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Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

MIW815 (ADU-S100) and PDR001 (spartalizumab)

Trial Indication(s)

Advanced/metastatic solid tumors and lymphomas

Protocol Number

CMIW815X2102J

Protocol Title

A Phase Ib, open label, multicenter study of the safety and efficacy of MIW815 (ADU-S100) administered by intratumoral injection with PDR001 to patients with advanced/metastatic solid tumors or lymphomas

Clinical Trial Phase

Phase 1

Phase of Drug Development

Phase 1 (MIW815) and Phase 3 (PDR001)

Study Start/End Dates

Study Start Date: September 2017 (Actual)
Primary Completion Date: December 2020 (Actual)
Study Completion Date: December 2020 (Actual)

Reason for Termination (If applicable)

On 11-Dec-2019 Novartis communicated to all Investigators participating in CMIW815X2102J study of the decision to halt further enrollment of patients. This decision was based on the totality of the available data that included minimal anti-tumor activity, as well as a lack of an abscopal effect. Importantly, this recruitment halt was not a consequence of any safety concern. Study termination was implemented prior to enrollment of subjects in the dose confirmation and the dose expansion parts of the study. No maximum tolerated dose (MTD) or recommended dose for expansion (RDE) was declared. The last patient reached their 150-day safety follow up on 18-Dec-2020 (global last patient last visit).

Study Design/Methodology

This was a Phase Ib, multi-center, open-label study of MIW815 in combination with PDR001 in subjects with advanced/metastatic solid tumors or lymphomas.

This study consisted of two parts: Dose escalation/dose confirmation and dose expansion.

- Dose escalation/dose confirmation part: Patients were treated with MIW815 via intratumoral injection in combination with a fixed intravenous (i.v.) dose of PDR001, to determine safety, tolerability and the maximum tolerated dose (MTD) and/or recommended dose for expansion (RDE) of the combination. There were 3 groups planned as described below.
  - Group A: Dose escalation in solid tumor or lymphoma patients with cutaneous or subcutaneous accessible lesions. PDR001 400 mg administered via i.v. infusion as a fixed dose on Day 1 of each 28-day cycle and MIW815 administered via intratumoral injection on Days 1, 8 and 15 of each 28-day cycle.
  - Group B: Dose escalation in solid tumor or lymphoma patients with cutaneous or subcutaneous accessible lesions. PDR001 400 mg administered via i.v. infusion as a fixed dose and MIW815 administered via intratumoral injection, both on Day 1 only of each 28-day cycle.
  - Group C: Dose confirmation in solid tumor patients with visceral lesions accessible by ultrasound or computed tomography guidance. PDR001 400 mg i.v. as a fixed dose and MIW815 as a fixed dose at the MTD/RDE determined in Group B administered on Day 1 only of each 28-day cycle. Group C was planned to open only if biologic and/or anti-tumor activity had been demonstrated in Group B.

- Dose escalation: Once a declared suitable dose and schedule for further investigation had been identified for group A or B and initial safety for group C had been confirmed, patients were to be enrolled in the corresponding dose expansion part of the study in order to better characterize safety, tolerability and preliminary anti-tumor activity of MIW815.

The study completed the dose escalation part and was terminated prior to enrolling patients in the dose confirmation (Group C) and dose expansion parts.

Centers

12 centers in 8 countries: United States(4), Australia(2), Canada(1), Japan(1), Switzerland(1), Germany(1), Netherlands(1), Spain(1)

Objectives:

The primary objective of the trial was to characterize the safety and tolerability of MIW815 given with PDR001 and to identify recommended doses and schedules for future studies. The following related endpoints were assessed:

- Incidence of Dose Limiting Toxicities (DLTs) during the first cycle
- Incidence of adverse events and serious adverse events

The secondary objectives were:

- To evaluate the preliminary anti-tumor activity of the combination of MIW815 with PDR001 in terms of:
  - Overall Response Rate (BOR) and Disease Control Rate (DCR) according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1), immune-related Response Criteria (irRC) and Cheson 2014 for lymphomas
  - Progression-Free Survival (PFS) and Duration of Response (DOR) according to RECIST v1.1 for solid tumors and Cheson 2014 for lymphomas
- To characterize the pharmacokinetics (PK) of MIW815 and PDR001
- To assess the pharmacodynamic effects of study treatment in injected and distal tumor lesions

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

The study treatment is the combination of MIW815 and PDR001. A treatment cycle is defined as 28 days and the first dose of study treatment was administered on Cycle 1 Day 1.

