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Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Spartalizumab/PDR001 in combination with:
CJM112,
Nazartinib/EGF816,
canakinumab/ACZ885 and
trametinib/TMT212

Trial Indication(s)

Triple Negative Breast Cancer (TNBC),
Non-Small Cell Lung Cancer (NSCLC),
Colorectal Cancer (CRC)

Protocol Number

CPDR001X2103

Protocol Title

Phase Ib, open-label, multi-center study to characterize the safety, tolerability and pharmacodynamics (PD) of PDR001 in combination with CJM112, EGF816, Ilaris® (canakinumab) or Mekinist® (trametinib)

Clinical Trial Phase

Phase 1

Phase of Drug Development

Ib

Study Start/End Dates

Study Start Date: August 2016 (Actual)
Primary Completion Date: March 2021 (Actual)
Study Completion Date: March 2021 (Actual)

Reason for Termination (If applicable)

NA

Study Design/Methodology

This was a Phase Ib, multi-center, open-label study, to characterize the safety, tolerability, PK, PD and antitumor activity of PDR001 in combination with canakinumab, CJM112, trametinib and EGF816 and s.a. canakinumab in subjects with TNBC, NSCLC and CRC. The study comprised a dose escalation part for combination treatments only, followed by a dose expansion part.

Centers

23 centers in 9 countries: Belgium(2), Canada(2), United States(4), Singapore(2), Spain(4), France(4), Israel(1), Taiwan(2), Italy(2)

Objectives:

To characterize the safety and tolerability of PDR001 in combination with canakinumab, CJM112, trametinib or EGF816, and of single-agent canakinumab

and to identify recommended doses and schedules for future studies.

To characterize changes in the immune infiltrate in tumors.

To further characterize the safety of PDR001 in combination with canakinumab, CJM112, trametinib or EGF816 and of single-agent canakinumab

To estimate the anti-tumor activity of PDR001 in combination with canakinumab, CJM112, trametinib or EGF816, and of single-agent canakinumab

To characterize the pharmacokinetics of all study drugs in combination, and of single-agent canakinumab

To assess immunogenicity of PDR001, canakinumab and CJM112.

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

Canakinumab 100 mg liquid in vial for subcutaneous (s.c.) administration - Once every 8 weeks

CJM112 150 mg liquid in vial intravenous (i.v.) administration - Once every 4 weeks (The starting dose for alternative Q2W schedule maintained the same highest total cycle dose assessed to be safe on the Q4W schedule.)

PDR001 100 mg powder for solution for i.v. infusion - Once every 4 weeks

EGF816 25 mg tablet for oral administration - Dosing on Day 1 to Day 10 of Cycle 1, then stop. (The starting dose for longer duration schedules (Cycles 1-3 and Cycles 1-6) was the highest dose assessed to be safe on the Cycle 1 schedule.)

Trametinib 0.5 mg tablet for oral administration - Once daily

Statistical Methods

Four adaptive Bayesian logistic regression model (BLRM) guided by Escalation With Overdose Control (EWOC) principle were used to make dose recommendations and estimate the Maximum Tolerated Dose (MTD)(s)/ Recommended Dose for Expansion (RDE)(s) during the dose escalation parts of the study for PDR001 in combination with canakinumab, PDR001 in combination with CJM112, PDR001 in combination with trametinib and PDR001 in combination with EGF816.

In the dose escalation part, each of the dose-toxicity (DLT) relationship of PDR001 in combination with canakinumab, PDR001 in combination with CJM112, PDR001 in combination with trametinib or PDR001 in combination with EGF816 was described by a 5 parameter BLRM that comprised single agent dose-DLT relationship parts, which allowed the incorporation of historical single agent toxicity data and an interaction part.

A secondary objective was to assess the preliminary anti-tumor activity of PDR001 in combination with canakinumab, CJM112, trametinib or EGF816 and of Single agent (s.a.) canakinumab based on investigator assessment of overall lesion response according to Response Evaluation Criteria In Solid Tumors (RECIST) v1.1 and irRC. Overall response rate (ORR), best overall response (BOR) and disease control rate (DCR) were summarized by number and percent of subjects and the corresponding 95% CI were calculated using Clopper-Pearson method. Progression free survival (PFS) and treatment free survival (TFS) were analyzed using Kaplan-Meier estimates for each treatment group/disease group at Recommended Dose for Expansion (RDE).

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:
- Patients with advanced/metastatic cancer, with measurable disease as determined by RECIST version 1.1, who have progressed despite standard therapy or are intolerant to standard therapy, and for whom no effective therapy is available.

Patients must fit into one of the following groups:
- Colorectal cancer (CRC) (not mismatch repair deficient by local assay including PCR and/or immunohistochemistry)
-Non-small cell lung cancer (NSCLC) (adenocarcinoma)
-Triple Negative Breast Cancer (TNBC) (D
-ECOG Performance Status ≤ 2
-Patient must have a site of disease amenable to biopsy, and be a candidate for tumor biopsy according to the treating institution's guidelines. Patient must be willing to undergo a new tumor biopsy at baseline, and again during therapy on this study.

-Prior therapy with PD-1/PDL-1 inhibitors is allowed provided any toxicity attributed to prior PD-1- or PD-L1-directed therapy did not lead to discontinuation of therapy.
-Written informed consent must be obtained prior to any screening procedures other than procedures performed as part of standard of care.

Exclusion Criteria:
- Presence of symptomatic central nervous system (CNS) metastases, or CNS metastases that require local CNS-directed therapy, or increasing doses of corticosteroids within the prior 2 weeks.
- History of severe hypersensitivity reactions to other monoclonal antibodies.
- Out of range laboratory values for measures of hepatic and renal function, electrolytes and blood counts
- Impaired cardiac function or clinically significant cardiac disease.
- Patients with active, known or suspected autoimmune disease.
- Human Immunodeficiency Virus infection at screening.
- Escalation part: Active Hepatitis B (HBV) or Hepatitis C (HCV) virus infection at screening.
Expansion part: Patients with active HBV or HCV are excluded, excepting those patients undergoing treatment for HBV or HCV.
- Malignant disease, other than that being treated in this study.
- Recent systemic anti-cancer therapy
- Active infection requiring systemic antibiotic therapy.
- Patients requiring chronic treatment with systemic steroid therapy, other than replacement dose steroids in the setting of adrenal insufficiency or treatment with low, stable dose of
steroid (<10mg/ day prednisone or equivalent) for stable CNS metastatic disease.
- Patients receiving systemic treatment with any immunosuppressive medication, excepting the above
- Use of any live vaccines against infectious diseases (e.g. influenza, varicella, pneumococcus) within 4 weeks of initiation of study treatment.
- Participation in an interventional, investigational study within 2 weeks of the first dose of study treatment.
- Presence of ≥ CTCAE grade 2 toxicity (except alopecia and ototoxicity, which are excluded if ≥ CTCAE grade 3) due to prior cancer therapy.
- Recent use of hematopoietic colony-stimulating growth factors (e.g. G-CSF, GMCSF, M-CSF)

Additional exclusion criteria for Combination arm PDR001+canakinumab and single-agent canakinumab
- Patients with tuberculosis (TB). Note: Patient with latent TB may be
eligible based on the investigator's benefit-risk assessment.
- Patients who have been infected with HBV or HCV including those with

inactive disease.

Additional exclusion criteria for Combination arm PDR001+CJM112
- Patients with TB. Note: Patient with latent TB may be eligible based on the investigator's benefit-risk assessment.
- Patients with history of and/or active inflammatory bowel disease.
- Active skin or soft tissue infection including cellulitis, erysipelas, impetigo, furuncle,carbuncle, abscess, or fasciitis.
- Active candida infection, including mucocutaneous infection or history of invasive candidiasis.

Additional exclusion criteria for Combination arm PDR001+trametinib
- Patients with history of retinal vein oclusion.
- Patients with history of interstitial lung disease or pneumonitis.
- Patients with cardiomyopathy and/or LVEF < LLN.
- Impairment of gastrointestinal function or GI disease that may significantly alter the absorption of oral combination partners.
- Hemoglobin (Hgb) < 9 g/dL without growth factor or transfusion support
- Women of child-bearing potential using hormonal contraception, unless an additional contraception method is also used according to the Mekinist® label.

Additional exclusion criteria for Combination arm PDR001+EGF816
- NSCLC patients with EGFR mutant tumors.
- Strong inhibitors and strong inducers of CYP3A4 should not be used concomitantly.
- Patients with history of interstitial lung disease.
- Patients who have been infected with HBV or HCV including those with inactive disease.
- Impairment of gastrointestinal function or GI disease that may significantly alter the absorption of oral combination partners
- Patients cannot have received radiotherapy to lung fields within 6 months of study treatment start.

Participant Flow Table - Treatment Period 1 – part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Arm/Group Description	PDR + ACZ	PDR + ACZ	PDR + ACZ Recommended Dose for	PDR + ACZ Recommended Dose for	PDR + ACZ Recommended Dose for	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM

	100mg Q8W	300mg Q8W	Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Expansion (RDE) Colorectal Cancer (CRC)	25mg Q4W	75mg Q4W	225mg Q4W	450mg Q4W	450mg Q2W	900mg Q4W	900mg Q2W
Started	6	13	32	22	34	6	6	6	6	6	5	6
Completed	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed	6	13	32	22	34	6	6	6	6	6	5	6
Adverse Event	0	1	1	0	1	0	0	0	0	0	0	0
Physician Decision	0	0	1	0	2	0	0	0	1	0	0	0
Progressive disease	6	11	30	19	31	6	4	5	5	5	5	6
Study terminated by sponsor	0	0	0	1	0	0	0	0	0	0	0	0
Withdrawal by Subject	0	1	0	2	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	2	1	0	1	0	0

Participant Flow Table - Treatment Period 1 – part 2 of 2

PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC	Total

Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	
Started	6	7	12	11	9	6	6	23	20	15	20	283
Completed	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed	6	7	12	11	9	6	6	23	20	15	20	283
Adverse Event	0	1	0	2	0	1	1	1	0	0	0	9
Physician Decision	0	0	1	0	0	0	0	0	0	0	0	5
Progressive disease	6	5	10	9	8	5	3	20	17	13	19	248
Study terminated by sponsor	0	0	0	0	0	0	0	0	0	0	0	1
Withdrawal by Subject	0	0	1	0	0	0	0	0	1	2	0	7
Death	0	1	0	0	1	0	2	2	2	0	1	13

Participant Flow Table - Treatment Period 2 – part 1 of 2

	PDR + ACZ	PDR + ACZ	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM

	100mg Q8W	300mg Q8W				25mg Q4W	75mg Q4W	225mg Q4W	450mg Q4W	450mg Q2W	900mg Q4W	900mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Started	2	1	1	4	4	1	0	0	0	1	0	0
Completed	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed	2	1	1	4	4	1	0	0	0	1	0	0
Physician Decision	1	0	1	2	0	0	0	0	0	0	0	0
Progressive disease	1	1	0	2	4	1	0	0	0	1	0	0
Adverse Event	0	0	0	0	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0	0	0	0	0

Participant Flow Table - Treatment Period 2 – part 2 of 2

	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks	PDR + TMT 1.5 mg QD, 2 Weeks	PDR + TMT 1.5 mg QD, 3 Weeks	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC	Total

				on/1 Week off	on/2 Weeks off	on/1 Week off						
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	
Started	0	0	1	1	2	0	0	1	8	4	12	43
Completed	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed	0	0	1	1	2	0	0	1	8	4	12	43
Physician Decision	0	0	0	0	0	0	0	0	0	1	0	5
Progressive disease	0	0	1	1	1	0	0	1	6	3	12	35
Adverse Event	0	0	0	0	1	0	0	0	0	0	0	1
Death	0	0	0	0	0	0	0	0	2	0	0	2

Post-treatment f-up for pts who disc. – part 1 of 2

PDR + ACZ 100mg Q8W	**PDR + ACZ 300mg Q8W**	**PDR + ACZ RDE TNBC**	**PDR + ACZ RDE NSCLC**	**PDR + ACZ RDE CRC**	**PDR + CJM 25mg Q4W**	**PDR + CJM 75mg Q4W**	**PDR + CJM 225mg Q4W**	**PDR + CJM 450mg Q4W**	**PDR + CJM 450mg Q2W**	**PDR + CJM 900mg Q4W**	**PDR + CJM 900mg Q2W**

Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Started	0	0	0	0	0	0	0	0	0	0	0	0
Completed	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed	0	0	0	0	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0	0	0	0	0
Withdrawal by Subject	0	0	0	0	0	0	0	0	0	0	0	0

Post-treatment f-up for pts who disc. – part 2 of 2

	PDR + CJM 1200mg Q4W	**PDR + TMT 0.5mg QD**	**PDR + TMT 1mg QD**	**PDR + TMT 1mg QD, 3 Weeks on/1 Week off**	**PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off**	**PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off**	**PDR + EGF816 25mg QD**	**PDR + EGF816 50mg QD**	**s.a. ACZ RDE TNBC**	**s.a. ACZ RDE NSCLC**	**s.a. ACZ RDE CRC**	**Total**
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1	PDR + TMT 1.5 mg QD, 2 Weeks on/2	PDR + TMT 1.5 mg QD, 3 Weeks on/1	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE)	

				Week off	Weeks off	Week off			Negative Breast Cancer (TNBC)	Small Cell Lung Cancer (NSCLC)	Colorectal Cancer (CRC)	
Started	0	0	0	0	0	0	1	0	0	1	0	2
Completed	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed	0	0	0	0	0	0	1	0	0	1	0	2
Death	0	0	0	0	0	0	0	0	0	1	0	1
Withdrawal by Subject	0	0	0	0	0	0	1	0	0	0	0	1

Baseline Characteristics

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Number of Participants [units: participants]	6	13	32	22	34	6	6	6	6	6	5	6
Age Continuous (units: years) Mean ± Standard Deviation												
	58.5±9.27	62.5±4.91	48.4±10.60	58.5±10.20	62.1±12.28	48.5±13.92	51.7±12.04	49.0±10.56	47.8±11.44	58.5±5.32	61.8±10.08	48.8±11.96
Age Categorical (units: Participants) Count of Participants (Not Applicable)												
<=18 years	0	0	0	0	0	0	0	0	0	0	0	0
Between 18	4	9	31	15	17	6	6	5	6	6	4	6

and 65 years												
>=65 years	2	4	1	7	17	0	0	1	0	0	1	0
Sex: Female, Male (units: Participants) Count of Participants (Not Applicable)												
Female	2	9	32	10	12	4	3	5	4	5	3	1
Male	4	4	0	12	22	2	3	1	2	1	2	5
Race/Ethnicity, Customized (units: Participants) Count of Participants (Not Applicable)												
Caucasian	4	10	20	15	26	3	3	3	4	3	4	3
Black	0	1	0	0	1	1	1	1	0	1	0	0
Asian	1	1	0	6	0	0	2	1	1	0	0	2
Unknown	0	0	10	1	3	1	0	0	1	2	1	0
Other	1	1	2	0	4	1	0	1	0	0	0	1

Part 2 of 2

	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC	Total
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks	PDR + TMT 1.5 mg QD, 2 Weeks	PDR + TMT 1.5 mg QD, 3 Weeks	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	Single agent (s.a.) ACZ Recommended Dose for	Single agent (s.a.) ACZ Recommended Dose for	Single agent (s.a.) ACZ Recommended Dose for	

				on/1 Week off	on/2 Weeks off	on/1 Week off			Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Expansion (RDE) Colorectal Cancer (CRC)	
Number of Participants [units: participants]	6	7	12	11	9	6	6	23	20	15	20	283
Age Continuous (units: years) Mean ± Standard Deviation												
	60.3±9.20	58.0±12.74	58.7±14.23	59.5±9.42	55.1±10.30	60.3±14.32	45.7±13.65	57.4±12.10	55.6±9.80	62.5±9.18	64.0±9.38	NA±NA[]
Age Categorical (units: Participants) Count of Participants (Not Applicable)												
<=18 years	0	0	0	0	0	0	0	0	0	0	0	0
Between 18 and 65 years	4	5	7	9	8	3	6	16	17	10	10	210
>=65 years	2	2	5	2	1	3	0	7	3	5	10	73
Sex: Female, Male (units: Participants) Count of Participants (Not Applicable)												
Female	3	5	7	7	6	4	3	14	20	5	7	171
Male	3	2	5	4	3	2	3	9	0	10	13	112

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

Caucasian	3	6	5	10	7	4	4	20	14	11	17	199
Black	0	0	0	0	0	0	1	1	0	0	1	9
Asian	2	1	5	0	1	1	1	2	3	3	1	34
Unknown	0	0	1	0	1	0	0	0	2	1	1	25
Other	1	0	1	1	0	1	0	0	1	0	0	16

Primary Outcome Result(s)

Frequency of treatment-emergent Adverse Events (AEs) and Serious Adverse Events (SAEs) as a measure of safety

(Time Frame: Adverse events were reported from first dose of study treatment until end of study treatment plus 30 days post treatment, up to a maximum time frame of 116.3 weeks (approx. 2.2 years).)

