N = 4	**Phase I 20 mg QD fasted N = 7**	**Phase I 40 mg QD fasted N = 3**	**Phase I 80 mg QD fasted N = 8**	**Phase I 120 mg QD fasted N = 8**	**Phase I 160 mg QD fasted N = 5**	**Phase I 240 mg QD fasted N = 6**	**Phase I 300 mg QD fasted N = 4**	**Phase I 500 mg QD fasted N = 18**	**Phase I 800 mg QD fasted N = 4**	**Phase I 60 mg BID fasted N = 8**	**Phase I 80 mg BID fasted N = 11**	**Phase I 120 mg BID fasted N = 11**	**Phase I 150 mg BID fasted N = 8**	**Phase I 300 mg BID fasted N = 30**	**Phase I 450 mg BID fasted N = 4**
Arm/Group Description	Phase I 10 mg QD fasted	Phase I 20 mg QD fasted	Phase I 40 mg QD fasted	Phase I 80 mg QD fasted	Phase I 120 mg QD fasted	Phase I 160 mg QD fasted	Phase I 240 mg QD fasted	Phase I 300 mg QD fasted	Phase I 500 mg QD fasted	Phase I 800 mg QD fasted	Phase I 60 mg BID fasted	Phase I 80 mg BID fasted	Phase I 120 mg BID fasted	Phase I 150 mg BID fasted	Phase I 300 mg BID fasted	Phase I 450 mg BID fasted
Total # Affected by any Serious	2	3	1	4	3	3	4	2	6	2	4	8	6	2	15	3

Adverse Event																
Total # at Risk by any Serious Adverse Event	4	7	3	8	8	5	6	4	18	4	8	11	11	8	30	4
Blood and lymphatic system disorders																
Anaemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	1 (25. 00%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	2 (50. 00%)
Febrile neutropenia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	2 (6.6 7%)	0 (0.0 0%)
Neutropenia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	1 (25. 00%)
Thrombocytopenia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	1 (12. 50%)	2 (18. 18%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)
Cardiac disorders																
Left ventricular dysfunction	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Gastrointestinal disorders																
Abdominal pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Abdominal pain upper	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)

Ascites	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	2 (6.6 7%)	0 (0.0 0%)
Colitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Dysphagia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Ileus	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Intestinal obstruction	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Nausea	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)
Obstruction gastric	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Oesophageal stenosis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Pancreatitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Small intestinal obstruction	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Upper gastrointestinal haemorrhage	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Vomiting	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
General disorders and																

administration site conditions																
Condition aggravated	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Fatigue	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
General physical health deterioration	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)
Multiple organ dysfunction syndrome	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Pyrexia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (25. 00%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Hepatobiliary disorders																
Cholestasis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Infections and infestations																
COVID-19	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Pneumocystis jirovecii pneumonia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)

Pneumonia	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (12. 50%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	2 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)
Pneumonia mycoplasmal	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Pneumonia pneumococcal	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Postoperative wound infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Respiratory tract infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Salmonella bacteraemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Sepsis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Septic shock	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Sinusitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Staphylococcal bacteraemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Suspected COVID-19	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)

Urinary tract infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Injury, poisoning and procedural complications																
Clavicle fracture	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Vascular access complication	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Investigations																
Alanine aminotransferase increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Neutrophil count decreased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Platelet count decreased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)
Red blood cell morphology abnormal	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)
Metabolism and																

nutrition disorders																
Dehydration	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Hyponatraemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Musculoskeletal and connective tissue disorders																
Back pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Bone pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)																
Cancer pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Leukaemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Lymphangiosis carcinomatosa	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Malignant neoplasm progression	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)

Malignant pleural effusion	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Metastatic neoplasm	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Tumour associated fever	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Tumour pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Nervous system disorders																
Bell's palsy	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Cerebrovascular accident	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Presyncope	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Spinal cord compression	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Psychiatric disorders																
Confusional state	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Renal and urinary disorders																
Acute kidney injury	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)