In Group A, patients were given PDR001 400 mg via i.v. infusion as a fixed dose on Day 1 of each 28-day cycle and escalating doses of MIW815 (50 µg, 100 µ, 200 µ, 400 µ, 800 µ, 1600 µ and 3200 µ) via intratumoral injection on Days 1, 8 and 15 of each 28-day cycle (3W/1W).

In Group B, patients were given PDR001 400 mg via intravenous infusion as a fixed dose and escalating doses of MIW815 (50 µg, 100 µ, 200 µ, 400 µ, 800 µ, 1600 µ and 3200 µ) via intratumoral injection, both on Day 1 only of each 28-day cycle.

A patient could continue study treatment until the patient experienced unacceptable toxicity, disease progression and/or study treatment was discontinued at the discretion of the investigator or the patient. Patients were treated for a median time of 6.14 weeks in Group A and 4.43 weeks in Group B with a maximum duration of treatment of 72.3 weeks and 50.9 weeks in Group A and B, respectively.

Statistical Methods

The primary variables were frequency, severity and seriousness of AEs, lab abnormalities, vital signs changes and electrocardiogram (ECG) changes. For the dose escalation part, DLTs during the 1st cycle were assessed. The Safety set, that comprised all patients who received at least one dose of study treatment, was used for summaries and listings of safety data with the exception of DLTs for which the Dose-Determining set (DDS) was used. The DDS included all patients from the dose escalation/dose confirmation part who received at least one dose of study treatment and met a minimum exposure criterion and had sufficient safety evaluations, or experienced a DLT during cycle 1 (the first 28 days of dosing).

Secondary endpoints (ORR, PFS, DOR, DCR) were to assess the preliminary anti-tumor activity of MIW815 and PDR001. Evaluation of anti-tumor activity was based on local investigator assessment according to RECIST v1.1, irRC or Cheson 2014 for lymphomas. All analyses were presented using the Full Analysis Set (FAS) that comprised all patients who received at least one dose of study treatment.

PK parameters were determined by non-compartmental methods using the pharmacokinetic profile of MIW815 and PDR001. Concentration values below the lower limit of quantification (LLOQ) were handled as zero in the calculations of mean, coefficient of variation (CV) of mean, standard deviation, minimum, median and maximum, but handled as missing for the calculation of the geometric means and their CV.

In regards to biomarkers, induction of tumor infiltrating lymphocytes (TILs) and cytokines in the injected lesion (local pharmacodynamic effect) and in a non-injected lesion (distal pharmacodynamic effect) were assessed using paired tumor samples at screening and on-treatment.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:
ECOG ≤ 1
Willing to undergo tumor biopsies from injected and distal lesions
Must have two biopsy accessible lesions:

Exclusion Criteria:
Symptomatic or untreated leptomeningeal disease.
Presence of symptomatic central nervous system metastases
Impaired cardiac function or clinically significant cardiac disease
Active autoimmune disease or a documented history of autoimmune disease, except vitiligo or resolved childhood asthma/atopy.
Active infection requiring systemic antibiotic therapy.
Known history of human immunodeficiency virus infection.
Active Epstein-Barr virus, hepatitis B virus or hepatitis C virus
Malignant disease, other than that being treated in this study