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Number of Participants Analyzed [units: participants]	6	13	32	22	34	6	6	6	6	6	5	6
Frequency of treatment-emergent Adverse Events (AEs) and Serious Adverse Events (SAEs) as a measure of safety (units: Participants) Count of Participants (Not Applicable)												
Adverse events (AEs) All grades	5 (83.33%)	13 (100%)	32 (100%)	22 (100%)	34 (100%)	6 (100%)	6 (100%)	5 (83.33%)	6 (100%)	6 (100%)	5 (100%)	6 (100%)
Treatment-related AEs All grades	1 (16.67%)	8 (61.54%)	19 (59.38%)	14 (63.64%)	18 (52.94%)	3 (50%)	4 (66.67%)	3 (50%)	2 (33.33%)	3 (50%)	1 (20%)	3 (50%)
Serious Adverse events (SAEs) All grades	1 (16.67%)	5 (38.46%)	8 (25%)	9 (40.91%)	13 (38.24%)	1 (16.67%)	5 (83.33%)	2 (33.33%)	3 (50%)	4 (66.67%)	3 (60%)	1 (16.67%)

Treatment-related SAEs All grades	0 (%)	0 (%)	0 (%)	2 (9.09%)	1 (2.94%)	0 (%)	2 (33.33%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)
Fatal SAEs All grades	0 (%)	1 (7.69%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (33.33%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	0 (%)
AEs leading to discontinuation All grades	0 (%)	1 (7.69%)	1 (3.13%)	0 (%)	2 (5.88%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	0 (%)
AEs leading to discontinuation - Treatment-related All grades	0 (%)	0 (%)	0 (%)	0 (%)	1 (2.94%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
AEs leading to dose adjustment/interruption All grades	1 (16.67%)	3 (23.08%)	5 (15.63%)	4 (18.18%)	3 (8.82%)	1 (16.67%)	2 (33.33%)	2 (33.33%)	0 (%)	2 (33.33%)	2 (40%)	1 (16.67%)
AEs requiring additional therapy All grades	5 (83.33%)	9 (69.23%)	26 (81.25%)	19 (86.36%)	30 (88.24%)	5 (83.33%)	5 (83.33%)	4 (66.67%)	5 (83.33%)	6 (100%)	5 (100%)	5 (83.33%)

Part 2 of 2

	PDR + CJM 1200mg Q4W	**PDR + TMT 0.5mg QD**	**PDR + TMT 1mg QD**	**PDR + TMT 1mg QD, 3 Weeks on/1 Week off**	**PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off**	**PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off**	**PDR + EGF816 25mg QD**	**PDR + EGF816 50mg QD of C1**	**PDR + EGF816 50mg QD > C1**	**s.a. ACZ RDE TNBC**	**s.a. ACZ RDE NSCLC**	**s.a. ACZ RDE CRC**
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD of C1	PDR + EGF816 50mg QD > C1	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorecta

										Negative Breast Cancer (TNBC)	Small Cell Lung Cancer (NSCLC)	l Cancer (CRC)
Number of Participants Analyzed [units: participants]	6	7	12	11	9	6	6	13	10	20	15	20
Frequency of treatment-emergent Adverse Events (AEs) and Serious Adverse Events (SAEs) as a measure of safety (units: Participants) Count of Participants (Not Applicable)												
Adverse events (AEs) All grades	6 (100%)	7 (100%)	12 (100%)	11 (100%)	9 (100%)	6 (100%)	6 (100%)	12 (92.31%)	9 (90%)	20 (100%)	14 (93.33%)	19 (95%)
Treatment-related AEs All grades	4 (66.67%)	7 (100%)	12 (100%)	7 (63.64%)	8 (88.89%)	6 (100%)	5 (83.33%)	6 (46.15%)	6 (60%)	5 (25%)	3 (20%)	5 (25%)
Serious Adverse events (SAEs) All grades	2 (33.33%)	5 (71.43%)	4 (33.33%)	4 (36.36%)	5 (55.56%)	4 (66.67%)	2 (33.33%)	4 (30.77%)	2 (20%)	6 (30%)	4 (26.67%)	7 (35%)
Treatment-related SAEs All grades	0 (%)	1 (14.29%)	0 (%)	1 (9.09%)	0 (%)	2 (33.33%)	1 (16.67%)	0 (%)	0 (%)	1 (5%)	0 (%)	0 (%)
Fatal SAEs All grades	0 (%)	1 (14.29%)	0 (%)	1 (9.09%)	1 (11.11%)	0 (%)	1 (16.67%)	2 (15.38%)	2 (20%)	1 (5%)	0 (%)	0 (%)
AEs leading to discontinuation All grades	0 (%)	2 (28.57%)	0 (%)	2 (18.18%)	1 (11.11%)	1 (16.67%)	1 (16.67%)	0 (%)	1 (10%)	0 (%)	0 (%)	0 (%)
AEs leading to discontinuation - Treatment-related All grades	0 (%)	1 (14.29%)	0 (%)	1 (9.09%)	0 (%)	1 (16.67%)	1 (16.67%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
AEs leading to dose adjustment/interruption All grades	2 (33.33%)	3 (42.86%)	9 (75%)	5 (45.45%)	4 (44.44%)	3 (50%)	1 (16.67%)	3 (23.08%)	0 (%)	2 (10%)	0 (%)	1 (5%)
AEs requiring additional therapy All grades	5 (83.33%)	6 (85.71%)	12 (100%)	11 (100%)	9 (100%)	6 (100%)	5 (83.33%)	9 (69.23%)	8 (80%)	15 (75%)	9 (60%)	14 (70%)

Median Relative dose intensity (%) by treatment period

(Time Frame: Up to 2 years)

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Number of Participants Analyzed [units: participants]	6	13	32	22	34	6	6	6	6	6	5	6
Median Relative dose intensity (%) by treatment period (units: Percent Relative dose intensity) Median (Inter-Quartile Range)												
Treatment Period 1	100.00 (85.71 to 100.00)	100.00 (100.00 to 100.00)	100.00 (100.00 to 100.00)	100.00 (85.71 to 100.00)	100.00 (100.00 to 100.00)	100.00 (100.00 to 100.00)	100.00 (75.00 to 100.00)	100.00 (66.67 to 100.00)	81.67 (80.00 to 100.00)	100.00 (100.00 to 100.00)	100.00 (66.67 to 100.00)	100.00 (80.00 to 100.00)
Treatment Period 2 (n=2,1,1,4,4,1,0,0,0,1,0,0,0,0,1,1,2,0,0,0,1,0,0,0)	77.78 (66.67 to 88.89)	100.00 (100.00 to 100.00)	85.00 (85.00 to 85.00)	100.00 (95.00 to 100.00)	100.00 (100.00 to 100.00)	87.50 (87.50 to 87.50)				100.00 (100.00 to 100.00)		

Overall (n=6,13,32,22,34,6,6,6,6,6,5,6,6,7,12,11,9,6,6,13,10,0,0,0)	100.00 (70.59 to 100.00)	100.00 (90.91 to 100.00)	100.00 (100.00 to 100.00)	100.00 (75.00 to 100.00)	100.00 (100.00 to 100.00)	100.00 (81.25 to 100.00)	100.00 (75.00 to 100.00)	100.00 (66.67 to 100.00)	81.67 (80.00 to 100.00)	100.00 (100.00 to 100.00)	100.00 (66.67 to 100.00)	100.00 (80.00 to 100.00)

Part 2 of 2

	PDR + CJM 1200mg Q4W	**PDR + TMT 0.5mg QD**	**PDR + TMT 1mg QD**	**PDR + TMT 1mg QD, 3 Weeks on/1 Week off**	**PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off**	**PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off**	**PDR + EGF816 25mg QD**	**PDR + EGF816 50mg QD of C1**	**PDR + EGF816 50mg QD > C1**	**s.a. ACZ RDE TNBC**	**s.a. ACZ RDE NSCLC**	**s.a. ACZ RDE CRC**
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD of C1	PDR + EGF816 50mg QD > C1	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed [units: participants]	6	7	12	11	9	6	6	13	10	0	0	0
Treatment Period 1	100.00 (100.00 to 100.00)	100.00 (80.00 to 100.00)	100.00 (100.00 to 100.00)	100.00 (85.71 to 100.00)	100.00 (85.71 to 100.00)	87.50 (66.67 to 100.00)	92.85 (75.00 to 100.00)	100.00 (85.71 to 100.00)	100.00 (100.00 to 100.00)			

Treatment Period 2 (n=2,1,1,4,4,1,0,0,0,1,0,0,0,0,1,1,2,0,0,0,1,0,0,0)			100.00 (100.00 to 100.00)	100.00 (100.00 to 100.00)	87.50 (75.00 to 100.00)				100.0 (100.0 to 100.0)	
Overall (n=6,13,32,22,34,6,6,6,6,6,5,6,6,7,12,11,9,6,6,13,10,0,0,0)	100.00 (100.00 to 100.00)	100.00 (80.00 to 100.00)	100.00 (90.00 to 100.00)	100.00 (75.00 to 100.00)	100.00 (80.00 to 100.00)	87.50 (66.67 to 100.00)	92.85 (75.00 to 100.00)	100.00 (85.71 to 100.00)	100.00 (100.00 to 100.00)	

Number of subjects with at least one dose reduction and/or interruption by reason-n (%)

(Time Frame: Up to 2 years)

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Number of Participants Analyzed [units: participants]	6	13	32	22	34	6	6	6	6	6	5	6

Number of subjects with at least one dose reduction and/or interruption by reason-n (%)
(units: Participants)
Count of Participants (Not Applicable)

Adverse Event	1 (16.67%)	2 (15.38%)	1 (3.13%)	3 (13.64%)	0 (%)	0 (%)	1 (16.67%)	1 (16.67%)	0 (%)	0 (%)	1 (20%)	0 (%)
Subject was out of country	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Physician decision	0 (%)	0 (%)	0 (%)	1 (4.55%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Part 2 of 2

	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD of C1	PDR + EGF816 50mg QD > C1	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD of C1	PDR + EGF816 50mg QD > C1	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed [units: participants]	6	7	12	11	9	6	6	13	10	0	0	0

Number of subjects with at least one dose reduction and/or interruption by reason-n (%)
(units: Participants)
Count of Participants (Not Applicable)

Adverse Event	0 (%)	0 (%)	2 (16.67%)	1 (9.09%)	2 (22.22%)	1 (16.67%)	0 (%)	1 (7.69%)	0 (%)	(NaN%)	(NaN%)	(NaN%)
Subject was out of country	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)
Physician decision	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)

Dose limiting toxicities by primary system organ class and preferred term (Escalation only)

(Time Frame: Up to 6 cycles (Week 24))

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Number of Participants Analyzed [units: participants]	6	13	0	0	0	4	3	4	6	6	4	6

Dose limiting toxicities by primary system organ class and preferred term (Escalation only)
(units: Participants)
Count of Participants (Not Applicable)

Number of subjects with at least one event All grades	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)
Gastrointestinal disorders All grades - Autoimmune colitis All grades	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)
Skin and subcutaneous tissue disorders - Dermatitis acneiform - All grades	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Skin and subcutaneous tissue disorders - Rash - All grades	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Investigations - Blood creatine phosphokinase increased - All grades	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Respiratory, thoracic and mediastinal disorders - Pneumonitis - All grades	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Infections and infestations -	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Herpes zoster -
All grades

Part 2 of 2

	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD of C1	PDR + EGF816 50mg QD > C1	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD of C1	PDR + EGF816 50mg QD > C1	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed [units: participants]	3	6	11	9	7	4	4	8	9	0	0	0
Dose limiting toxicities by primary system organ class and preferred term (Escalation only) (units: Participants) Count of Participants (Not Applicable)												
Number of subjects with at least one event All grades	0 (%)	1 (16.67%)	2 (18.18%)	1 (11.11%)	1 (14.29%)	2 (50%)	0 (%)	1 (12.5%)	0 (%)	(NaN%)	(NaN%)	(NaN%)

Gastrointestinal disorders All grades - Autoimmune colitis All grades	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)
Skin and subcutaneous tissue disorders - Dermatitis acneiform - All grades	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)	0 (%)	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)
Skin and subcutaneous tissue disorders - Rash - All grades	0 (%)	0 (%)	1 (9.09%)	0 (%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)
Investigations - Blood creatine phosphokinase increased - All grades	0 (%)	1 (16.67%)	1 (9.09%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)
Respiratory, thoracic and mediastinal disorders - Pneumonitis - All grades	0 (%)	0 (%)	0 (%)	1 (11.11%)	0 (%)	1 (25%)	0 (%)	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)
Infections and infestations - Herpes zoster - All grades	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (12.5%)	0 (%)	(NaN%)	(NaN%)	(NaN%)

Secondary Outcome Result(s)

Best overall response as per RECIST v1.1 as per Investigator assessment

(Time Frame: Up to 6 months (Treatment Period 1))

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Number of Participants Analyzed [units: participants]	6	13	32	22	34	6	6	6	6	6	5	6
Best overall response as per RECIST v1.1 as per Investigator assessment (units: Participants) Count of Participants (Not Applicable)												
Best overall response, n (%) - Complete response (CR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Best overall response, n (%) - Partial	1 (16.67%)	0 (%)	0 (%)	4 (18.18%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

response (PR)												
Best overall response, n (%) - Stable disease (SD)	0 (%)	2 (15.38%)	5 (15.63%)	7 (31.82%)	6 (17.65%)	1 (16.67%)	1 (16.67%)	1 (16.67%)	3 (50%)	3 (50%)	1 (20%)	1 (16.67%)
Best overall response, n (%) - Progressive disease (PD)	5 (83.33%)	5 (38.46%)	19 (59.38%)	8 (36.36%)	23 (67.65%)	4 (66.67%)	3 (50%)	5 (83.33%)	3 (50%)	2 (33.33%)	4 (80%)	5 (83.33%)
Best overall response, n (%) - Unknown	0 (%)	6 (46.15%)	8 (25%)	3 (13.64%)	5 (14.71%)	1 (16.67%)	2 (33.33%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	0 (%)

Part 2 of 2

	PDR + CJM 1200mg Q4W	**PDR + TMT 0.5mg QD**	**PDR + TMT 1mg QD**	**PDR + TMT 1mg QD, 3 Weeks on/1 Week off**	**PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off**	**PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off**	**PDR + EGF816 25mg QD**	**PDR + EGF816 50mg QD**	**s.a. ACZ RDE TNBC**	**s.a. ACZ RDE NSCLC**	**s.a. ACZ RDE CRC**
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)