Haematuria	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Hydronephrosis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Renal failure	0 (0.0 0%)	0 (0.0 0%)	1 (33. 33%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Respiratory, thoracic and mediastinal disorders																
Acute respiratory failure	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Epistaxis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Haemoptysis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Pleural effusion	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	1 (9.0 9%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Pulmonary embolism	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)
Respiratory failure	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)
Vascular disorders																
Arterial haemorrhage	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.3 3%)	0 (0.0 0%)

NOVARTIS

Other (Not Including Serious) Adverse Events

Time Frame	On treatment Adverse events and deaths : from first dose of study treatment until 30 days after last treatment up to maximum duration of 5.4 years
Source Vocabulary for Table Default	MedDRA (27.1)
Collection Approach for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

	Phase I 10 mg QD fasted N = 4	**Phase I 20 mg QD fasted N = 7**	**Phase I 40 mg QD fasted N = 3**	**Phase I 80 mg QD fasted N = 8**	**Phase I 120 mg QD fasted N = 8**	**Phase I 160 mg QD fasted N = 5**	**Phase I 240 mg QD fasted N = 6**	**Phase I 300 mg QD fasted N = 4**	**Phase I 500 mg QD fasted N = 18**	**Phase I 800 mg QD fasted N = 4**	**Phase I 60 mg BID fasted N = 8**	**Phase I 80 mg BID fasted N = 11**	**Phase I 120 mg BID fasted N = 11**	**Phase I 150 mg BID fasted N = 8**	**Phase I 300 mg BID fasted N = 30**	**Phase I 450 mg BID fasted N = 4**
Arm/Group Description	Phase I 10 mg QD fasted	Phase I 20 mg QD fasted	Phase I 40 mg QD fasted	Phase I 80 mg QD fasted	Phase I 120 mg QD fasted	Phase I 160 mg QD fasted	Phase I 240 mg QD fasted	Phase I 300 mg QD fasted	Phase I 500 mg QD fasted	Phase I 800 mg QD fasted	Phase I 60 mg BID fasted	Phase I 80 mg BID fasted	Phase I 120 mg BID fasted	Phase I 150 mg BID fasted	Phase I 300 mg BID fasted	Phase I 450 mg BID fasted
Total # Affected by any Other	4	6	3	8	8	5	6	4	18	4	8	11	11	8	29	4

Adverse Event																
Total # at Risk by any Other Adverse Event	4	7	3	8	8	5	6	4	18	4	8	11	11	8	30	4
Blood and lymphatic system disorders																
Anaemia	1 (25.00%)	2 (28.57%)	1 (33.33%)	1 (12.50%)	2 (25.00%)	1 (20.00%)	1 (16.67%)	2 (50.00%)	6 (33.33%)	3 (75.00%)	1 (12.50%)	3 (27.27%)	4 (36.36%)	0 (0.0 0%)	15 (50.00%)	3 (75.00%)
Iron deficiency anaemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Leukopenia	0 (0.0 0%)	1 (14.29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25.00%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	2 (50.00%)
Lymphopenia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	2 (25.00%)	3 (27.27%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (25.00%)
Neutropenia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	3 (75.00%)	2 (11.11%)	2 (50.00%)	4 (50.00%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	6 (20.0 0%)	3 (75.00%)
Thrombocytopenia	0 (0.0 0%)	1 (14.29%)	1 (33.33%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	1 (16.67%)	2 (50.00%)	3 (16.67%)	2 (50.00%)	5 (62.50%)	1 (9.0 9%)	3 (27.27%)	1 (12.50%)	6 (20.0 0%)	2 (50.00%)
Cardiac disorders																
Mitral valve thickening	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Pericardial effusion	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Sinus bradycardia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (25.00%)
Supraventricular	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)

extrasystoles																
Tachycardia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	1 (25. 00%)
Tricuspid valve disease	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Ear and labyrinth disorders																
Ear pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
External ear inflammation	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
Hypoacusis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Middle ear effusion	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Vertigo	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Endocrine disorders																
Adrenal insufficiency	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
Hypopituitarism	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hypothyroidism	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Eye disorders																

Blepharitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
Dry eye	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Eye oedema	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Glaucoma	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Papilloedema	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Periorbital oedema	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Retinopathy	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Uveitis	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Vision blurred	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Gastrointestinal disorders																
Abdominal discomfort	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Abdominal distension	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (6.67 %)	0 (0.0 0%)
Abdominal pain	0 (0.0 0%)	2 (28. 57%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	2 (40. 00%)	2 (33. 33%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	1 (12. 50%)	1 (9.0 9%)	2 (18. 18%)	0 (0.0 0%)	3 (10.0 0%)	0 (0.0 0%)
Abdominal pain upper	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	1 (25. 00%)	0 (0.0 0%)	1 (9.0 9%)	1 (9.0 9%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Abdominal rigidity	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Angular cheilitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)

Ascites	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Constipatio n	1 (25. 00%)	2 (28. 57%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	2 (33. 33%)	0 (0.0 0%)	4 (22. 22%)	1 (25. 00%)	0 (0.0 0%)	1 (9.0 9%)	2 (18. 18%)	0 (0.0 0%)	4 (13.3 3%)	1 (25. 00%)
Dental caries	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Dental discomfort	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Diarrhoea	1 (25. 00%)	2 (28. 57%)	0 (0.0 0%)	1 (12. 50%)	1 (12. 50%)	1 (20. 00%)	1 (16. 67%)	1 (25. 00%)	4 (22. 22%)	3 (75. 00%)	3 (37. 50%)	2 (18. 18%)	2 (18. 18%)	3 (37. 50%)	12 (40. 00%)	1 (25. 00%)
Dry mouth	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Dyspepsia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Dysphagia	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	2 (25. 00%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Gastric ulcer	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Gastrooeso phageal reflux disease	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	1 (9.0 9%)	0 (0.0 0%)	3 (10.0 0%)	0 (0.0 0%)
Gingival bleeding	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Haemorrhoi ds	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Ileus	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (25. 00%)
Inguinal hernia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Intestinal stenosis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (25. 00%)

Nausea	1 (25.00%)	3 (42.86%)	0 (0.0 0%)	1 (12.50%)	1 (12.50%)	3 (60.00%)	3 (50.00%)	0 (0.0 0%)	8 (44.44%)	3 (75.00%)	1 (12.50%)	2 (18.18%)	3 (27.27%)	3 (37.50%)	11 (36.67%)	2 (50.00%)
Odynophagia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25.00%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Oesophagitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.56%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Rectal haemorrhage	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Stomatitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09%)	1 (9.09%)	0 (0.0 0%)	1 (3.33 %)	1 (25.00%)
Tooth loss	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.00 %)	0 (0.0 0%)
Toothache	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	1 (25.00%)
Vomiting	2 (50.00%)	2 (28.57%)	0 (0.0 0%)	1 (12.50%)	2 (25.00%)	1 (20.00%)	2 (33.33%)	1 (25.00%)	7 (38.89%)	2 (50.00%)	1 (12.50%)	3 (27.27%)	2 (18.18%)	0 (0.0 0%)	10 (33.33%)	1 (25.00%)
General disorders and administration site conditions																
Asthenia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	2 (33.33%)	1 (25.00%)	2 (11.11%)	0 (0.0 0%)	2 (25.00%)	2 (18.18%)	2 (18.18%)	2 (25.00%)	4 (13.33%)	1 (25.00%)
Chills	0 (0.0 0%)	1 (14.29%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Chronic fatigue syndrome	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.56%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Early satiety	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.56%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)

Face oedema	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Facial pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Fatigue	3 (75. 00%)	2 (28. 57%)	1 (33. 33%)	2 (25. 00%)	2 (25. 00%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	2 (11. 11%)	2 (50. 00%)	1 (12. 50%)	1 (9.0 9%)	4 (36. 36%)	0 (0.0 0%)	5 (16.6 7%)	1 (25. 00%)
Gait disturbance	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
General physical health deterioration	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (25. 00%)
Hyperthermia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Influenza like illness	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
Localised oedema	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Malaise	1 (25. 00%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
Mucosal inflammation	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	1 (25. 00%)
Non-cardiac chest pain	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Oedema	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Oedema peripheral	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (18. 18%)	1 (9.0 9%)	0 (0.0 0%)	3 (10.0 0%)	1 (25. 00%)
Pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (3.33 %)	0 (0.0 0%)