Participant Flow Table

Overall Study

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W	Total
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	
Started	7	10	13	9	9	8	11	5	5	6	7	4	7	5	106
Completed	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed	7	10	13	9	9	8	11	5	5	6	7	4	7	5	106
Adverse Event	0	0	1	0	0	0	0	1	0	0	0	0	0	0	2
Physician Decision	1	2	5	3	2	0	2	1	2	1	0	1	0	0	20
Progressive Disease	5	6	5	5	7	7	8	3	2	4	7	3	6	4	72

Study terminated by sponsor	0	0	1	0	0	1	1	0	0	0	0	0	0	0	3
Subject/guardian decision	1	1	1	1	0	0	0	0	1	1	0	0	1	0	7
Death	0	1	0	0	0	0	0	0	0	0	0	0	0	1	2

Baseline Characteristics

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	**Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W**	**Total**
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	
Number of Particip	7	10	13	9	9	8	11	5	5	6	7	4	7	5	106

ants [units: particip ants]															
Age Continuous (units: years) Mean ± Standard Deviation															
	53.0±12.58	57.4±18.19	60.6±14.55	65.2±12.45	56.3±10.91	61.5±13.71	55.6±15.91	58.2±18.43	67.2±10.99	57.3±6.19	64.1±12.99	71.0±9.83	54.4±14.99	65.4±10.83	59.8±13.78
Sex: Female, Male (units: participants) Count of Participants (Not Applicable)															
Female	3	6	9	4	7	4	7	4	1	2	2	2	4	1	56
Male	4	4	4	5	2	4	4	1	4	4	5	2	3	4	50
Race/Ethnicity, Customized (units: participants) Count of Participants (Not Applicable)															
Caucasian	4	8	12	6	7	6	5	4	5	6	7	4	4	5	83
Black	0	2	0	0	1	0	0	0	0	0	0	0	1	0	4
Asian	3	0	1	3	1	2	3	1	0	0	0	0	2	0	16
Other	0	0	0	0	0	0	3	0	0	0	0	0	0	0	3

Primary Outcome Result(s)

Incidence of Dose Limiting Toxicities (DLTs) during the first cycle

(Time Frame: 28 days)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	7	9	12	9	8	8	10	5	5	6	7	4	6	4

Incidence of Dose Limiting Toxicities (DLTs) during the first cycle
(units: participants)
Count of Participants (Not Applicable)

0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (10%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Incidence of adverse events

(Time Frame: From the day of the first dose of study treatment up to 150 days after the last dose, up to maximum duration of 94 weeks)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	**Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W**
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	7	10	13	9	9	8	11	5	5	6	7	4	7	5

Incidence of adverse events
(units: participants)
Count of Participants (Not Applicable)

AEs	7 (100%)	10 (100%)	13 (100%)	9 (100%)	9 (100%)	8 (100%)	11 (100%)	5 (100%)	5 (100%)	6 (100%)	6 (85.71%)	4 (100%)	5 (71.43%)	5 (100%)
AEs suspected to be drug related	4 (57.14%)	5 (50%)	11 (84.62%)	5 (55.56%)	4 (44.44%)	7 (87.5%)	9 (81.82%)	4 (80%)	2 (40%)	5 (83.33%)	3 (42.86%)	3 (75%)	4 (57.14%)	4 (80%)
Grade 3-4 AEs	6 (85.71%)	4 (40%)	6 (46.15%)	4 (44.44%)	4 (44.44%)	4 (50%)	4 (36.36%)	3 (60%)	3 (60%)	2 (33.33%)	1 (14.29%)	2 (50%)	4 (57.14%)	4 (80%)
Grade 3-4 AEs suspected to be drug related	2 (28.57%)	1 (10%)	2 (15.38%)	1 (11.11%)	0 (%)	2 (25%)	2 (18.18%)	2 (40%)	0 (%)	1 (16.67%)	0 (%)	0 (%)	0 (%)	1 (20%)
SAEs	5 (71.43%)	4 (40%)	6 (46.15%)	3 (33.33%)	3 (33.33%)	2 (25%)	1 (9.09%)	1 (20%)	2 (40%)	1 (16.67%)	1 (14.29%)	2 (50%)	3 (42.86%)	3 (60%)
SAEs suspected to be drug related	2 (28.57%)	1 (10%)	2 (15.38%)	0 (%)	0 (%)	2 (25%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	1 (25%)	0 (%)	0 (%)
AEs leading to discontinuation	0 (%)	1 (10%)	1 (7.69%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (20%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
AEs requiring dose adjusted/temporarily interrupted	3 (42.86%)	3 (30%)	4 (30.77%)	4 (44.44%)	2 (22.22%)	2 (25%)	5 (45.45%)	1 (20%)	0 (%)	0 (%)	0 (%)	1 (25%)	1 (14.29%)	0 (%)