Number of Participants Analyzed [units: participants]	6	7	12	11	9	6	6	23	20	15	20
Best overall response as per RECIST v1.1 as per Investigator assessment (units: Participants) Count of Participants (Not Applicable)											
Best overall response, n (%) - Complete response (CR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Best overall response, n (%) - Partial response (PR)	0 (%)	0 (%)	1 (8.33%)	1 (9.09%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Best overall response, n (%) - Stable disease (SD)	1 (16.67%)	1 (14.29%)	2 (16.67%)	5 (45.45%)	4 (44.44%)	0 (%)	1 (16.67%)	2 (8.7%)	2 (10%)	1 (6.67%)	2 (10%)
Best overall response, n (%) - Progressive disease (PD)	5 (83.33%)	5 (71.43%)	8 (66.67%)	3 (27.27%)	4 (44.44%)	5 (83.33%)	3 (50%)	18 (78.26%)	17 (85%)	13 (86.67%)	18 (90%)
Best overall response, n (%) - Unknown	0 (%)	1 (14.29%)	1 (8.33%)	2 (18.18%)	1 (11.11%)	1 (16.67%)	2 (33.33%)	3 (13.04%)	1 (5%)	1 (6.67%)	0 (%)

Progression-free survival based on investigator assessment as per RECIST v1.1

(Time Frame: Up to 18 months (1.5 years))

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Number of Participants Analyzed [units: participants]	6	13	32	22	34	6	6	6	6	6	5	6
Progression-free survival based on investigator assessment as per RECIST v1.1 (units: Participants) Count of Participants (Not Applicable)												
Progression free survival, n (%) - Progression	6 (100%)	7 (53.85%)	24 (75%)	17 (77.27%)	28 (82.35%)	5 (83.33%)	3 (50%)	5 (83.33%)	5 (83.33%)	4 (66.67%)	5 (100%)	6 (100%)
Progression free survival, n (%) - Death	0 (%)	3 (23.08%)	2 (6.25%)	0 (%)	3 (8.82%)	0 (%)	2 (33.33%)	1 (16.67%)	0 (%)	1 (16.67%)	0 (%)	0 (%)
Progression free survival, n (%) - Censored	0 (%)	3 (23.08%)	6 (18.75%)	5 (22.73%)	3 (8.82%)	1 (16.67%)	1 (16.67%)	0 (%)	1 (16.67%)	1 (16.67%)	0 (%)	0 (%)

Part 2 of 2

	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed [units: participants]	6	7	12	11	9	6	6	23	20	15	20
Progression-free survival based on investigator assessment as per RECIST v1.1 (units: Participants) Count of Participants (Not Applicable)											
Progression free survival, n (%) - Progression	5 (83.33%)	6 (85.71%)	11 (91.67%)	7 (63.64%)	7 (77.78%)	5 (83.33%)	3 (50%)	20 (86.96%)	19 (95%)	14 (93.33%)	20 (100%)
Progression free survival, n (%) - Death	0 (%)	1 (14.29%)	0 (%)	2 (18.18%)	1 (11.11%)	1 (16.67%)	2 (33.33%)	1 (4.35%)	1 (5%)	0 (%)	0 (%)
Progression free survival, n (%) - Censored	1 (16.67%)	0 (%)	1 (8.33%)	2 (18.18%)	1 (11.11%)	0 (%)	1 (16.67%)	2 (8.7%)	0 (%)	1 (6.67%)	0 (%)

Progression-free survival based on investigator assessment using Kaplan-Meier method as per RECIST v1.1

(Time Frame: Kaplan-Meier estimates at 3, 6, 9, and 12 months)

Part 1 of 4

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)
Number of Participants Analyzed [units: participants]	6	13	32	22
Kaplan-Meier estimates (%) PFS rate (95% CI) at 3 months	16.7 (0.8 to 51.7)	10.0 (0.6 to 35.8)	15.5 (4.9 to 31.6)	47.0 (23.7 to 67.3)
Kaplan-Meier estimates (%) PFS rate (95% CI) at 6 months	16.7 (0.8 to 51.7)	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	3.9 (0.3 to 16.5)	35.2 (14.8 to 56.6)

Kaplan-Meier estimates (%) PFS rate (95% CI) at 9 months	16.7 (0.8 to 51.7)	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	3.9 (0.3 to 16.5)	29.4 (10.9 to 50.8)
Kaplan-Meier estimates (%) PFS rate (95% CI) at 12 months	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	3.9 (0.3 to 16.5)	23.5 (7.4 to 44.6)

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Progression-free survival based on investigator assessment using Kaplan-Meier method as per RECIST v1.1

(Time Frame: Kaplan-Meier estimates at 3, 6, 9, and 12 months)

Part 2 of 4

	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W
Arm/Group Description	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W
Number of Participants Analyzed [units: participants]	34	6	6	6

Kaplan-Meier estimates (%) PFS rate (95% CI) at 3 months	18.8 (7.6 to 33.7)	20.0 (0.8 to 58.2)	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	16.7 (0.8 to 51.7)
Kaplan-Meier estimates (%) PFS rate (95% CI) at 6 months	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]
Kaplan-Meier estimates (%) PFS rate (95% CI) at 9 months	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]
Kaplan-Meier estimates (%) PFS rate (95% CI) at 12 months	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545555657585960]

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Progression-free survival based on investigator assessment using Kaplan-Meier method as per RECIST v1.1

(Time Frame: Kaplan-Meier estimates at 3, 6, 9, and 12 months)

Part 3 of 4

	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD
Arm/Group Description	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD
Number of Participants Analyzed [units: participants]	6	6	5	6	6	7	12
Kaplan-Meier estimates (%) PFS rate (95% CI) at 3 months	33.3 (4.6 to 67.6)	60.0 (12.6 to 88.2)	20.0 (0.8 to 58.2)	16.7 (0.8 to 51.7)	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	14.3 (0.7 to 46.5)	18.2 (2.9 to 44.2)
Kaplan-Meier estimates (%) PFS rate (95% CI) at 6 months	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]

Kaplan-Meier estimates (%) PFS rate (95% CI) at 9 months	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]
Kaplan-Meier estimates (%) PFS rate (95% CI) at 12 months	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]	NA (NA to NA)[123456789101112131415161718192021222324252627282930313233343536373839404142434445464748495051525354555657585960]

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Progression-free survival based on investigator assessment using Kaplan-Meier method as per RECIST v1.1

(Time Frame: Kaplan-Meier estimates at 3, 6, 9, and 12 months)

Part 4 of 4

	PDR + TMT 1mg QD,	PDR + TMT 1.5 mg QD, 2	PDR + TMT 1.5 mg QD, 3	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC

	3 Weeks on/1 Week off	Weeks on/2 Weeks off	Weeks on/1 Week off					
Arm/Group Description	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed [units: participants]	11	9	6	6	23	20	15	20
Kaplan-Meier estimates (%) PFS rate (95% CI) at 3 months	36.4 (11.2 to 62.7)	44.4 (13.6 to 71.9)	NA (NA to NA)[123456789101112 13141516171819202122 23242526272829303132 33343536373839404142 43444546474849505152 5354555657585960]	16.7 (0.8 to 51.7)	5.2 (0.4 to 21.1)	10.0 (1.7 to 27.2)	7.1 (0.5 to 27.5)	5.0 (0.3 to 20.5)
Kaplan-Meier estimates (%) PFS rate (95% CI) at 6 months	27.3 (6.5 to 53.9)	33.3 (7.8 to 62.3)	NA (NA to NA)[123456789101112 13141516171819202122 23242526272829303132 33343536373839404142 43444546474849505152 5354555657585960]	NA (NA to NA)[123456789101112 13141516171819202122 23242526272829303132 33343536373839404142 43444546474849505152 5354555657585960]	NA (NA to NA)[123456789101112 13141516171819202122 23242526272829303132 33343536373839404142 43444546474849505152 5354555657585960]	5.0 (0.3 to 20.5)	NA (NA to NA)[123456789101112 13141516171819202122 23242526272829303132 33343536373839404142 43444546474849505152 5354555657585960]	NA (NA to NA)[123456789101112 13141516171819202122 23242526272829303132 33343536373839404142 43444546474849505152 5354555657585960]
Kaplan-Meier estimates	NA (NA to NA)[123456	16.7 (1.1 to 49.3)	NA (NA to NA)[123456789101112	NA (NA to NA)[123456789101112	NA (NA to NA)[123456789101112	NA (NA to NA)[123456789101112	NA (NA to NA)[123456789101112	NA (NA to NA)[123456789101112

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(%) PFS rate (95% CI) at 9 months	7891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]		1314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	1314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	1314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	1314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	1314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	1314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]
Kaplan-Meier estimates (%) PFS rate (95% CI) at 12 months	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]	NA (NA to NA)[1234567891011121314151617181920212223242526272829303132333435363738394041424344454647484950515253545556575859 60]

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Treatment free survival as per investigator assessment

(Time Frame: Up to 1 year, at which time the1 surviving patient was censored.)

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Number of Participants Analyzed [units: participants]	6	13	32	22	34	0	0	0	0	0	0	0
Treatment free survival, n (%) - Progression	1 (16.67%)	0 (%)	1 (3.13%)	4 (18.18%)	1 (2.94%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)
Treatment free survival, n (%) - Censored	0 (%)	0 (%)	0 (%)	1 (4.55%)	0 (%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)

Treatment free survival as per investigator assessment

(Time Frame: Up to 1 year, at which time the1 surviving patient was censored.)

Part 2 of 2

	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1	PDR + TMT 1.5 mg QD, 2 Weeks on/2	PDR + TMT 1.5 mg QD, 3 Weeks on/1	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC

Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed [units: participants]	0	7	12	11	9	6	0	0	0	0	0
Treatment free survival, n (%) - Progression	(NaN%)	0 (%)	0 (%)	1 (9.09%)	3 (33.33%)	0 (%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)
Treatment free survival, n (%) - Censored	(NaN%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)	(NaN%)

Treatment free survival rate (95% CI) as per investigator assessment

(Time Frame: 3, 6, 9, and 12 months)

Part 1 of 3

PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W

Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W
Number of Participants Analyzed [units: participants]	6	13	32	22	34	0	0	0
TFS rate (95% CI) at 3 months	100.0 (100.0 to 100.0)	0 (0 to 0)	100.0 (100.0 to 100.0)	100.0 (100.0 to 100.0)	NA (NA to NA)[12345678910111213141 5]			
TFS rate (95% CI) at 6 months	100.0 (100.0 to 100.0)	0 (0 to 0)	100.0 (100.0 to 100.0)	80.0 (20.4 to 96.9)	NA (NA to NA)[12345678910111213141 5]			
TFS rate (95% CI) at 9 months	NA (NA to NA)[12345678910111213141 5]	0 (0 to 0)	NA (NA to NA)[12345678910111213141 5]	40.0 (5.2 to 75.3)	NA (NA to NA)[12345678910111213141 5]			
TFS rate (95% CI) at 12 months	NA (NA to NA)[12345678910111213141 5]	0 (0 to 0)	NA (NA to NA)[12345678910111213141 5]	40.0 (5.2 to 75.3)	NA (NA to NA)[12345678910111213141 5]			

[1] not applicable
[2] not applicable
[3] not applicable
[4] not applicable
[5] not applicable
[6] not applicable
[7] not applicable
[8] not applicable
[9] not applicable
[10] not applicable
[11] not applicable
[12] not applicable
[13] not applicable
[14] not applicable

[15] not applicable

Treatment free survival rate (95% CI) as per investigator assessment

(Time Frame: 3, 6, 9, and 12 months)

Part 2 of 3

	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off
Arm/Group Description	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off
Number of Participants Analyzed [units: participants]	0	0	0	0	0	7	12	11
TFS rate (95% CI) at 3 months						0 (0 to 0)	0 (0 to 0)	NA (NA to NA)[12345678910111213141 5]
TFS rate (95% CI) at 6 months						0 (0 to 0)	0 (0 to 0)	NA (NA to NA)[12345678910111213141 5]
TFS rate (95% CI) at 9 months						0 (0 to 0)	0 (0 to 0)	NA (NA to NA)[12345678910111213141 5]
TFS rate (95% CI) at 12 months						0 (0 to 0)	0 (0 to 0)	NA (NA to NA)[12345678910111213141 5]

[1] not applicable
[2] not applicable

[3] not applicable
[4] not applicable
[5] not applicable
[6] not applicable
[7] not applicable
[8] not applicable
[9] not applicable
[10] not applicable
[11] not applicable
[12] not applicable
[13] not applicable
[14] not applicable
[15] not applicable

Treatment free survival rate (95% CI) as per investigator assessment

(Time Frame: 3, 6, 9, and 12 months)

Part 3 of 3

	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC
Arm/Group Description	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed	9	6	0	0	0	0	0

[units: participants]		
TFS rate (95% CI) at 3 months	33.3 (0.9 to 77.4)	0 (0 to 0)
TFS rate (95% CI) at 6 months	NA (NA to NA)[12345678910111213141 5]	0 (0 to 0)
TFS rate (95% CI) at 9 months	NA (NA to NA)[12345678910111213141 5]	0 (0 to 0)
TFS rate (95% CI) at 12 months	NA (NA to NA)[12345678910111213141 5]	0 (0 to 0)

[1] not applicable
[2] not applicable
[3] not applicable
[4] not applicable
[5] not applicable
[6] not applicable
[7] not applicable
[8] not applicable
[9] not applicable
[10] not applicable
[11] not applicable
[12] not applicable
[13] not applicable
[14] not applicable
[15] not applicable

Summary of primary PK parameters for PDR001 - AUClast (h*ug/mL)

(Time Frame: Period 1 Cycle 1 Day 1)

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W

Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W
Number of Participants Analyzed [units: participants]	5	12	2	0	4	6	5	6	6	6
Summary of primary PK parameters for PDR001 - AUClast (h*ug/mL) (units: h*ug/mL) Geometric Mean (Geometric Coefficient of Variation)										

Period 1 Cycle 1 Day 1	33900 (39.2 %)	30100 (40.4 %)	25300 (12.4 %)		29300 (10.6 %)	26100 (32.9 %)	26800 (11.0 %)	26900 (38.5 %)	27700 (27.6 %)	32400 (40.7 %)

Summary of primary PK parameters for PDR001 - AUClast (h*ug/mL)

(Time Frame: Period 1 Cycle 1 Day 1)

Part 2 of 2

	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD
Arm/Group Description	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD
Number of Participants Analyzed [units: participants]	5	6	6	7	12	10	8	6	6	21
Summary of primary PK parameters for PDR001 - AUClast (h*ug/mL) (units: h*ug/mL) Geometric Mean										

(Geometric Coefficient of Variation)										
Period 1 Cycle 1 Day 1	22100 (52.1 %)	24100 (20.3 %)	22200 (33.7 %)	25300 (45.5 %)	31300 (15.8 %)	27800 (27.4 %)	27000 (41.2 %)	21400 (47.7 %)	28200 (35.0 %)	28100 (29.8 %)

Summary of primary PK parameters for PDR001 - Cmax (h)

(Time Frame: Period 1 Cycle 1 Day 1 and Period 1 Cycle 3 Day 1 (Day 57))

Part 1 of 2

	PDR + ACZ 100mg Q8W	**PDR + ACZ 300mg Q8W**	**PDR + ACZ RDE TNBC**	**PDR + ACZ RDE NSCLC**	**PDR + ACZ RDE CRC**	**PDR + CJM 25mg Q4W**	**PDR + CJM 75mg Q4W**	**PDR + CJM 225mg Q4W**	**PDR + CJM 450mg Q4W**	**PDR + CJM 450mg Q2W**
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W
Number of Participants Analyzed [units: participants]	5	12	6	11	8	6	5	6	6	6
Period 1 Cycle 1 Day 1 (n=5,12,2,0,4,6,5,6,6,6,5,6,6,7,12,10,8,6,6,21)	132 (37.8%)	113 (29.7%)	137 (15.5%)		104 (31.6%)	107 (34.9%)	115 (16.9%)	97.5 (35.7%)	106 (27.5%)	121 (38.4%)

Period 1 Cycle 3 Day 1 (n=1,4,6,11,8,2,1,0,4,1,0,2,1,3,2,1,5,0,1,3)	76.8 (NA%) [123456]	164 (60.2%)	205 (31.8%)	164 (25.3%)	132 (35.6%)	139 (6.6%)	159 (NA%)[123456]		147 (21.8%)	231 (NA%)[123456]

[1] Not applicable when n = 1.
[2] Not applicable when n = 1.
[3] Not applicable when n = 1.
[4] Not applicable when n = 1.
[5] Not applicable when n = 1.
[6] Not applicable when n = 1.