Peripheral swelling	1 (25.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Pyrexia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (25.00%)	0 (0.0 0%)	0 (0.0 0%)	1 (25.00%)	4 (22.22%)	0 (0.0 0%)	3 (37.50%)	3 (27.27%)	3 (27.27%)	4 (50.00%)	5 (16.67%)	1 (25.00%)
Supraclavicular fossa pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Swelling	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Swelling face	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Temperature regulation disorder	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Xerosis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16.67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hepatobiliary disorders																
Cholestasis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hepatic cytolysis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hepatic vein thrombosis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hyperbilirubinaemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Jaundice	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Immune system disorders																

Hypersensitivity	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Infections and infestations																
Abdominal infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Bronchitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (6.67 %)	0 (0.0 0%)
Bronchitis viral	0 (0.0 0%)	0 (0.0 0%)	1 (33. 33%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Candida infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Cellulitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
COVID-19	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (11. 11%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (9.0 9%)	1 (12. 50%)	1 (3.33 %)	0 (0.0 0%)
Ear infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Folliculitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
Gastroenteritis viral	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Gingivitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Herpes ophthalmic	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Influenza	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Lower respiratory tract infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)

Lower respiratory tract infection bacterial	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Nasopharyngitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
Oral candidiasis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Oral fungal infection	0 (0.0 0%)	0 (0.0 0%)	1 (33. 33%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Oral viral infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Periodontitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Peritonsillar abscess	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Pharyngitis	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Pneumocystis jirovecii pneumonia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Pneumonia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Respiratory tract infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (3.33 %)	0 (0.0 0%)
Respiratory tract infection viral	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Septic shock	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)

Sinusitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Soft tissue infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Tooth infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Upper respiratory tract infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (6.67 %)	0 (0.0 0%)
Urinary tract infection	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Viral upper respiratory tract infection	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Injury, poisoning and procedural complications																
Clavicle fracture	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Contusion	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Eye contusion	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Fall	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Post procedural haematoma	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)

Procedural pain	0 (0.0 0%)	0 (0.0 0%)	1 (33. 33%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Radiation skin injury	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Skin laceration	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Transfusion reaction	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Vascular access complicatio n	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Investigation s																
Alanine aminotransf erase increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	1 (12. 50%)	0 (0.0 0%)	1 (9.0 9%)	1 (12. 50%)	3 (10.0 0%)	0 (0.0 0%)
Amylase increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Aspartate aminotransf erase increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	1 (12. 50%)	0 (0.0 0%)	2 (18. 18%)	2 (25. 00%)	4 (13.3 3%)	0 (0.0 0%)
Blood albumin decreased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	2 (6.67 %)	0 (0.0 0%)
Blood alkaline phosphatas e increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	1 (25. 00%)	0 (0.0 0%)	1 (9.0 9%)	1 (9.0 9%)	1 (12. 50%)	4 (13.3 3%)	1 (25. 00%)
Blood bilirubin increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	1 (12. 50%)	1 (3.33 %)	0 (0.0 0%)

Blood calcium decreased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Blood creatine increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Blood creatine phosphokinase increased	0 (0.0 0%)	0 (0.0 0%)	1 (33. 33%)	1 (12. 50%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	1 (3.33 %)	1 (25. 00%)
Blood creatinine increased	1 (25. 00%)	0 (0.0 0%)	1 (33. 33%)	2 (25. 00%)	2 (25. 00%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	2 (11. 11%)	2 (50. 00%)	0 (0.0 0%)	2 (18. 18%)	2 (18. 18%)	1 (12. 50%)	3 (10.0 0%)	0 (0.0 0%)
Blood lactate dehydrogenase increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Blood magnesium decreased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Blood phosphorus decreased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Blood sodium increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Blood uric acid increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
C-reactive protein increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (25. 00%)