Secondary Outcome Result(s)

Overall Response Rate (ORR) based on RECIST v1.1 for solid tumors and Cheson 2014 for lymphomas

(Time Frame: From start of treatment until end of treatment, assessed up to 72.3 weeks)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	7	10	13	9	9	8	11	5	5	6	7	4	7	5

Overall Response Rate (ORR) based on RECIST v1.1 for solid tumors and Cheson 2014 for lymphomas
(units: percentage of participants)
Number (90% Confidence Interval)

	28.6 (5.3 to 65.9)	10.0 (0.5 to 39.4)	15.4 (2.8 to 41.0)	11.1 (0.6 to 42.9)	0 (0.0 to 28.3)	25.0 (4.6 to 60.0)	9.1 (0.5 to 36.4)	0 (0.0 to 45.1)	0 (0.0 to 45.1)	0 (0.0 to 39.3)	0 (0.0 to 34.8)	0 (0.0 to 52.7)	14.3 (0.7 to 52.1)	20.0 (1.0 to 65.7)

Disease Control Rate (DCR) based on RECIST v1.1 for solid tumors and Cheson 2014 for lymphomas

(Time Frame: From start of treatment until end of treatment, assessed up to 72.3 weeks)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	**Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W**
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	7	10	13	9	9	8	11	5	5	6	7	4	7	5

Disease Control Rate (DCR) based on RECIST v1.1 for solid tumors and Cheson 2014 for lymphomas
(units: percentage of participants)
Number (90% Confidence Interval)

	28.6 (5.3 to 65.9)	30.0 (8.7 to 60.7)	53.8 (28.7 to 77.6)	33.3 (9.8 to 65.5)	11.1 (0.6 to 42.9)	25.0 (4.6 to 60.0)	18.2 (3.3 to 47.0)	20.0 (1.0 to 65.7)	20.0 (1.0 to 65.7)	16.7 (0.9 to 58.2)	14.3 (0.7 to 52.1)	50.0 (9.8 to 90.2)	28.6 (5.3 to 65.9)	60.0 (18.9 to 92.4)

Overall Response Rate (ORR) based on irRC for solid tumors

(Time Frame: From start of treatment until end of treatment, assessed up to 72.3 weeks)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	**Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W**
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units:	7	9	12	8	9	8	11	5	5	5	7	4	7	5

participants]														
Overall Response Rate (ORR) based on irRC for solid tumors (units: percentage of participants) Number (90% Confidence Interval)														
	28.6 (5.3 to 65.9)	11.1 (0.6 to 42.9)	16.7 (3.0 to 43.8)	12.5 (0.6 to 47.1)	0 (0.0 to 28.3)	25.0 (4.6 to 60.0)	9.1 (0.5 to 36.4)	20.0 (1.0 to 65.7)	0 (0.0 to 45.1)	0 (0.0 to 45.1)	0 (0.0 to 34.8)	0 (0.0 to 52.7)	14.3 (0.7 to 52.1)	20.0 (1.0 to 65.7)

Disease Control Rate (DCR) based on irRC for solid tumors

(Time Frame: From start of treatment until end of treatment, assessed up to 72.3 weeks)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	**Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W**
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants	7	9	12	8	9	8	11	5	5	5	7	4	7	5