Summary of primary PK parameters for PDR001 - Cmax (h)

(Time Frame: Period 1 Cycle 1 Day 1 and Period 1 Cycle 3 Day 1 (Day 57))

Part 2 of 2

	PDR + CJM 900mg Q4W	**PDR + CJM 900mg Q2W**	**PDR + CJM 1200mg Q4W**	**PDR + TMT 0.5mg QD**	**PDR + TMT 1mg QD**	**PDR + TMT 1mg QD, 3 Weeks on/1 Week off**	**PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off**	**PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off**	**PDR + EGF816 25mg QD**	**PDR + EGF816 50mg QD**
Arm/Group Description	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD
Number of Participants Analyzed [units: participants]	5	6	6	7	12	10	8	6	6	21
Period 1 Cycle 1 Day 1 (n=5,12,2,0,4,6,5,6,6,6,5,6,6,7,12,10,8,6,6,21)	76.8 (67.2%)	81.1 (20.2%)	87.4 (23.5%)	94.6 (35.7%)	115 (21.4%)	83.4 (35.6%)	90.8 (41.6%)	75.1 (61.7%)	119 (21.4%)	99.0 (25.9%)
Period 1 Cycle 3 Day 1 (n=1,4,6,11,8,2,1,0,4,1,0,2,1,3,2,1,5,0,1,3)		114 (33.6%)	161 (NA%)[123456]	100 (29.7%)	169 (0.4%)	143 (NA%)[123456]	97.9 (81.9%)		124 (NA%)[123456]	150 (17.7%)

[1] Not applicable when n = 1.
[2] Not applicable when n = 1.

[3] Not applicable when n = 1.
[4] Not applicable when n = 1.
[5] Not applicable when n = 1.
[6] Not applicable when n = 1.

Summary of primary PK parameters for canakinumab - AUClast (h*ug/mL)

(Time Frame: Period 1 Cycle 1 Day 1)

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed [units: participants]	6	12	27	21	33	13	9	13
Summary of primary PK parameters for canakinumab - AUClast (h*ug/mL) (units: h*ug/mL) Geometric Mean								

(Geometric Coefficient of Variation)								
Period 1 Cycle 1 Day 1	6190000 (39.6 %)	12100000 (75. 1%)	24000000 (114. 9%)	31300000 (40. 3%)	23500000 (47. 4%)	23500000 (66. 2%)	33600000 (38. 0%)	25100000 (35. 4%)

Summary of primary PK parameters for canakinumab - Cmax (h)

(Time Frame: Period 1 Cycle 1 Day 1)

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed [units: participants]	6	12	27	21	33	13	9	13
Summary of primary PK parameters for canakinumab - Cmax (h) (units: h) Geometric Mean (Geometric Coefficient of Variation)								

Period 1 Cycle 1 Day 1	10400 (47.1%)	20300 (67.0%)	40900 (85.5%)	47800 (36.2%)	42900 (42.2%)	35900 (73.1%)	44400 (35.8%)	36700 (26.6%)

Summary of primary PK parameters for CJM112 - AUClast (h*ug/mL)

(Time Frame: Period 1 Cycle 1 Day 1)

	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W
Arm/Group Description	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W
Number of Participants Analyzed [units: participants]	6	5	6	6	2	5	5	6
Summary of primary PK parameters for CJM112 - AUClast (h*ug/mL) (units: h*ug/mL) Geometric Mean (Geometric Coefficient of Variation)								
Period 1 Cycle 1 Day 1	1280000 (39.6 %)	2120000 (30.5 %)	6980000 (33.9 %)	14400000 (26.5 %)	15100000 (12.0 %)	27600000 (33.4 %)	19000000 (45.5 %)	47300000 (36.8 %)

Summary of primary PK parameters for CJM112 - Cmax (h)

(Time Frame: Period 1 Cycle 1 Day 1)

	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W
Arm/Group Description	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W
Number of Participants Analyzed [units: participants]	6	5	6	6	2	5	5	6
Summary of primary PK parameters for CJM112 - Cmax (h) (units: h) Geometric Mean (Geometric Coefficient of Variation)								
Period 1 Cycle 1 Day 1	8210 (49.9%)	16000 (17.5%)	44500 (25.4%)	88800 (27.2%)	116000 (17.1%)	189000 (21.2%)	121000 (61.6%)	290000 (28.0%)

Summary of primary PK parameters for trametinib - AUClast (h*ug/mL)

(Time Frame: Period 1 Cycle 1 Day 1 and Period 1 Cycle 2 Day 1 (Day 29))

	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off
Arm/Group Description	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3	PDR + TMT 1.5 mg QD, 2	PDR + TMT 1.5 mg QD, 3

			Weeks on/1 Week off	Weeks on/2 Weeks off	Weeks on/1 Week off
Number of Participants Analyzed [units: participants]	6	11	10	8	6
Summary of primary PK parameters for trametinib - AUClast (h*ug/mL) (units: h*ug/mL) Geometric Mean (Geometric Coefficient of Variation)					
Period 1 Cycle 1 Day 1	3.25 (151.4%)	11.0 (47.3%)	10.9 (62.4%)	16.9 (66.0%)	14.2 (70.7%)
Period 1 Cycle 2 Day 1 (n=3,9,8,7,3)	27.7 (63.6%)	75.9 (28.0%)	25.4 (54.5%)	28.1 (35.0%)	57.5 (85.0%)

Summary of primary PK parameters for trametinib - Cmax (h)

(Time Frame: Period 1 Cycle 1 Day 1 and Period 1 Cycle 2 Day 1 (Day 29))

	PDR + TMT 0.5mg QD	**PDR + TMT 1mg QD**	**PDR + TMT 1mg QD, 3 Weeks on/1 Week off**	**PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off**	**PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off**
Arm/Group Description	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off
Number of Participants Analyzed [units: participants]	6	11	10	8	6
Summary of primary PK parameters for trametinib - Cmax (h) (units: h) Geometric Mean (Geometric Coefficient of Variation)					
Period 1 Cycle 1 Day 1	1.19 (107.0%)	3.45 (68.0%)	3.68 (77.0%)	5.56 (90.2%)	3.73 (86.0%)
Period 1 Cycle 2 Day 1 (n=3,9,8,7,3)	6.04 (81.6%)	15.9 (34.5%)	5.96 (64.2%)	8.19 (52.8%)	13.0 (107.9%)

Summary of primary PK parameters for EGF816 - AUClast (h*ug/mL)

(Time Frame: Period 1 Cycle 1 Day 1)

	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD
Arm/Group Description	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD
Number of Participants Analyzed [units: participants]	6	22
Summary of primary PK parameters for EGF816 - AUClast (h*ug/mL) (units: h*ug/mL) Geometric Mean (Geometric Coefficient of Variation)		
Period 1 Cycle 1 Day 1	263 (54.0%)	539 (110.0%)

Summary of primary PK parameters for EGF816 - Cmax (h)

(Time Frame: Period 1 Cycle 1 Day 1)

	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD
Arm/Group Description	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD
Number of Participants Analyzed [units: participants]	6	22
Summary of primary PK parameters for EGF816 - Cmax (h) (units: h)		

Geometric Mean (Geometric Coefficient of Variation)		
Period 1 Cycle 1 Day 1	71.2 (41.0%)	139 (92.6%)

Anti-Drug Antibody incidence - PDR001

(Time Frame: Baseline)

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W
Number of Participants Analyzed [units: participants]	5	9	22	15	25	4	5	5	6	6
Subjects with ADA-negative sample at baseline	5 (100%)	9 (100%)	20 (90.91%)	14 (93.33%)	25 (100%)	4 (100%)	5 (100%)	5 (100%)	6 (100%)	4 (66.67%)
Subjects with ADA-positive sample at baseline	0 (%)	0 (%)	2 (9.09%)	1 (6.67%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (33.33%)

ADA-negative	3 (60%)	9 (100%)	17 (77.27%)	13 (86.67%)	20 (80%)	4 (100%)	5 (100%)	5 (100%)	5 (83.33%)	3 (50%)
ADA-positive (i.e., ADA incidence)	2 (40%)	0 (%)	3 (13.64%)	1 (6.67%)	5 (20%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	1 (16.67%)
Treatment-induced ADA-positive	2 (40%)	0 (%)	3 (13.64%)	1 (6.67%)	5 (20%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	1 (16.67%)

Anti-Drug Antibody incidence - PDR001

(Time Frame: Baseline)

Part 2 of 2

	PDR + CJM 900mg Q4W	**PDR + CJM 900mg Q2W**	**PDR + CJM 1200mg Q4W**	**PDR + TMT 0.5mg QD**	**PDR + TMT 1mg QD**	**PDR + TMT 1mg QD, 3 Weeks on/1 Week off**	**PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off**	**PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off**	**PDR + EGF816 25mg QD**	**PDR + EGF816 50mg QD**
Arm/Group Description	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD
Number of Participants Analyzed [units: participants]	4	6	3	6	8	7	7	4	4	19

Subjects with ADA-negative sample at baseline	3 (75%)	6 (100%)	3 (100%)	6 (100%)	8 (100%)	7 (100%)	7 (100%)	4 (100%)	4 (100%)	19 (100%)
Subjects with ADA-positive sample at baseline	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
ADA-negative	3 (75%)	6 (100%)	3 (100%)	5 (83.33%)	7 (87.5%)	3 (42.86%)	6 (85.71%)	4 (100%)	4 (100%)	12 (63.16%)
ADA-positive (i.e., ADA incidence)	0 (%)	0 (%)	0 (%)	1 (16.67%)	1 (12.5%)	4 (57.14%)	1 (14.29%)	0 (%)	0 (%)	7 (36.84%)
Treatment-induced ADA-positive	0 (%)	0 (%)	0 (%)	1 (16.67%)	1 (12.5%)	4 (57.14%)	1 (14.29%)	0 (%)	0 (%)	7 (36.84%)

Anti-Drug Antibody incidence - canakinumab

(Time Frame: Baseline)

	PDR + ACZ 100mg Q8W	**PDR + ACZ 300mg Q8W**	**PDR + ACZ RDE TNBC**	**PDR + ACZ RDE NSCLC**	**PDR + ACZ RDE CRC**
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed [units: participants]	5	9	22	15	25

Anti-Drug Antibody incidence - canakinumab (units: Participants) Count of Participants (Not Applicable)					
Subjects with ADA-negative sample at baseline	1 (20%)	0 (%)	0 (%)	1 (6.67%)	0 (%)
ADA-negative	1 (20%)	0 (%)	0 (%)	1 (6.67%)	0 (%)

Anti-Drug Antibody incidence - CJM112

(Time Frame: Baseline)

	PDR + CJM 25mg Q4W	**PDR + CJM 75mg Q4W**	**PDR + CJM 225mg Q4W**	**PDR + CJM 450mg Q4W**	**PDR + CJM 450mg Q2W**	**PDR + CJM 900mg Q4W**	**PDR + CJM 900mg Q2W**	**PDR + CJM 1200mg Q4W**
Arm/Group Description	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W	PDR + CJM 1200mg Q4W
Number of Participants Analyzed [units: participants]	4	5	5	6	6	4	6	3
Anti-Drug Antibody incidence - CJM112 (units: participants) Count of Participants (Not Applicable)								
Subjects with ADA-negative sample at baseline	2 (50%)	4 (80%)	2 (40%)	1 (16.67%)	0 (%)	1 (25%)	0 (%)	0 (%)
Subjects with ADA-positive sample at baseline	0 (%)	0 (%)	0 (%)	0 (%)	3 (50%)	0 (%)	0 (%)	0 (%)
ADA-negative	1 (25%)	3 (60%)	0 (%)	1 (16.67%)	0 (%)	0 (%)	0 (%)	0 (%)
ADA-positive (i.e., ADA incidence)	1 (25%)	1 (20%)	2 (40%)	0 (%)	0 (%)	1 (25%)	0 (%)	0 (%)

Treatment-induced ADA-positive [1]	1 (25%)	1 (20%)	2 (40%)	0 (%)	0 (%)	1 (25%)	0 (%)	0 (%)

Summary statistics for percent marker area for CD8 from tumor samples

(Time Frame: Baseline and Cycle 3)

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Number of Participants Analyzed [units: participants]	6	11	27	17	29	6	6	5	5	4	5	6
Baseline Median	0.13 (0.0 to 2.5)	0.35 (0.0 to 1.1)	0.26 (0.0 to 4.0)	1.39 (0.2 to 8.0)	0.25 (0.0 to 2.2)	0.95 (0.2 to 1.6)	0.71 (0.2 to 2.3)	0.81 (0.2 to 3.7)	0.17 (0.0 to 2.5)	2.86 (0.4 to 7.6)	0.16 (0.0 to 1.4)	0.30 (0.0 to 2.7)
Cycle 3 Median (n=3,2,4,6,9,1,1,0,3,3,0,3,1,3,3,3,2,0,1,4,7,6,11)	1.25 (0.4 to 3.6)	0.47 (0.3 to 0.7)	2.60 (1.7 to 8.9)	2.03 (0.3 to 7.4)	0.76 (0.0 to 14.6)	1.05 (1.05 to 1.05)	0.44 (0.44 to 0.44)		1.60 (1.6 to 6.3)	0.49 (0.2 to 2.5)		1.79 (0.1 to 16.2)

Summary statistics for percent marker area for CD8 from tumor samples

(Time Frame: Baseline and Cycle 3)

Part 2 of 2

	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed [units: participants]	5	5	10	8	8	5	5	23	17	12	18
Baseline Median	0.37 (0.2 to 2.7)	1.45 (0.3 to 5.9)	0.45 (0.0 to 3.5)	0.17 (0.0 to 1.3)	0.20 (0.0 to 2.6)	1.13 (0.1 to 4.4)	0.30 (0.0 to 2.5)	0.48 (0.1 to 5.9)	0.30 (0.0 to 7.3)	0.51 (0.2 to 5.2)	0.38 (0.0 to 2.4)
Cycle 3 Median (n=3,2,4,6,9,1,1,0,3,3,0,3,1,3,3,3,2,0,1,4,7,6,11)	0.65 (0.65 to 0.65)	2.02 (0.1 to 13.0)	2.58 (1.0 to 10.6)	2.94 (1.8 to 3.2)	2.79 (1.5 to 4.1)		1.95 (1.95 to 1.95)	1.68 (0.3 to 3.3)	1.08 (0.1 to 8.1)	1.34 (0.1 to 14.7)	0.20 (0.0 to 1.3)

Summary statistics for histopathology of intrastromal tumor infiltrating lymphocytes (TILs) by H&E stain

(Time Frame: Baseline and Cycle 3)

Part 1 of 2

	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 1200mg Q4W
Arm/Group Description	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 1200mg Q4W
Number of Participants Analyzed [units: participants]	2	29	2	2	2	3	3	1
Baseline Median	1.0 (1 to 1)	2.0 (0 to 5)	3.0 (1 to 5)	1.0 (1 to 1)	2.0 (1 to 3)	1.0 (1 to 1)	1.0 (0 to 5)	2.0 (2 to 2)
Cycle 3 Median (n=0,4,0,1,0,1,1,0,1,1,0,1,0,0,0,7)		9.0 (2 to 10)		5.0 (5 to 5)		1.0 (1 to 1)	4.0 (4 to 4)	

Summary statistics for histopathology of intrastromal tumor infiltrating lymphocytes (TILs) by H&E stain

(Time Frame: Baseline and Cycle 3)

Part 2 of 2

	PDR + TMT	PDR + TMT	PDR + TMT 1mg QD, 3	PDR + TMT 1.5 mg QD, 2	PDR + TMT 1.5 mg QD, 3	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	s.a. ACZ RDE TNBC

	0.5mg QD	1mg QD	Weeks on/1 Week off	Weeks on/2 Weeks off	Weeks on/1 Week off			
Arm/Group Description	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)
Number of Participants Analyzed [units: participants]	3	2	1	2	1	2	6	18
Baseline Median	2.0 (0 to 5)	3.0 (1 to 5)	1.0 (1 to 1)	2.0 (1 to 3)	1.0 (1 to 1)	2.0 (2 to 2)	4.0 (0 to 15)	3.0 (1 to 5)
Cycle 3 Median (n=0,4,0,1,0,1,1,0,1,1,0,1,0,0,0,7)	5.0 (5 to 5)	7.0 (7 to 7)		2.0 (2 to 2)				2.0 (1 to 5)

All Collected Deaths

(Time Frame: From treatment start up to a maximum time frame of 116 weeks (approx. 2.2 yrs.) for on-treatment deaths and 182 weeks (approx. 3.5 years) for total deaths.))