Electrocardiogram QT prolonged	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Gamma-glutamyltransferase increased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	1 (12. 50%)	6 (20.0 0%)	1 (25. 00%)
Hepatic enzyme abnormal	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Lipase increased	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (40. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	3 (10.0 0%)	0 (0.0 0%)
Lymphocyte count decreased	0 (0.0 0%)	1 (14. 29%)	1 (33. 33%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (11. 11%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	2 (18. 18%)	1 (12. 50%)	3 (10.0 0%)	0 (0.0 0%)
Neutrophil count decreased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (12. 50%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	3 (16. 67%)	1 (25. 00%)	2 (25. 00%)	0 (0.0 0%)	1 (9.0 9%)	1 (12. 50%)	2 (6.67 %)	1 (25. 00%)
Platelet count decreased	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	2 (50. 00%)	0 (0.0 0%)	3 (27. 27%)	0 (0.0 0%)	4 (50. 00%)	5 (16.6 7%)	2 (50. 00%)
Protein total decreased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
SARS-CoV-2 test negative	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	2 (25. 00%)	0 (0.00 %)	1 (25. 00%)
SARS-CoV-2 test positive	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Vitamin D decreased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Weight decreased	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (12. 50%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (11. 11%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	5 (16.6 7%)	1 (25. 00%)

White blood cell count decreased	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	4 (22. 22%)	1 (25. 00%)	1 (12. 50%)	1 (9.0 9%)	2 (18. 18%)	1 (12. 50%)	5 (16.6 7%)	1 (25. 00%)
Metabolism and nutrition disorders																
Cell death	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Decreased appetite	2 (50. 00%)	4 (57. 14%)	0 (0.0 0%)	3 (37. 50%)	0 (0.0 0%)	2 (40. 00%)	2 (33. 33%)	0 (0.0 0%)	2 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	2 (18. 18%)	4 (36. 36%)	1 (12. 50%)	9 (30.0 0%)	2 (50. 00%)
Dehydration	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	3 (27. 27%)	0 (0.0 0%)	2 (6.67 %)	1 (25. 00%)
Fluid retention	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Hyperamylasaemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hypercalcaemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Hypercholesterolaemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Hyperglycaemia	0 (0.0 0%)	0 (0.0 0%)	1 (33. 33%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Hyperkalaemia	0 (0.0 0%)	0 (0.0 0%)	1 (33. 33%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hypernatraemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hypoalbuminaemia	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	1 (25. 00%)
Hypocalcaemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (6.67 %)	0 (0.0 0%)
Hypochloraemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)

Hypoglycaemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hypokalaemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	3 (27. 27%)	2 (25. 00%)	6 (20.0 0%)	0 (0.0 0%)
Hypomagnesaemia	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	1 (12. 50%)	1 (9.0 9%)	1 (9.0 9%)	3 (37. 50%)	3 (10.0 0%)	0 (0.0 0%)
Hyponatraemia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	2 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	1 (12. 50%)	2 (6.67 %)	0 (0.0 0%)
Hypophosphataemia	0 (0.0 0%)	1 (14. 29%)	1 (33. 33%)	2 (25. 00%)	1 (12. 50%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	1 (5.5 6%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (25. 00%)	3 (10.0 0%)	0 (0.0 0%)
Vitamin D deficiency	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Musculoskeletal and connective tissue disorders																
Arthralgia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Back pain	2 (50. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	1 (16. 67%)	1 (25. 00%)	4 (22. 22%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	2 (6.67 %)	0 (0.0 0%)
Bone pain	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Groin pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Muscle spasms	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Muscular weakness	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Musculoskeletal chest pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)

Myalgia	0 (0.0 0%)	0 (0.0 0%)	1 (33. 33%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Neck pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Pain in extremity	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	1 (12. 50%)	1 (9.0 9%)	1 (9.0 9%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Spinal pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Synovitis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Temporomandibular pain and dysfunction syndrome	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)																
Cancer pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Tumour associated fever	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Tumour haemorrhage	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Tumour pain	0 (0.0 0%)	1 (14. 29%)	1 (33. 33%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	3 (27. 27%)	1 (9.0 9%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
Nervous system disorders																

Bell's palsy	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Dizziness	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	1 (25. 00%)
Drooling	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Dysgeusia	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	2 (6.67 %)	1 (25. 00%)
Febrile convulsion	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Headache	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	1 (12. 50%)	1 (9.0 9%)	2 (18. 18%)	0 (0.0 0%)	2 (6.67 %)	0 (0.0 0%)
Myoclonus	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Neuralgia	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Neuropathy peripheral	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	3 (16. 67%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Peripheral motor neuropathy	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Presyncope	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Sciatica	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Somnolence	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
Taste disorder	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	1 (25. 00%)
Transient ischaemic attack	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)