Analyzed [units: participants]														
Disease Control Rate (DCR) based on irRC for solid tumors (units: percentage of participants) Number (90% Confidence Interval)														
	28.6 (5.3 to 65.9)	22.2 (4.1 to 55.0)	58.3 (31.5 to 81.9)	37.5 (11.1 to 71.1)	11.1 (0.6 to 42.9)	25.0 (4.6 to 60.0)	18.2 (3.3 to 47.0)	40.0 (7.6 to 81.1)	20.0 (1.0 to 65.7)	20.0 (1.0 to 65.7)	14.3 (0.7 to 52.1)	50.0 (9.8 to 90.2)	28.6 (5.3 to 65.9)	60.0 (18.9 to 92.4)

Progression-Free Survival (PFS) based on RECIST v1.1 for solid tumors and Cheson 2014 for lymphomas

(Time Frame: From start of treatment to first documented progression or death, assessed up to 72.3 weeks)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of	0	10	13	0	0	0	11	0	0	0	0	0	0	0

Participants Analyzed [units: participants]															
Progression-Free Survival (PFS) based on RECIST v1.1 for solid tumors and Cheson 2014 for lymphomas (units: months) Median (90% Confidence Interval)															
	1.8 (1.5 to 5.4)	4.2 (1.9 to 7.6)						1.8 (1.4 to 1.9)							

Duration of Response (DOR) based on RECIST v1.1 for solid tumors and Cheson 2014 for lymphomas

(Time Frame: From first documented response (CR or PR) to first documented progression or death, assessed up to 72.3 weeks)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle

Number of Participants Analyzed [units: participants]	0	1	2	0	0	0	1	0	0	0	0	0	0	0

Duration of Response (DOR) based on RECIST v1.1 for solid tumors and Cheson 2014 for lymphomas
(units: months)
Median (90% Confidence Interval)

		NA (NA to NA)[2]	NA (14.1 to NA)[1]			]	NA (NA to NA)[2]							

[1] Not available - Insufficient number of patients with events.
[2] Not available - The only patient analyzed was censored.

Maximum observed plasma concentration (Cmax) of MIW815

(Time Frame: pre dose, immediately after start of injection, 15 and 30 minutes, 1, 2 and 4 hours after start of MIW815 intratumoral injection on Cycle 1 Day 1, Cycle 1 Day 15 (only group A) and Cycle 3 Day 1. The duration of each cycle was 28 days.)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	**Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W**
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administ	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administ	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administ	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administ	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administ	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administ	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administ	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-

	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	day cycle	day cycle	day cycle	day cycle	day cycle	day cycle	day cycle
Number of Participants Analyzed [units: participants]	7 (C1D1), 7 (C1D15), 2 (C3D1)	10 (C1D1), 8 (C1D15), 2 (C3D1)	12 (C1D1), 10 (C1D15), 7 (C3D1)	8 (C1D1), 7 (C1D15), 2 (C3D1)	8 (C1D1), 6 (C1D15), 2 (C3D1)	8 (C1D1), 7 (C1D15), 5 (C3D1)	10 (C1D1), 8 (C1D15), 3 (C3D1)	4 (C1D1), 0 (C1D15), 2 (C3D1)	5 (C1D1), 0 (C1D15), 1 (C3D1)	5 (C1D1), 0 (C1D15), 3 (C3D1)	7 (C1D1), 0 (C1D15), 3 (C3D1)	3 (C1D1), 0 (C1D15), 2 (C3D1)	5 (C1D1), 0 (C1D15), 4 (C3D1)	5 (C1D1), 0 (C1D15), 3 (C3D1)
Maximum observed plasma concentration (Cmax) of MIW815 (units: ng/mL) Geometric Mean (Geometric Coefficient of Variation)														
Cycle 1 Day 1 (C1D1)	1.48 (287.7 %)	1.52 (311.5 %)	3.02 (143.6 %)	3.56 (734.0 %)	18.4 (192.5 %)	26.5 (167.0 %)	49.9 (204.4 %)	0.475 (159.8 %)	1.72 (193.3 %)	1.68 (253.5 %)	4.90 (98.0%)	34.9 (158.1 %)	14.3 (151.9 %)	29.0 (117.3 %)
Cycle 1 Day 15 (C1D15)	1.47 (99.0%)	1.81 (411.8 %)	2.69 (182.1 %)	2.19 (227.0 %)	25.8 (98.3%)	17.1 (150.9 %)	77.9 (81.7%)							
Cycle 3 Day 1 (C3D1)	2.29 (859.6 %)	4.57 (61.5%)	0.925 (293.3 %)	0.532 (1748.4 %)	12.2 (3.5%)	28.0 (85.1%)	25.7 (447.9 %)	1.00 (64.4%)	NA (NA%)[1]	0.750 (156.1 %)	4.46 (31.3%)	7.16 (2.5%)	10.4 (45.4%)	97.6 (38.9%)