Part 1 of 2

	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	PDR + ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	PDR + ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Number of Participants Analyzed [units: participants]	6	13	32	22	34	6	6	6	6	6	5	6
On-treatment Deaths	0 (%)	1 (7.69%)	3 (9.38%)	1 (4.55%)	1 (2.94%)	1 (16.67%)	1 (16.67%)	1 (16.67%)	0 (%)	1 (16.67%)	0 (%)	0 (%)
All Deaths	1 (16.67%)	6 (46.15%)	18 (56.25%)	12 (54.55%)	22 (64.71%)	4 (66.67%)	3 (50%)	3 (50%)	0 (%)	4 (66.67%)	3 (60%)	3 (50%)

All Collected Deaths

(Time Frame: From treatment start up to a maximum time frame of 116 weeks (approx. 2.2 yrs.) for on-treatment deaths and 182 weeks (approx. 3.5 years) for total deaths.))

Part 2 of 2

	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD of C1	PDR + EGF816 50mg QD > C1	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/2 Weeks off	PDR + TMT 1.5 mg QD, 3 Weeks on/1 Week off	PDR + EGF816 25mg QD	PDR + EGF816 50mg QD of C1	PDR + EGF816 50mg QD > C1	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Triple Negative Breast Cancer (TNBC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Non-Small Cell Lung Cancer (NSCLC)	Single agent (s.a.) ACZ Recommended Dose for Expansion (RDE) Colorectal Cancer (CRC)
Number of Participants Analyzed [units: participants]	6	7	12	11	9	6	6	13	10	20	15	20
On-treatment Deaths	0 (%)	1 (14.29%)	1 (8.33%)	1 (9.09%)	1 (11.11%)	1 (16.67%)	1 (16.67%)	3 (23.08%)	3 (30%)	4 (20%)	0 (%)	1 (5%)
All Deaths	1 (16.67%)	4 (57.14%)	1 (8.33%)	6 (54.55%)	2 (22.22%)	4 (66.67%)	5 (83.33%)	8 (61.54%)	6 (60%)	16 (80%)	7 (46.67%)	14 (70%)

Safety Results

All-Cause Mortality - Part 1 of 2

(Time Frame: Adverse events were reported from first dose of study treatment until end of study treatment plus 30 days post treatment, up to a maximum time frame of 116.3 weeks (approx. 2.2 years).)

	PDR + ACZ 100mg Q8W N = 6	PDR + ACZ 300mg Q8W N = 13	PDR + ACZ RDE TNBC N = 32	PDR + ACZ RDE NSCLC N = 22	PDR + ACZ RDE CRC N = 34	PDR + CJM 25mg Q4W N = 6	PDR + CJM 75mg Q4W N = 6	PDR + CJM 225mg Q4W N = 6	PDR + CJM 450mg Q4W N = 6	PDR + CJM 450mg Q2W N = 6	PDR + CJM 900mg Q4W N = 5	PDR + CJM 900mg Q2W N = 6
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Total participants affected	0 (0.00%)	1 (7.69%)	3 (9.38%)	1 (4.55%)	1 (2.94%)	1 (16.67%)	1 (16.67%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)

	PDR + ACZ 100mg Q8W N = 6	PDR + ACZ 300mg Q8W N = 13	PDR + ACZ RDE TNBC N = 32	PDR + ACZ RDE NSCLC N = 22	PDR + ACZ RDE CRC N = 34	PDR + CJM 25mg Q4W N = 6	PDR + CJM 75mg Q4W N = 6	PDR + CJM 225mg Q4W N = 6	PDR + CJM 450mg Q4W N = 6	PDR + CJM 450mg Q2W N = 6	PDR + CJM 900mg Q4W N = 5	PDR + CJM 900mg Q2W N = 6
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W

Total participants affected	0 (0.00%)	1 (7.69%)	3 (9.38%)	1 (4.55%)	1 (2.94%)	1 (16.67%)	1 (16.67%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)

All-Cause Mortality - Part 2 of 2

(Time Frame: Adverse events were reported from first dose of study treatment until end of study treatment plus 30 days post treatment, up to a maximum time frame of 116.3 weeks (approx. 2.2 years).)

	PDR + CJM 1200mg Q4W N = 6	**PDR + TMT 0.5mg QD N = 7**	**PDR + TMT 1mg QD N = 12**	**PDR + TMT 1mg QD, 3 Weeks on/ 1 Week off N = 11**	**PDR + TMT 1.5 mg QD, 3 Weeks on/ 1 Week off N = 6**	**PDR + TMT 1.5 mg QD, 2 Weeks on/ 2 Weeks off N = 9**	**PDR + EGF816 25mg QD of C1 N = 6**	**PDR + EGF816 50mg QD of C1 N = 13**	**PDR + EGF816 50mg QD more than C1 N = 10**	**s.a. ACZ RDE TNBC N = 20**	**s.a. ACZ RDE NSCLC N = 15**	**s.a. ACZ RDE CRC N = 20**	**All Subjects N = 283**
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/ 1 Week off	PDR + TMT 1.5 mg QD, 3 Weeks on/ 1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/ 2 Weeks off	PDR + EGF816 25mg QD of C1	PDR + EGF816 50mg QD of C1	PDR + EGF816 50mg QD more than C1	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC	All Subjects
Total participants affected	0 (0.00%)	1 (14.29%)	1 (8.33%)	1 (9.09%)	1 (16.67%)	1 (11.11%)	1 (16.67%)	3 (23.08%)	3 (30.00%)	4 (20.00%)	0 (0.00%)	1 (5.00%)	27 (9.54%)

	PDR + CJM 1200m	**PDR + TMT 0.5mg**	**PDR + TMT 1mg**	**PDR + TMT 1mg**	**PDR + TMT 1.5 mg QD,**	**PDR + TMT 1.5 mg QD,**	**PDR + EGF816 25mg**	**PDR + EGF816 50mg**	**PDR + EGF816 50mg**	**s.a. ACZ RDE**	**s.a. ACZ RDE**	**s.a. ACZ RDE**	**All Subject**

	g Q4W N = 6	QD N = 7	QD N = 12	QD, 3 Weeks on/ 1 Week off N = 11	3 Weeks on/ 1 Week off N = 6	2 Weeks on/ 2 Weeks off N = 9	QD of C1 N = 6	QD of C1 N = 13	QD more than C1 N = 10	TNBC N = 20	NSCLC N = 15	CRC N = 20	s N = 283
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/ 1 Week off	PDR + TMT 1.5 mg QD, 3 Weeks on/ 1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/ 2 Weeks off	PDR + EGF816 25mg QD of C1	PDR + EGF816 50mg QD of C1	PDR + EGF816 50mg QD more than C1	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC	All Subjects
Total participants affected	0 (0.00 %)	1 (14.29 %)	1 (8.33 %)	1 (9.09 %)	1 (16.67 %)	1 (11.11 %)	1 (16.67 %)	3 (23.08 %)	3 (30.00 %)	4 (20.00 %)	0 (0.00 %)	1 (5.00 %)	27 (9.54 %)

Serious Adverse Events by System Organ Class - Part 1 of 2

Time Frame	Adverse events were reported from first dose of study treatment until end of study treatment period plus 30 days post treatment, up to a maximum time frame of 116.3 weeks (approx. 2.2 years).)
Source Vocabulary for Table Default	MedDRA (24.0)
Assessment Type for Table Default	Systematic Assessment

	PDR + ACZ	PDR + ACZ	PDR + ACZ	PDR + ACZ	PDR + ACZ	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM	PDR + CJM

	100mg Q8W N = 6	300mg Q8W N = 13	RDE TNBC N = 32	RDE NSCLC N = 22	RDE CRC N = 34	25mg Q4W N = 6	75mg Q4W N = 6	225mg Q4W N = 6	450mg Q4W N = 6	450mg Q2W N = 6	900mg Q4W N = 5	900mg Q2W N = 6
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Total participants affected	1 (16.67 %)	5 (38.46 %)	8 (25.00 %)	9 (40.91 %)	13 (38.24 %)	1 (16.67 %)	5 (83.33 %)	2 (33.33 %)	3 (50.00 %)	4 (66.67 %)	3 (60.00 %)	1 (16.67 %)
Blood and lymphatic system disorders												
Anaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thrombocytopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cardiac disorders												
Cardiac tamponade	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Left ventricular dysfunction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pericardial effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pericarditis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Endocrine disorders												
Adrenal insufficiency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal disorders												

Abdominal distension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal pain	0 (0.00 %)	0 (0.00 %)	1 (3.13 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal pain upper	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (4.55 %)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ascites	0 (0.00 %)	0 (0.00 %)	1 (3.13 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Autoimmune colitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)
Autoimmune pancreatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (4.55 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diarrhoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Enterocutaneous fistula	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Intestinal obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (5.88%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Large intestinal obstruction	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nausea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pancreatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rectal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Small intestinal obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Subileus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Vomiting	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (5.88%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
General disorders and administration site conditions												
Fatigue	0 (0.00 %)	1 (7.69 %)	1 (3.13 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Non-cardiac chest pain	0 (0.00 %)	0 (0.00 %)	2 (6.25 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oedema peripheral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pain	0 (0.00 %)	0 (0.00 %)	1 (3.13 %)	1 (4.55 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pyrexia	0 (0.00 %)	0 (0.00 %)	2 (6.25 %)	1 (4.55 %)	1 (2.94%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Hepatobiliary disorders												
Biliary obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cholecystitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatic failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatobiliary disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatomegaly	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypertransaminasaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (4.55 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Jaundice	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Infections and infestations												
Cellulitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cystitis	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Disseminated varicella zoster virus infection	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Escherichia sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastroenteritis viral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infected lymphocele	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Influenza	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Liver abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Retroperitoneal abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Streptococcal sepsis	0 (0.00 %)	0 (0.00 %)	1 (3.13 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Systemic infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract infection	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Injury, poisoning and procedural complications												
Femur fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infusion related reaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Spinal compression fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Investigations												
Alanine aminotransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Aspartate aminotransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Bilirubin conjugated increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Blood bilirubin increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Gamma-glutamyltransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Lipase increased	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metabolism and nutrition disorders												
Dehydration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Type 1 diabetes mellitus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal and connective tissue disorders												
Bone pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)												
Cancer pain	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	1 (4.55 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infected neoplasm	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metastases to central nervous system	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tumour pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nervous system disorders												
Aphasia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Brachial plexopathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Cerebral haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cerebrovascular accident	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (4.55 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Dizziness	0 (0.00 %)	0 (0.00 %)	1 (3.13 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperaesthesia	0 (0.00 %)	0 (0.00 %)	1 (3.13 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Intercostal neuralgia	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Myasthenia gravis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neurological decompensation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Seizure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Transient ischaemic attack	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal and urinary disorders												
Acute kidney injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nephrolithiasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary incontinence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary retention	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory, thoracic and mediastinal disorders												
Acute respiratory failure	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bronchial obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Dyspnoea	0 (0.00 %)	0 (0.00 %)	1 (3.13 %)	1 (4.55 %)	1 (2.94%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Haemoptysis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (4.55 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lung disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Orthopnoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pleural effusion	0 (0.00 %)	0 (0.00 %)	1 (3.13 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pulmonary embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin and subcutaneous tissue disorders												
Erythema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vascular disorders												
Hypotension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (4.55 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypovolaemic shock	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Superior vena cava syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (4.55 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Part 2 of 2

Time Frame	Adverse events were reported from first dose of study treatment until end of study treatment period plus 30 days post treatment, up to a maximum time frame of 116.3 weeks (approx. 2.2 years).)
Source Vocabulary for Table Default	MedDRA (24.0)
Assessment Type for Table Default	Systematic Assessment

	PDR + CJM 1200mg Q4W N = 6	**PDR + TMT 0.5mg QD N = 7**	**PDR + TMT 1mg QD N = 12**	**PDR + TMT 1mg QD, 3 Weeks on/ 1 Week off N = 11**	**PDR + TMT 1.5 mg QD, 3 Weeks on/ 1 Week off N = 6**	**PDR + TMT 1.5 mg QD, 2 Weeks on/ 2 Weeks off N = 9**	**PDR + EGF81 6 25mg QD of C1 N = 6**	**PDR + EGF81 6 50mg QD of C1 N = 13**	**PDR + EGF81 6 50mg QD more than C1 N = 10**	**s.a. ACZ RDE TNBC N = 20**	**s.a. ACZ RDE NSCLC N = 15**	**s.a. ACZ RDE CRC N = 20**	**All Subjects N = 283**
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/ 1 Week off	PDR + TMT 1.5 mg QD, 3 Weeks on/ 1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/ 2 Weeks off	PDR + EGF81 6 25mg QD of C1	PDR + EGF81 6 50mg QD of C1	PDR + EGF81 6 50mg QD more than C1	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC	All Subjects
Total participants affected	2 (33.33%)	5 (71.43%)	4 (33.33%)	4 (36.36%)	4 (66.67%)	5 (55.56%)	2 (33.33%)	4 (30.77%)	2 (20.00%)	6 (30.00%)	4 (26.67%)	7 (35.00%)	104 (36.75%)
Blood and lymphatic system disorders													
Anaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)

Cardiac disorders													
Cardiac tamponade	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35%)
Left ventricular dysfunction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Pericardial effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35%)
Pericarditis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Endocrine disorders													
Adrenal insufficiency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Gastrointestinal disorders													
Abdominal distension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Abdominal pain	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06%)
Abdominal pain upper	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Ascites	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	1 (5.00 %)	4 (1.41%)
Autoimmune colitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Autoimmune pancreatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Diarrhoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35%)
Enterocutaneous fistula	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)

Gastrointestinal haemorrhage	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Intestinal obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	6 (2.12%)
Large intestinal obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Nausea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Pancreatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Rectal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Small intestinal obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Subileus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Vomiting	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06%)
General disorders and administration site conditions													
Fatigue	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Non-cardiac chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Oedema peripheral	0 (0.00 %)	1 (14.2 9%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06%)
Pyrexia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	7 (2.47%)