VIth nerve paralysis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Psychiatric disorders																
Anxiety	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
Depression	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Depressive symptom	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Fear of eating	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Insomnia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (25. 00%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	2 (18. 18%)	0 (0.0 0%)	1 (12. 50%)	1 (3.33 %)	0 (0.0 0%)
Renal and urinary disorders																
Acute kidney injury	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	3 (10.0 0%)	0 (0.0 0%)
Haematuria	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	2 (40. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Nocturia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)
Pollakiuria	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Renal failure	0 (0.0 0%)	0 (0.0 0%)	1 (33. 33%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Renal impairment	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Urine flow decreased	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)

Reproductive system and breast disorders																
Amenorrhoea	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Pelvic pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Penile oedema	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Vaginal haemorrhage	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Respiratory, thoracic and mediastinal disorders																
Acute respiratory failure	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Aspiration	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Cough	1 (25. 00%)	2 (28. 57%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	5 (27. 78%)	0 (0.0 0%)	3 (37. 50%)	0 (0.0 0%)	1 (9.0 9%)	1 (12. 50%)	3 (10.0 0%)	0 (0.0 0%)
Dysphonia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Dyspnoea	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (12. 50%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	1 (9.0 9%)	1 (12. 50%)	2 (6.67 %)	0 (0.0 0%)
Epistaxis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	1 (9.0 9%)	0 (0.0 0%)	2 (6.67 %)	0 (0.0 0%)
Haemoptysis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)

Hiccups	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hypoxia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (25. 00%)
Lung infiltration	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Nasal congestion	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Oropharyng eal pain	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Pleural effusion	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	2 (18. 18%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Pneumoniti s	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Productive cough	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Pulmonary embolism	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (6.67 %)	0 (0.0 0%)
Pulmonary tumour thrombotic microangio pathy	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Respiratory failure	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Rhinorrhoe a	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Wheezing	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Skin and subcutaneou s tissue disorders																

Alopecia	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (11. 11%)	2 (50. 00%)	0 (0.0 0%)	0 (0.0 0%)	3 (27. 27%)	0 (0.0 0%)	3 (10.0 0%)	1 (25. 00%)
Dermatitis allergic	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Dry skin	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (6.67 %)	0 (0.0 0%)
Eczema	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Erythema	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hyperhidrosis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Night sweats	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	1 (3.33 %)	0 (0.0 0%)
Palmar-plantar erythrodysaesthesia syndrome	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Petechiae	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Prurigo	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Pruritus	0 (0.0 0%)	0 (0.0 0%)	1 (33. 33%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	2 (6.67 %)	1 (25. 00%)
Rash	1 (25. 00%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	6 (33. 33%)	1 (25. 00%)	2 (25. 00%)	0 (0.0 0%)	3 (27. 27%)	1 (12. 50%)	3 (10.0 0%)	0 (0.0 0%)
Rash maculo-papular	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Rash papular	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)

Rash pruritic	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Skin erosion	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Skin exfoliation	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Vascular disorders																
Flushing	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hypertension	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Hypotension	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Pallor	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.0 9%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Peripheral coldness	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (5.5 6%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Subclavian vein thrombosis	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)
Venous thrombosis limb	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)

Other Relevant Findings

N/A

Conclusion:

MAK683 single agent was found to be safe and tolerable. The recommended phase 2 dose (RP2D) of MAK683 was determined to be 300 mg BID. Considering that Embryonic ectoderm development (EED) is required for the basic activity of Polycomb Repressive Complex 2 (PRC2) and that the binding of lysine 27 on histone H3 (H3K27) with the EED can potentiate PRC2 activity, EED inhibition, which results in simultaneous targeting of Enhancer of zeste homolog 2 (EZH2) and disablement of PRC2 activity, remains a possible strategy for treatment in DLBCL and ES.

Date of Clinical Trial Report

08 July 2025