[1] Insufficient number of participants with values.

Time to reach maximum plasma concentration (Tmax) of MIW815

(Time Frame: pre dose, immediately after start of injection, 15 and 30 minutes, 1, 2 and 4 hours after start of MIW815 intratumoral injection on Cycle 1 Day 1, Cycle 1 Day 15 (only group A) and Cycle 3 Day 1. The duration of each cycle was 28 days.)

Group A – MIW815 50 ug Weekly 3W/1W + PDR001	**Group A – MIW815 100 ug Weekly 3W/1W + PDR001**	**Group A – MIW815 200 ug Weekly 3W/1W + PDR001**	**Group A – MIW815 400 ug Weekly 3W/1W + PDR001**	**Group A – MIW815 800 ug Weekly 3W/1W + PDR001**	**Group A – MIW815 1600 ug Weekly 3W/1W + PDR001**	**Group A – MIW815 3200 ug Weekly 3W/1W + PDR001**	**Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W**

	400 mg Q4W	400 mg Q4W	400 mg Q4W	400 mg Q4W	400 mg Q4W	400 mg Q4W	400 mg Q4W							
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	7 (C1D1), 7 (C1D15), 2 (C3D1)	10 (C1D1), 8 (C1D15), 2 (C3D1)	12 (C1D1), 10 (C1D15), 7 (C3D1)	8 (C1D1), 7 (C1D15), 2 (C3D1)	8 (C1D1), 6 (C1D15), 2 (C3D1)	8 (C1D1), 7 (C1D15), 5 (C3D1)	10 (C1D1), 8 (C1D15), 3 (C3D1)	4 (C1D1), 0 (C1D15), 2 (C3D1)	5 (C1D1), 0 (C1D15), 1 (C3D1)	5 (C1D1), 0 (C1D15), 3 (C3D1)	7 (C1D1), 0 (C1D15), 3 (C3D1)	3 (C1D1), 0 (C1D15), 2 (C3D1)	5 (C1D1), 0 (C1D15), 4 (C3D1)	5 (C1D1), 0 (C1D15), 3 (C3D1)
Time to reach maximum plasma concentration (Tmax) of MIW815 (units: hours) Median (Full Range)														
Cycle 1 Day 1 (C1D1)	0.0833 (0.0500 to 0.500)	0.0500 (0.0167 to 0.300)	0.0333 (0.00 to 0.317)	0.0500 (0.0333 to 0.300)	0.0667 (0.0167 to 0.233)	0.0500 (0.0167 to 0.250)	0.125 (0.0333 to 0.283)	0.0583 (0.0333 to 0.200)	0.0667 (0.0333 to 0.117)	0.0667 (0.0500 to 0.283)	0.0333 (0.0333 to 0.233)	0.0167 (0.0167 to 0.0667)	0.0833 (0.0333 to 0.317)	0.0500 (0.0500 to 0.417)
Cycle 1 Day 15 (C1D15)	0.0500 (0.0333 to 0.250)	0.0500 (0.0333 to 0.450)	0.117 (0.0333 to 0.383)	0.0500 (0.00 to 0.333)	0.0667 (0.0167 to 0.117)	0.0500 (0.0167 to 0.367)	0.0583 (0.0333 to 0.167)							
Cycle 3 Day 1 (C3D1)	0.0500 (0.0500 to 0.250)	0.0417 (0.0333 to 0.0500)	0.0833 (0.00 to 0.667)	0.0667 (0.0500 to 0.0833)	0.0833 (0.0333 to 0.133)	0.0500 (0.0167 to 0.300)	0.283 (0.0667 to 0.283)	0.0333 (0.0167 to 0.0500)	0.00 (0.00 to 0.00)	0.0833 (0.0667 to 0.333)	0.0833 (0.0500 to 0.283)	0.167 (0.0833 to 0.250)	0.175 (0.0333 to 0.283)	0.0667 (0.0333 to 0.0667)