Hepatobiliary disorders													
Biliary obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Cholecystitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35%)
Hepatic failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Hepatobiliary disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Hepatomegaly	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Hypertransamin asaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Jaundice	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35%)
Infections and infestations													
Cellulitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Cystitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Disseminated varicella zoster virus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Escherichia sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Gastroenteritis viral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Infected lymphocele	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)

Influenza	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Liver abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35%)
Pneumonia	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (22.22%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41%)
Respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Retroperitoneal abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Streptococcal sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Systemic infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Urinary tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06%)
Injury, poisoning and procedural complications													
Femur fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Infusion related reaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Spinal compression fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Investigations													
Alanine aminotransferase increased	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41%)

Aspartate aminotransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Bilirubin conjugated increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Blood bilirubin increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (15.38%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06%)
Gamma-glutamyltransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06%)
Lipase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Metabolism and nutrition disorders													
Dehydration	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Type 1 diabetes mellitus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Musculoskeletal and connective tissue disorders													
Bone pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Musculoskeletal chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)													
Cancer pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)

Infected neoplasm	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Metastases to central nervous system	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Tumour pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Nervous system disorders													
Aphasia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Brachial plexopathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Cerebral haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Cerebrovascular accident	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Dizziness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Hyperaesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Intercostal neuralgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Myasthenia gravis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Neurological decompensation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35%)
Seizure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35%)
Transient ischaemic attack	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)

Renal and urinary disorders													
Acute kidney injury	0 (0.00 %)	1 (14.29%)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41%)
Nephrolithiasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Urinary incontinence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Urinary retention	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Respiratory, thoracic and mediastinal disorders													
Acute respiratory failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Bronchial obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Dyspnoea	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	1 (9.09 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	9 (3.18%)
Haemoptysis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Lung disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Orthopnoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Pleural effusion	0 (0.00 %)	2 (28.57%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (10.00%)	1 (6.67 %)	1 (5.00 %)	7 (2.47%)
Pneumonitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)

Pulmonary embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Respiratory failure	0 (0.00 %)	1 (14.2 9%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	1 (5.00 %)	5 (1.77%)
Skin and subcutaneous tissue disorders													
Erythema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Vascular disorders													
Hypotension	0 (0.00 %)	1 (14.2 9%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71%)
Hypovolaemic shock	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)
Superior vena cava syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35%)

Other Adverse Events by System Organ Class - Part 1 of 2

Time Frame	Adverse events were reported from first dose of study treatment until end of study treatment period plus 30 days post treatment, up to a maximum time frame of 116.3 weeks (approx. 2.2 years).
Source Vocabulary for Table Default	MedDRA (24.0)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	0%

	PDR + ACZ 100mg Q8W N = 6	PDR + ACZ 300mg Q8W N = 13	PDR + ACZ RDE TNBC N = 32	PDR + ACZ RDE NSCLC N = 22	PDR + ACZ RDE CRC N = 34	PDR + CJM 25mg Q4W N = 6	PDR + CJM 75mg Q4W N = 6	PDR + CJM 225mg Q4W N = 6	PDR + CJM 450mg Q4W N = 6	PDR + CJM 450mg Q2W N = 6	PDR + CJM 900mg Q4W N = 5	PDR + CJM 900mg Q2W N = 6
Arm/Group Description	PDR + ACZ 100mg Q8W	PDR + ACZ 300mg Q8W	PDR + ACZ RDE TNBC	PDR + ACZ RDE NSCLC	PDR + ACZ RDE CRC	PDR + CJM 25mg Q4W	PDR + CJM 75mg Q4W	PDR + CJM 225mg Q4W	PDR + CJM 450mg Q4W	PDR + CJM 450mg Q2W	PDR + CJM 900mg Q4W	PDR + CJM 900mg Q2W
Total participants affected	5 (83.33%)	13 (100.00%)	32 (100.00%)	22 (100.00%)	34 (100.00%)	6 (100.00%)	6 (100.00%)	5 (83.33%)	6 (100.00%)	6 (100.00%)	5 (100.00%)	6 (100.00%)
Blood and lymphatic system disorders												
Anaemia	4 (66.67%)	1 (7.69%)	5 (15.63%)	4 (18.18%)	7 (20.59%)	2 (33.33%)	2 (33.33%)	2 (33.33%)	1 (16.67%)	2 (33.33%)	3 (60.00%)	0 (0.00%)
Leukopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphadenopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphopenia	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutrophilia	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombocytopenia	1 (16.67%)	0 (0.00%)	2 (6.25%)	1 (4.55%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombocytosis	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders												

Angina pectoris	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Palpitations	1 (16.6 7%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pericardial effusion	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Right ventricular dysfunction	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sinus tachycardia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tachycardia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	1 (16.67 %)
Ear and labyrinth disorders												
Cerumen impaction	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Deafness	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear discomfort	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear pain	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoacusis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tinnitus	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vertigo	0 (0.00 %)	1 (7.69%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Endocrine disorders												
Hyperthyroidism	0 (0.00 %)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)

Hypothyroidism	0 (0.00 %)	1 (7.69%)	3 (9.38%)	1 (4.55%)	2 (5.88%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (16.67 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Eye disorders												
Blepharitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cataract	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diplopia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dry eye	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eye pruritus	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eyelid ptosis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Glaucoma	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Keratitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lacrimation increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ocular discomfort	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Uveitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vision blurred	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Visual impairment	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vitreous detachment	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Gastrointestinal disorders												
Abdominal discomfort	0 (0.00 %)	0 (0.00%)	2 (6.25%)	0 (0.00%)	2 (5.88%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal distension	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal mass	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal pain	0 (0.00 %)	1 (7.69%)	1 (3.13%)	3 (13.64 %)	6 (17.65 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal pain upper	0 (0.00 %)	0 (0.00%)	0 (0.00%)	4 (18.18 %)	2 (5.88%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anal pruritus	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ascites	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Constipation	0 (0.00 %)	1 (7.69%)	11 (34.38 %)	4 (18.18 %)	3 (8.82%)	1 (16.67 %)	3 (50.00 %)	1 (16.6 7%)	2 (33.33 %)	1 (16.67 %)	0 (0.00 %)	1 (16.67 %)
Diarrhoea	1 (16.6 7%)	1 (7.69%)	2 (6.25%)	2 (9.09%)	4 (11.76 %)	1 (16.67 %)	0 (0.00 %)	2 (33.3 3%)	1 (16.67 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Dry mouth	0 (0.00 %)	0 (0.00%)	2 (6.25%)	4 (18.18 %)	2 (5.88%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)
Dyspepsia	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysphagia	1 (16.6 7%)	0 (0.00%)	2 (6.25%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Flatulence	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal haemorrhage	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Gastrooesophageal reflux disease	0 (0.00 %)	1 (7.69%)	1 (3.13%)	1 (4.55%)	2 (5.88%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gingival bleeding	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haemorrhoids	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperaesthesia teeth	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ileus paralytic	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Intra-abdominal haematoma	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lip blister	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nausea	1 (16.67%)	3 (23.08 %)	9 (28.13 %)	6 (27.27 %)	7 (20.59 %)	2 (33.33 %)	1 (16.67 %)	0 (0.00 %)	1 (16.67 %)	1 (16.67 %)	1 (20.00 %)	0 (0.00 %)
Odynophagia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oesophagitis	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral pruritus	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Proctalgia	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rectal haemorrhage	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rectal ulcer	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Stomatitis	0 (0.00 %)	0 (0.00%)	2 (6.25%)	1 (4.55%)	1 (2.94%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Vomiting	0 (0.00 %)	2 (15.38 %)	11 (34.38 %)	3 (13.64 %)	7 (20.59 %)	1 (16.67 %)	2 (33.33 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
General disorders and administration site conditions												
Asthenia	0 (0.00 %)	1 (7.69%)	8 (25.00 %)	3 (13.64 %)	9 (26.47 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)
Axillary pain	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Chest discomfort	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Chills	1 (16.6 7%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Face oedema	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Facial pain	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Fatigue	2 (33.3 3%)	3 (23.08 %)	7 (21.88 %)	6 (27.27 %)	6 (17.65 %)	3 (50.00 %)	2 (33.33 %)	1 (16.6 7%)	1 (16.67 %)	1 (16.67 %)	2 (40.00 %)	1 (16.67 %)
Gait disturbance	0 (0.00 %)	1 (7.69%)	0 (0.00%)	1 (4.55%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Generalised oedema	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Inflammatory pain	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Influenza like illness	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infusion site rash	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Localised oedema	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Malaise	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nodule	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Non-cardiac chest pain	0 (0.00 %)	1 (7.69%)	1 (3.13%)	3 (13.64 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oedema peripheral	0 (0.00 %)	3 (23.08 %)	5 (15.63 %)	3 (13.64 %)	5 (14.71 %)	1 (16.67 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (33.33 %)
Pain	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Peripheral swelling	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pyrexia	1 (16.6 7%)	1 (7.69%)	1 (3.13%)	2 (9.09%)	4 (11.76 %)	0 (0.00 %)	1 (16.67 %)	1 (16.6 7%)	1 (16.67 %)	2 (33.33 %)	3 (60.00 %)	0 (0.00 %)
Xerosis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatobiliary disorders												
Cholangitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Cholestasis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatic cytolysis	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Hepatic pain	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperbilirubinaemia	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypertransaminasaemia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	2 (9.09%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Immune-mediated hepatitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Immune system disorders												
Seasonal allergy	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infections and infestations												
Bronchitis	0 (0.00 %)	0 (0.00%)	1 (3.13%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cellulitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	1 (2.94%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cholangitis infective	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Conjunctivitis	0 (0.00 %)	0 (0.00%)	2 (6.25%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cystitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Escherichia sepsis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Folliculitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fungal skin infection	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastroenteritis	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastroenteritis viral	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Herpes zoster	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Hordeolum	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infection	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infectious pleural effusion	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Influenza	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)
Lip infection	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Localised infection	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lower respiratory tract infection	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nasopharyngitis	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Onychomycosis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral candidiasis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral fungal infection	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral herpes	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Paronychia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia	1 (16.6 7%)	1 (7.69%)	0 (0.00%)	1 (4.55%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia bacterial	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Postoperative wound infection	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Pyelonephritis	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory tract infection	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rhinitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	2 (9.09%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sinusitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin infection	0 (0.00 %)	1 (7.69%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Spinal cord infection	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Systemic infection	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tooth abscess	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Tracheitis	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Upper respiratory tract infection	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract infection	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Vaginal infection	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vulvovaginal mycotic infection	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injury, poisoning and procedural complications												

Fall	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Forearm fracture	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lumbar vertebral fracture	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Multiple fractures	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Overdose	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Procedural pneumothorax	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rib fracture	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tooth fracture	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Wound haemorrhage	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Investigations												
Alanine aminotransferase increased	0 (0.00 %)	2 (15.38 %)	5 (15.63 %)	1 (4.55%)	7 (20.59 %)	1 (16.67 %)	2 (33.33 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Amylase decreased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Amylase increased	0 (0.00 %)	1 (7.69%)	1 (3.13%)	1 (4.55%)	3 (8.82%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Aspartate aminotransferase increased	0 (0.00 %)	3 (23.08 %)	4 (12.50 %)	2 (9.09%)	8 (23.53 %)	2 (33.33 %)	1 (16.67 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Bilirubin conjugated	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Bilirubin conjugated increased	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Blood albumin decreased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood alkaline phosphatase increased	1 (16.6 7%)	1 (7.69%)	4 (12.50 %)	0 (0.00%)	4 (11.76 %)	1 (16.67 %)	1 (16.67 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Blood bicarbonate increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood bilirubin	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood bilirubin increased	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	5 (14.71 %)	0 (0.00 %)	1 (16.67 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	2 (40.00 %)	0 (0.00 %)
Blood calcium decreased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood chloride decreased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood cholesterol increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood creatine increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood creatine phosphokinase increased	0 (0.00 %)	1 (7.69%)	1 (3.13%)	1 (4.55%)	2 (5.88%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Blood creatinine increased	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	1 (2.94%)	1 (16.67 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood glucose increased	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Blood lactate dehydrogenase increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood magnesium decreased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Blood potassium increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood pressure increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood thyroid stimulating hormone increased	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood urea increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood uric acid increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
C-reactive protein increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Creatinine renal clearance decreased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ejection fraction decreased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Electrocardiogram QT prolonged	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gamma-glutamyltransferase increased	0 (0.00 %)	0 (0.00%)	3 (9.38%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (20.00 %)	0 (0.00 %)
International normalised ratio increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)

Lipase increased	0 (0.00 %)	2 (15.38 %)	1 (3.13%)	1 (4.55%)	6 (17.65 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Lymphocyte count decreased	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neutrophil count decreased	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neutrophil count increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oxygen saturation decreased	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Platelet count decreased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Platelet count increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Protein total decreased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Protein total increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thyroxine free increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Transaminases increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Waist circumference increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Weight decreased	1 (16.6 7%)	0 (0.00%)	1 (3.13%)	1 (4.55%)	4 (11.76 %)	2 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Weight increased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
White blood cell count decreased	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Metabolism and nutrition disorders												
Appetite disorder	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Decreased appetite	3 (50.0 0%)	1 (7.69%)	8 (25.00 %)	11 (50.00 %)	8 (23.53 %)	3 (50.00 %)	1 (16.67 %)	0 (0.00 %)	1 (16.67 %)	1 (16.67 %)	1 (20.00 %)	1 (16.67 %)
Dehydration	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypercalcaemia	0 (0.00 %)	0 (0.00%)	3 (9.38%)	1 (4.55%)	2 (5.88%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Hyperchloraemia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypercreatinina emia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperglycaemia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Hyperkalaemia	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	2 (5.88%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypermagnesae mia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperphosphata emia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypertriglyceridaemia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperuricaemia	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoalbuminae mia	1 (16.6 7%)	1 (7.69%)	3 (9.38%)	1 (4.55%)	5 (14.71 %)	2 (33.33 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	2 (40.00 %)	0 (0.00 %)
Hypocalcaemia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (8.82%)	0 (0.00 %)	2 (33.33 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)

Hypoglycaemia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypokalaemia	0 (0.00 %)	0 (0.00%)	2 (6.25%)	1 (4.55%)	2 (5.88%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (16.67 %)	1 (20.00 %)	0 (0.00 %)
Hypomagnesaemia	0 (0.00 %)	0 (0.00%)	2 (6.25%)	2 (9.09%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (33.33 %)	0 (0.00 %)	0 (0.00 %)
Hyponatraemia	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	4 (11.76 %)	0 (0.00 %)	1 (16.67 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Hypophosphataemia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (20.00 %)	0 (0.00 %)
Hypoproteinaemia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metabolic acidosis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Polydipsia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal and connective tissue disorders												
Arthralgia	0 (0.00 %)	2 (15.38 %)	6 (18.75 %)	6 (27.27 %)	4 (11.76 %)	1 (16.67 %)	0 (0.00 %)	1 (16.6 7%)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Arthritis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Back pain	2 (33.33%)	4 (30.77 %)	2 (6.25%)	3 (13.64 %)	2 (5.88%)	2 (33.33 %)	1 (16.67 %)	1 (16.6 7%)	1 (16.67 %)	2 (33.33 %)	0 (0.00 %)	1 (16.67 %)
Bone pain	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Flank pain	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (20.00 %)	0 (0.00 %)
Groin pain	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Intervertebral disc disorder	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Limb discomfort	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Muscle spasms	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Muscular weakness	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal chest pain	0 (0.00 %)	1 (7.69%)	2 (6.25%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal pain	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Myalgia	1 (16.6 7%)	1 (7.69%)	2 (6.25%)	1 (4.55%)	1 (2.94%)	1 (16.67 %)	0 (0.00 %)	1 (16.6 7%)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	1 (16.67 %)
Neck pain	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Osteoporosis	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pain in extremity	0 (0.00 %)	1 (7.69%)	2 (6.25%)	1 (4.55%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pain in jaw	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Scoliosis	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Spinal pain	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tenosynovitis stenosans	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neoplasms benign, malignant and												

unspecified (incl cysts and polyps)													
Cancer pain	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	
Infected neoplasm	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	
Malignant pleural effusion	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	
Oncologic complication	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	
Tumour associated fever	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	
Tumour fistulisation	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	
Tumour haemorrhage	1 (16.6 7%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	
Tumour pain	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	2 (5.88%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	2 (33.33 %)	1 (16.67 %)	2 (40.00 %)	0 (0.00 %)	
Nervous system disorders													
Allodynia	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	
Aphasia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	
Balance disorder	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	
Cerebrovascular accident	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	
Dizziness	1 (16.6 7%)	2 (15.38 %)	1 (3.13%)	2 (9.09%)	1 (2.94%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	
Dysaesthesia	0 (0.00 %)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	