Area under the plasma concentration-time curve from time zero to the time of last quantifiable concentration (AUClast) of MIW815

(Time Frame: pre dose, immediately after start of injection, 15 and 30 minutes, 1, 2 and 4 hours after start of MIW815 intratumoral injection on Cycle 1 Day 1, Cycle 1 Day 15 (only group A) and Cycle 3 Day 1. The duration of each cycle was 28 days.)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	7 (C1D1), 7 (C1D15), 2 (C3D1)	10 (C1D1), 8 (C1D15), 2 (C3D1)	10 (C1D1), 10 (C1D15), 5 (C3D1)	8 (C1D1), 7 (C1D15), 2 (C3D1)	8 (C1D1), 6 (C1D15), 2 (C3D1)	8 (C1D1), 7 (C1D15), 5 (C3D1)	10 (C1D1), 8 (C1D15), 3 (C3D1)	4 (C1D1), 0 (C1D15), 2 (C3D1)	5 (C1D1), 0 (C1D15), 0 (C3D1)	5 (C1D1), 0 (C1D15), 3 (C3D1)	7 (C1D1), 0 (C1D15), 3 (C3D1)	3 (C1D1), 0 (C1D15), 2 (C3D1)	5 (C1D1), 0 (C1D15), 4 (C3D1)	5 (C1D1), 0 (C1D15), 3 (C3D1)

Area under the plasma concentration-time curve from time zero to the time of last quantifiable concentration (AUClast) of MIW815
(units: hr*ng/mL)
Geometric Mean (Geometric Coefficient of Variation)

Cycle 1 Day 1 (C1D1)	0.264 (177.3 %)	0.257 (181.8 %)	0.715 (166.1 %)	0.958 (1203.7 %)	4.83 (146.8 %)	9.18 (133.3 %)	21.3 (87.5%)	0.0457 (361.3 %)	0.398 (312.4 %)	0.454 (315.9 %)	1.37 (128.4 %)	5.81 (183.7 %)	5.58 (109.3 %)	17.1 (57.5%)
Cycle 1 Day 15 (C1D15)	0.253 (74.9%)	0.371 (286.9 %)	0.804 (151.7 %)	0.725 (235.7 %)	5.74 (61.2%)	7.19 (111.6 %)	24.8 (37.0%)							
Cycle 3 Day 1 (C3D1)	0.527 (289.5 %)	0.660 (83.4%)	0.338 (524.0 %)	0.0172 (4435.3 %)	2.92 (4.1%)	9.92 (49.6%)	17.4 (273.2 %)	0.347 (70.9%)		0.303 (206.6 %)	1.43 (126.8 %)	1.92 (125.8 %)	5.67 (37.4%)	20.7 (27.3%)

Area under the plasma concentration-time curve from time zero to infinity (AUCinf) of MIW815