Dysarthria	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysgeusia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Encephalopathy	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Facial neuralgia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Facial paresis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Headache	1 (16.6 7%)	0 (0.00%)	3 (9.38%)	2 (9.09%)	3 (8.82%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)
Hemiparesis	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hepatic encephalopathy	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypersomnia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoaesthesia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Intracranial mass	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Loss of consciousness	0 (0.00 %)	0 (0.00%)	0 (0.00%)	2 (9.09%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Memory impairment	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Monoplegia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Myoclonus	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neuralgia	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Neuropathy peripheral	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neurotoxicity	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ophthalmic migraine	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Paraesthesia	1 (16.6 7%)	0 (0.00%)	1 (3.13%)	2 (9.09%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Paralysis recurrent laryngeal nerve	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Peripheral motor neuropathy	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Peripheral sensory neuropathy	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Peroneal nerve palsy	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sciatica	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Seizure	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sensorimotor disorder	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Somnolence	0 (0.00 %)	0 (0.00%)	3 (9.38%)	1 (4.55%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Spinal cord compression	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Syncope	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Taste disorder	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Tremor	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
VIth nerve disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vocal cord paralysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Product issues												
Device occlusion	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders												
Anxiety	1 (16.67%)	0 (0.00%)	3 (9.38%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)
Bradyphrenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Depressed mood	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Depression	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hallucination	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Insomnia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Irritability	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mental status changes	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Mixed anxiety and depressive disorder	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sleep disorder	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal and urinary disorders												
Acute kidney injury	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anuria	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cystitis noninfective	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysuria	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	1 (2.94%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Haematuria	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	3 (13.64 %)	0 (0.00%)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haemorrhage urinary tract	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hydronephrosis	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Micturition disorder	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Micturition urgency	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nocturia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pollakiuria	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Polyuria	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Renal colic	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal failure	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urethral discharge	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary incontinence	1 (16.6 7%)	1 (7.69%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary retention	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract disorder	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract obstruction	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Reproductive system and breast disorders												
Balanoposthitis	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Breast mass	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Breast oedema	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Breast pain	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Genital pain	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Intermenstrual bleeding	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Menstruation irregular	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Pelvic pain	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Perineal pain	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pruritus genital	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Scrotal oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Testicular oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vaginal discharge	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vaginal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vulvovaginal pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders												
Aphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atelectasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchial obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchospasm	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)
Catarrh	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chronic obstructive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

pulmonary disease												
Cough	1 (16.67%)	3 (23.08%)	3 (9.38%)	4 (18.18%)	7 (20.59%)	1 (16.67%)	2 (33.33%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)
Dry throat	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphonia	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	2 (5.88%)	1 (16.67%)	1 (16.67%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	2 (33.33%)	4 (30.77%)	9 (28.13%)	8 (36.36%)	9 (26.47%)	1 (16.67%)	2 (33.33%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	1 (20.00%)	0 (0.00%)
Dyspnoea exertional	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)
Epistaxis	0 (0.00%)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemoptysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hiccups	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lung disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasal congestion	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasal dryness	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oropharyngeal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Orthopnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)

Pharyngeal inflammation	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pleural effusion	0 (0.00 %)	1 (7.69%)	1 (3.13%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	2 (33.33 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Pleuritic pain	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonitis	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Productive cough	0 (0.00 %)	0 (0.00%)	2 (6.25%)	2 (9.09%)	2 (5.88%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pulmonary embolism	0 (0.00 %)	1 (7.69%)	0 (0.00%)	1 (4.55%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pulmonary hypertension	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory failure	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory tract congestion	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rhinalgia	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rhinitis allergic	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rhinorrhoea	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Throat irritation	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Wheezing	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin and subcutaneous tissue disorders												

Acne	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Actinic keratosis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cold sweat	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dermatitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dermatitis acneiform	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)
Dry skin	1 (16.6 7%)	1 (7.69%)	1 (3.13%)	3 (13.64 %)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eczema	0 (0.00 %)	0 (0.00%)	1 (3.13%)	2 (9.09%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Erythema	0 (0.00 %)	1 (7.69%)	0 (0.00%)	2 (9.09%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hirsutism	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperhidrosis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lichen planus	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nail dystrophy	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nail toxicity	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Night sweats	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Onychoclasis	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Onycholysis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Papule	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Petechiae	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pruritus	0 (0.00 %)	3 (23.08 %)	5 (15.63 %)	5 (22.73 %)	5 (14.71 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Rash	1 (16.6 7%)	0 (0.00%)	2 (6.25%)	3 (13.64 %)	3 (8.82%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Rash erythematous	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash macular	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash maculo-papular	0 (0.00 %)	1 (7.69%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)
Rash pruritic	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Seborrhoeic dermatitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin discolouration	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin exfoliation	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin fissures	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin ulcer	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Umbilical haemorrhage	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Xeroderma	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vascular disorders												

Deep vein thrombosis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Embolism	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Flushing	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)
Hot flush	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypertension	0 (0.00 %)	1 (7.69%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (20.00 %)	0 (0.00 %)
Hypotension	0 (0.00 %)	0 (0.00%)	0 (0.00%)	2 (9.09%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lymphoedema	0 (0.00 %)	0 (0.00%)	2 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Orthostatic hypotension	0 (0.00 %)	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Superior vena cava syndrome	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thrombophlebitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vasculitis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vena cava thrombosis	1 (16.6 7%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Venous thrombosis	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Venous thrombosis limb	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Other Adverse Events by System Organ Class - Part 2 of 2

Time Frame	Adverse events were reported from first dose of study treatment until end of study treatment period plus 30 days post treatment, up to a maximum time frame of 116.3 weeks (approx. 2.2 years).
Source Vocabulary for Table Default	MedDRA (24.0)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	0%

	PDR + CJM 1200mg Q4W N = 6	**PDR + TMT 0.5mg QD N = 7**	**PDR + TMT 1mg QD N = 12**	**PDR + TMT 1mg QD, 3 Weeks on/ 1 Week off N = 11**	**PDR + TMT 1.5 mg QD, 3 Weeks on/ 1 Week off N = 6**	**PDR + TMT 1.5 mg QD, 2 Weeks on/ 2 Weeks off N = 9**	**PDR + EGF816 25mg QD of C1 N = 6**	**PDR + EGF816 50mg QD of C1 N = 13**	**PDR + EGF816 50mg QD more than C1 N = 10**	**s.a. ACZ RDE TNBC N = 20**	**s.a. ACZ RDE NSCLC N = 15**	**s.a. ACZ RDE CRC N = 20**	**All Subjects N = 283**
Arm/Group Description	PDR + CJM 1200mg Q4W	PDR + TMT 0.5mg QD	PDR + TMT 1mg QD	PDR + TMT 1mg QD, 3 Weeks on/ 1 Week off	PDR + TMT 1.5 mg QD, 3 Weeks on/ 1 Week off	PDR + TMT 1.5 mg QD, 2 Weeks on/ 2 Weeks off	PDR + EGF816 25mg QD of C1	PDR + EGF816 50mg QD of C1	PDR + EGF816 50mg QD more than C1	s.a. ACZ RDE TNBC	s.a. ACZ RDE NSCLC	s.a. ACZ RDE CRC	All Subjects
Total participants affected	6 (100.00%)	7 (100.00%)	12 (100.00%)	10 (90.91%)	6 (100.00%)	9 (100.00%)	6 (100.00%)	12 (92.31%)	9 (90.00%)	20 (100.00%)	14 (93.33%)	19 (95.00%)	276 (97.53%)
Blood and lymphatic system disorders													
Anaemia	1 (16.67%)	1 (14.29%)	4 (33.33%)	5 (45.45%)	0 (0.00%)	3 (33.33%)	2 (33.33%)	2 (15.38%)	5 (50.00%)	7 (35.00%)	3 (20.00%)	0 (0.00%)	66 (23.32%)

Leukopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Lymphadenopathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (10.00%)	2 (0.71 %)
Lymphopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Neutropenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Neutrophilia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Thrombocytopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	7 (2.47 %)
Thrombocytosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Cardiac disorders													
Angina pectoris	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Palpitations	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Pericardial effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Right ventricular dysfunction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Sinus tachycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (15.38%)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Tachycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Ear and labyrinth disorders													

Cerumen impaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Deafness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Ear discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Ear pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Hypoacusis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	3 (1.06 %)
Tinnitus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Vertigo	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Endocrine disorders													
Hyperthyroidism	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (22.22%)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	8 (2.83 %)
Hypothyroidism	0 (0.00 %)	0 (0.00 %)	2 (16.67 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (10.00 %)	0 (0.00 %)	0 (0.00 %)	15 (5.30 %)
Eye disorders													
Blepharitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35 %)
Cataract	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35 %)
Diplopia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	1 (5.00 %)	2 (0.71 %)
Dry eye	0 (0.00 %)	2 (28.57%)	0 (0.00 %)	1 (9.09 %)	1 (16.67%)	2 (22.22%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	7 (2.47 %)
Eye pruritus	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

Eyelid ptosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Glaucoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	2 (0.71 %)
Keratitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35 %)
Lacrimation increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Ocular discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Uveitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Vision blurred	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	2 (22.22%)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	5 (1.77 %)
Visual impairment	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Vitreous detachment	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Gastrointestinal disorders													
Abdominal discomfort	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	6 (2.12 %)
Abdominal distension	0 (0.00 %)	1 (14.29%)	2 (16.67 %)	0 (0.00 %)	0 (0.00 %)	2 (22.22%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	2 (10.00%)	9 (3.18 %)
Abdominal mass	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Abdominal pain	0 (0.00 %)	1 (14.29%)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	2 (33.33%)	1 (7.69 %)	1 (10.00%)	0 (0.00 %)	1 (6.67 %)	3 (15.00%)	22 (7.77 %)
Abdominal pain upper	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.00%)	3 (15.00 %)	0 (0.00 %)	1 (5.00 %)	15 (5.30 %)
Anal pruritus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)

Ascites	2 (33.33%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	2 (10.00%)	9 (3.18%)
Constipation	0 (0.00%)	2 (28.57%)	3 (25.00%)	2 (18.18%)	1 (16.67%)	1 (11.11%)	3 (50.00%)	1 (7.69%)	1 (10.00%)	3 (15.00%)	2 (13.33%)	4 (20.00%)	51 (18.02%)
Diarrhoea	1 (16.67%)	3 (42.86%)	4 (33.33%)	0 (0.00%)	1 (16.67%)	3 (33.33%)	0 (0.00%)	4 (30.77%)	2 (20.00%)	2 (10.00%)	1 (6.67%)	1 (5.00%)	37 (13.07%)
Dry mouth	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	1 (16.67%)	2 (22.22%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.00%)	16 (5.65%)
Dyspepsia	0 (0.00%)	1 (14.29%)	0 (0.00%)	2 (18.18%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.00%)	7 (2.47%)
Dysphagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (5.00%)	1 (6.67%)	0 (0.00%)	8 (2.83%)
Flatulence	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.00%)	4 (1.41%)
Gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Gastrooesophageal reflux disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (2.47%)
Gingival bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Hyperaesthesia teeth	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Ileus paralytic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	1 (0.35%)
Intra-abdominal haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Lip blister	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)

Nausea	4 (66.67%)	3 (42.86%)	0 (0.00%)	3 (27.27%)	0 (0.00%)	1 (11.11%)	3 (50.00%)	1 (7.69%)	1 (10.00%)	4 (20.00%)	1 (6.67%)	4 (20.00%)	57 (20.14%)
Odynophagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Oesophagitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Oral pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Proctalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.71%)
Rectal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	1 (5.00%)	5 (1.77%)
Rectal ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Stomatitis	1 (16.67%)	0 (0.00%)	1 (8.33%)	2 (18.18%)	2 (33.33%)	3 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	14 (4.95%)
Vomiting	2 (33.33%)	1 (14.29%)	3 (25.00%)	5 (45.45%)	0 (0.00%)	1 (11.11%)	2 (33.33%)	2 (15.38%)	1 (10.00%)	2 (10.00%)	3 (20.00%)	1 (5.00%)	50 (17.67%)
General disorders and administration site conditions													
Asthenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (27.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (15.38%)	1 (10.00%)	6 (30.00%)	3 (20.00%)	6 (30.00%)	44 (15.55%)
Axillary pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	2 (0.71%)
Chest discomfort	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.71%)
Chills	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	5 (1.77%)
Face oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.06%)

Facial pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Fatigue	3 (50.0 0%)	3 (42.8 6%)	5 (41.67 %)	3 (27.2 7%)	1 (16.6 7%)	3 (33.3 3%)	4 (66.6 7%)	3 (23.0 8%)	3 (30.0 0%)	2 (10.00 %)	2 (13.3 3%)	3 (15.0 0%)	70 (24.7 3%)
Gait disturbance	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Generalised oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Inflammatory pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Influenza like illness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	2 (0.71 %)
Infusion site rash	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Localised oedema	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Malaise	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Nodule	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Non-cardiac chest pain	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (15.00 %)	1 (6.67 %)	3 (15.0 0%)	13 (4.59 %)
Oedema peripheral	0 (0.00 %)	3 (42.8 6%)	2 (16.67 %)	2 (18.1 8%)	0 (0.00 %)	3 (33.3 3%)	1 (16.6 7%)	0 (0.00 %)	2 (20.0 0%)	2 (10.00 %)	0 (0.00 %)	2 (10.0 0%)	37 (13.0 7%)
Pain	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	1 (5.00 %)	5 (1.77 %)
Peripheral swelling	0 (0.00 %)	1 (14.2 9%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Pyrexia	2 (33.3 3%)	2 (28.5 7%)	3 (25.00 %)	3 (27.2 7%)	2 (33.3 3%)	2 (22.2 2%)	0 (0.00 %)	2 (15.3 8%)	4 (40.0 0%)	1 (5.00 %)	1 (6.67 %)	1 (5.00 %)	40 (14.1 3%)
Xerosis	0 (0.00 %)	0 (0.00 %)	2 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)

Hepatobiliary disorders													
Cholangitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Cholestasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Hepatic cytolysis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Hepatic pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Hyperbilirubinaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	1 (5.00 %)	0 (0.00 %)	1 (5.00 %)	6 (2.12 %)
Hypertransaminasaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	3 (1.06 %)
Immune-mediated hepatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Immune system disorders													
Seasonal allergy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Infections and infestations													
Bronchitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Cellulitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Cholangitis infective	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Conjunctivitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	5 (1.77 %)

Cystitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Escherichia sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Folliculitis	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Fungal skin infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Gastroenteritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Gastroenteritis viral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Herpes zoster	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Hordeolum	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Infectious pleural effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Influenza	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	3 (1.06 %)
Lip infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Localised infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Lower respiratory tract infection	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Nasopharyngitis	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	5 (1.77 %)

Onychomycosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Oral candidiasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35 %)
Oral fungal infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35 %)
Oral herpes	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Paronychia	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	6 (2.12 %)
Pneumonia bacterial	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Postoperative wound infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Pyelonephritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	5 (1.77 %)
Rhinitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Sinusitis	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Skin infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	3 (1.06 %)
Spinal cord infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Systemic infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

Tooth abscess	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Tracheitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Upper respiratory tract infection	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Urinary tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	5 (1.77 %)
Vaginal infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Vulvovaginal mycotic infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Injury, poisoning and procedural complications													
Fall	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Forearm fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Lumbar vertebral fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Multiple fractures	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35 %)
Overdose	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Procedural pneumothorax	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Rib fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

Tooth fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Wound haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Investigations													
Alanine aminotransferase increased	1 (16.67%)	2 (28.57%)	1 (8.33 %)	2 (18.18%)	1 (16.67%)	1 (11.11%)	0 (0.00 %)	2 (15.38%)	2 (20.00%)	4 (20.00 %)	1 (6.67 %)	1 (5.00 %)	38 (13.43%)
Amylase decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Amylase increased	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	3 (27.27%)	0 (0.00 %)	3 (33.33%)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	1 (5.00 %)	3 (20.00%)	0 (0.00 %)	19 (6.71 %)
Aspartate aminotransferase increased	1 (16.67%)	2 (28.57%)	2 (16.67 %)	2 (18.18%)	1 (16.67%)	2 (22.22%)	1 (16.67%)	2 (15.38%)	1 (10.00%)	9 (45.00 %)	1 (6.67 %)	1 (5.00 %)	47 (16.61%)
Bilirubin conjugated	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Bilirubin conjugated increased	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	2 (15.38%)	2 (20.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	11 (3.89 %)
Blood albumin decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (6.67 %)	0 (0.00 %)	2 (0.71 %)
Blood alkaline phosphatase increased	0 (0.00 %)	0 (0.00 %)	2 (16.67 %)	1 (9.09 %)	1 (16.67%)	0 (0.00 %)	2 (33.33%)	3 (23.08%)	3 (30.00%)	4 (20.00 %)	2 (13.33%)	2 (10.00%)	34 (12.01%)
Blood bicarbonate increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35 %)
Blood bilirubin	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	2 (0.71 %)
Blood bilirubin increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (27.27%)	0 (0.00 %)	3 (33.33%)	0 (0.00 %)	3 (23.08%)	3 (30.00%)	2 (10.00 %)	0 (0.00 %)	1 (5.00 %)	25 (8.83 %)

Blood calcium decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Blood chloride decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Blood cholesterol increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Blood creatine increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Blood creatine phosphokinase increased	0 (0.00 %)	1 (14.29%)	4 (33.33 %)	4 (36.36%)	2 (33.33%)	5 (55.56%)	0 (0.00 %)	2 (15.38%)	0 (0.00 %)	3 (15.00 %)	0 (0.00 %)	0 (0.00 %)	28 (9.89 %)
Blood creatinine increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	7 (2.47 %)
Blood glucose increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Blood lactate dehydrogenase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (15.00 %)	2 (13.33%)	1 (5.00 %)	7 (2.47 %)
Blood magnesium decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	2 (0.71 %)
Blood potassium increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Blood pressure increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Blood thyroid stimulating hormone increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Blood urea increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

Blood uric acid increased	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
C-reactive protein increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	2 (13.33%)	0 (0.00 %)	3 (1.06 %)
Creatinine renal clearance decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Ejection fraction decreased	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Electrocardiogram QT prolonged	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Gamma-glutamyltransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (18.18%)	0 (0.00 %)	1 (11.11%)	1 (16.67%)	1 (7.69 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	1 (5.00 %)	14 (4.95 %)
International normalised ratio increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	1 (7.69 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Lipase increased	0 (0.00 %)	1 (14.29%)	4 (33.33 %)	2 (18.18%)	0 (0.00 %)	2 (22.22%)	1 (16.67%)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	2 (13.33%)	0 (0.00 %)	25 (8.83 %)
Lymphocyte count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (15.00 %)	2 (13.33%)	1 (5.00 %)	7 (2.47 %)
Neutrophil count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (10.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Neutrophil count increased	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

Oxygen saturation decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Platelet count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Platelet count increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35 %)
Protein total decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35 %)
Protein total increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35 %)
Thyroxine free increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35 %)
Transaminases increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	1 (6.67 %)	3 (15.0 0%)	8 (2.83 %)
Waist circumference increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Weight decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (7.69 %)	0 (0.00 %)	1 (5.00 %)	1 (6.67 %)	2 (10.0 0%)	16 (5.65 %)
Weight increased	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
White blood cell count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	2 (10.00 %)	0 (0.00 %)	0 (0.00 %)	5 (1.77 %)
Metabolism and nutrition disorders													
Appetite disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Decreased appetite	0 (0.00 %)	3 (42.8 6%)	1 (8.33 %)	4 (36.3 6%)	0 (0.00 %)	2 (22.2 2%)	0 (0.00 %)	1 (7.69 %)	2 (20.0 0%)	1 (5.00 %)	3 (20.0 0%)	5 (25.0 0%)	61 (21.5 5%)

Dehydration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	2 (15.3 8%)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	6 (2.12 %)
Hypercalcaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	3 (15.00 %)	1 (6.67 %)	0 (0.00 %)	14 (4.95 %)
Hyperchloraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Hypercreatininaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Hyperglycaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	2 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	7 (2.47 %)
Hyperkalaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	6 (2.12 %)
Hypermagnesaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35 %)
Hyperphosphataemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Hypertriglyceridaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35 %)
Hyperuricaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Hypoalbuminaemia	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	2 (18.1 8%)	0 (0.00 %)	2 (22.2 2%)	1 (16.6 7%)	2 (15.3 8%)	1 (10.0 0%)	3 (15.00 %)	0 (0.00 %)	0 (0.00 %)	29 (10.2 5%)
Hypocalcaemia	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	3 (15.00 %)	0 (0.00 %)	0 (0.00 %)	12 (4.24 %)
Hypoglycaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Hypokalaemia	0 (0.00 %)	1 (14.2 9%)	1 (8.33 %)	1 (9.09 %)	0 (0.00 %)	3 (33.3 3%)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	2 (10.00 %)	1 (6.67 %)	0 (0.00 %)	18 (6.36 %)
Hypomagnesaemia	0 (0.00 %)	1 (14.2 9%)	1 (8.33 %)	0 (0.00 %)	1 (16.6 7%)	1 (11.1 1%)	0 (0.00 %)	1 (7.69 %)	1 (10.0 0%)	3 (15.00 %)	0 (0.00 %)	0 (0.00 %)	15 (5.30 %)
Hyponatraemia	0 (0.00 %)	2 (28.5 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (22.2 2%)	1 (16.6 7%)	2 (15.3 8%)	0 (0.00 %)	2 (10.00 %)	1 (6.67 %)	0 (0.00 %)	18 (6.36 %)

Hypophosphataemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	4 (30.77%)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	12 (4.24 %)
Hypoproteinaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Metabolic acidosis	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Polydipsia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Musculoskeletal and connective tissue disorders													
Arthralgia	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	1 (9.09 %)	1 (16.67%)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	1 (10.00%)	3 (15.00 %)	2 (13.33%)	1 (5.00 %)	33 (11.66%)
Arthritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Back pain	1 (16.67%)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	2 (10.00 %)	2 (13.33%)	1 (5.00 %)	29 (10.25%)
Bone pain	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Flank pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	6 (2.12 %)
Groin pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Intervertebral disc disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Limb discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Muscle spasms	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	2 (22.22%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	6 (2.12 %)
Muscular weakness	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	5 (1.77 %)

Musculoskeletal chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (33.33%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (10.00%)	8 (2.83 %)
Musculoskeletal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Myalgia	0 (0.00 %)	2 (28.57%)	2 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	16 (5.65 %)
Neck pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Osteoporosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Pain in extremity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	6 (2.12 %)
Pain in jaw	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Scoliosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Spinal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Tenosynovitis stenosans	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)													
Cancer pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Infected neoplasm	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Malignant pleural effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

Oncologic complication	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Tumour associated fever	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Tumour fistulisation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Tumour haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Tumour pain	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	1 (5.00 %)	0 (0.00 %)	1 (5.00 %)	13 (4.59 %)
Nervous system disorders													
Allodynia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Aphasia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Balance disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Cerebrovascular accident	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Dizziness	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (15.00 %)	0 (0.00 %)	1 (5.00 %)	15 (5.30 %)
Dysaesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Dysarthria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Dysgeusia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Encephalopathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

Facial neuralgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Facial paresis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Headache	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	1 (9.09 %)	1 (16.67%)	1 (11.11%)	1 (16.67%)	1 (7.69 %)	3 (30.00%)	3 (15.00 %)	0 (0.00 %)	1 (5.00 %)	23 (8.13 %)
Hemiparesis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Hepatic encephalopathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	2 (0.71 %)
Hypersomnia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Hypoaesthesia	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (10.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Intracranial mass	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35 %)
Loss of consciousness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Memory impairment	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Monoplegia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Myoclonus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Neuralgia	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Neuropathy peripheral	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (10.00 %)	0 (0.00 %)	0 (0.00 %)	5 (1.77 %)
Neurotoxicity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35 %)

Ophthalmic migraine	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Paraesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Paralysis recurrent laryngeal nerve	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Peripheral motor neuropathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Peripheral sensory neuropathy	0 (0.00 %)	0 (0.00 %)	2 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Peroneal nerve palsy	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Sciatica	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (10.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Seizure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Sensorimotor disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Somnolence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	6 (2.12 %)
Spinal cord compression	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Syncope	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Taste disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Tremor	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

VIth nerve disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Vocal cord paralysis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Product issues													
Device occlusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Psychiatric disorders													
Anxiety	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	1 (7.69 %)	0 (0.00 %)	2 (10.00 %)	0 (0.00 %)	0 (0.00 %)	11 (3.89 %)
Bradyphrenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Confusional state	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35 %)
Depressed mood	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Depression	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Hallucination	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Insomnia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	1 (5.00 %)	4 (1.41 %)
Irritability	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Mental status changes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Mixed anxiety and depressive disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

Sleep disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Renal and urinary disorders													
Acute kidney injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Anuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Cystitis noninfective	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Dysuria	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	7 (2.47 %)
Haematuria	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	8 (2.83 %)
Haemorrhage urinary tract	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Hydronephrosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Micturition disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Micturition urgency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Nocturia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Pollakiuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	4 (1.41 %)
Polyuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Renal colic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35 %)

Renal failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Urethral discharge	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Urinary incontinence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Urinary retention	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Urinary tract disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Urinary tract obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Reproductive system and breast disorders													
Balanoposthitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Breast mass	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Breast oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Breast pain	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Genital pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Intermenstrual bleeding	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Menstruation irregular	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Pelvic pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)

Perineal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Pruritus genital	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Scrotal oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Testicular oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Vaginal discharge	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Vaginal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Vulvovaginal pruritus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Respiratory, thoracic and mediastinal disorders													
Aphonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35 %)
Atelectasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Bronchial obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Bronchospasm	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Catarrh	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	2 (0.71 %)
Chronic obstructive pulmonary disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

Cough	2 (33.33%)	2 (28.57%)	4 (33.33%)	3 (27.27%)	2 (33.33%)	5 (55.56%)	2 (33.33%)	1 (7.69%)	1 (10.00%)	2 (10.00%)	2 (13.33%)	1 (5.00%)	51 (18.02%)
Dry throat	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Dysphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	10 (3.53%)
Dyspnoea	1 (16.67%)	3 (42.86%)	1 (8.33%)	4 (36.36%)	1 (16.67%)	3 (33.33%)	1 (16.67%)	6 (46.15%)	3 (30.00%)	6 (30.00%)	2 (13.33%)	1 (5.00%)	70 (24.73%)
Dyspnoea exertional	0 (0.00%)	1 (14.29%)	1 (8.33%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (2.47%)
Epistaxis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (11.11%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.41%)
Haemoptysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	1 (5.00%)	2 (0.71%)
Hiccups	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.06%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.71%)
Lung disorder	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.06%)
Nasal congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.41%)
Nasal dryness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Nasal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.00%)	1 (0.35%)
Oropharyngeal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	2 (0.71%)
Orthopnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)
Pharyngeal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.35%)

Pleural effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	1 (16.67%)	0 (0.00 %)	1 (16.67%)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	11 (3.89 %)
Pleuritic pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35 %)
Pneumonitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (18.18%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Productive cough	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	11 (3.89 %)
Pulmonary embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	5 (1.77 %)
Pulmonary hypertension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Respiratory failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Respiratory tract congestion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Rhinalgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	1 (0.35 %)
Rhinitis allergic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Rhinorrhoea	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	5 (1.77 %)
Throat irritation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Wheezing	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35 %)
Skin and subcutaneous tissue disorders													
Acne	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)

Actinic keratosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Cold sweat	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Dermatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Dermatitis acneiform	0 (0.00 %)	1 (14.29%)	2 (16.67 %)	2 (18.18%)	2 (33.33%)	4 (44.44%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	12 (4.24 %)
Dry skin	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	2 (15.38%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	13 (4.59 %)
Eczema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Erythema	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	1 (16.67%)	1 (11.11%)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	9 (3.18 %)
Hirsutism	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Hyperhidrosis	0 (0.00 %)	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Lichen planus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Nail dystrophy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	0 (0.00 %)	1 (0.35 %)
Nail toxicity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Night sweats	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Onychoclasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Onycholysis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Papule	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

Petechiae	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Pruritus	0 (0.00 %)	0 (0.00 %)	4 (33.33 %)	0 (0.00 %)	0 (0.00 %)	3 (33.3 3%)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	29 (10.2 5%)
Rash	0 (0.00 %)	2 (28.5 7%)	6 (50.00 %)	2 (18.1 8%)	3 (50.0 0%)	5 (55.5 6%)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (6.67 %)	1 (5.00 %)	32 (11.3 1%)
Rash erythematous	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Rash macular	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Rash maculo-papular	0 (0.00 %)	0 (0.00 %)	2 (16.67 %)	1 (9.09 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	8 (2.83 %)
Rash pruritic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Seborrhoeic dermatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Skin discolouration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Skin exfoliation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Skin fissures	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Skin ulcer	0 (0.00 %)	1 (14.2 9%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Umbilical haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Xeroderma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Vascular disorders													
Deep vein thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)

Embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (9.09 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Flushing	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Hot flush	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (0.71 %)
Hypertension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (18.18%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	1 (6.67 %)	1 (5.00 %)	10 (3.53 %)
Hypotension	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Lymphoedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	4 (1.41 %)
Orthostatic hypotension	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (1.06 %)
Superior vena cava syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Thrombophlebitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Vasculitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Vena cava thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Venous thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)
Venous thrombosis limb	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (5.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.35 %)

Other Relevant Findings

NA

Conclusion:

The tolerability of PDR001 in combination with canakinumab, CJM112, trametinib, and EGF816 and of Single agent (s.a.) canakinumab is generally acceptable across the treatment groups. The observed efficacy of canakinumab in combination with PDR001 in subjects with heavily pre-treated advanced Non-Small Cell Lung Cancer (NSCLC) justifies further clinical evaluation.

Date of Clinical Trial Report

1 Nov 2021