(Time Frame: pre dose, immediately after start of injection, 15 and 30 minutes, 1, 2 and 4 hours after start of MIW815 intratumoral injection on Cycle 1 Day 1, Cycle 1 Day 15 (only group A) and Cycle 3 Day 1. The duration of each cycle was 28 days.)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	**Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W**
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of	3 (C1D1),	3 (C1D1),	7 (C1D1),	4 (C1D1),	7 (C1D1),	8 (C1D1),	10 (C1D1),	1 (C1D1),	2 (C1D1),	3 (C1D1),	5 (C1D1),	2 (C1D1),	5 (C1D1),	5 (C1D1),

Participants Analyzed [units: participants]	4 (C1D15), 0 (C3D1)	4 (C1D15), 1 (C3D1)	6 (C1D15), 2 (C3D1)	4 (C1D15), 0 (C3D1)	6 (C1D15), 2 (C3D1)	6 (C1D15), 5 (C3D1)	8 (C1D15), 2 (C3D1)	0 (C1D15), 1 (C3D1)	0 (C1D15), 0 (C3D1)	0 (C1D15), 2 (C3D1)	0 (C1D15), 3 (C3D1)	0 (C1D15), 1 (C3D1)	0 (C1D15), 4 (C3D1)	0 (C1D15), 3 (C3D1)
Area under the plasma concentration-time curve from time zero to infinity (AUCinf) of MIW815 (units: hr*ng/mL) Geometric Mean (Geometric Coefficient of Variation)														
Cycle 1 Day 1 (C1D1)	0.407 (53.9%)	0.541 (89.2%)	1.16 (64.5%)	3.47 (117.5 %)	4.37 (149.8 %)	9.23 (133.0 %)	21.6 (85.5%)	0.229 (NA%)[1]	0.861 (420.5 %)	0.781 (410.1 %)	2.02 (58.4%)	11.7 (7.9%)	5.67 (109.5 %)	17.2 (57.3%)
Cycle 1 Day 15 (C1D15)	0.304 (67.2%)	1.04 (99.2%)	1.61 (73.9%)	1.18 (56.0%)	5.92 (65.0%)	8.91 (94.9%)	25.3 (36.7%)							
Cycle 3 Day 1 (C3D1)		1.13 (NA%)[1]	0.870 (9.5%)		2.98 (4.3%)	10.1 (49.3%)	33.4 (213.7 %)	0.562 (NA%)[1]		0.702 (66.2%)	1.49 (125.3 %)	3.88 (NA%)[1]	5.82 (39.5%)	20.8 (27.6%)

[1] Insufficient number of participants with values.

Maximum observed serum concentration (Cmax) of PDR001

(Time Frame: pre dose, immediately after start of injection, 15 and 30 minutes, 1, 2 and 4 hours after start of PDR001 infusion on Cycle 1 Day 1.)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15	MIW815 100 ug administered on days 1, 8 and 15	MIW815 200 ug administered on days 1, 8 and 15	MIW815 400 ug administered on days 1, 8 and 15	MIW815 800 ug administered on days 1, 8 and 15	MIW815 1600 ug administered on days 1, 8 and 15	MIW815 3200 ug administered on days 1, 8 and 15	MIW815 50 ug and PDR001 400 mg administ	MIW815 100 ug and PDR001 400 mg administ	MIW815 200 ug and PDR001 400 mg administ	MIW815 400 ug and PDR001 400 mg administ	MIW815 800 ug and PDR001 400 mg administ	MIW815 1600 ug and PDR001 400 mg administ	MIW815 3200 ug and PDR001 400 mg administ

	and PDR001 400 mg administered on day 1 of each 28-day cycle	and PDR001 400 mg administered on day 1 of each 28-day cycle	and PDR001 400 mg administered on day 1 of each 28-day cycle	and PDR001 400 mg administered on day 1 of each 28-day cycle	and PDR001 400 mg administered on day 1 of each 28-day cycle	and PDR001 400 mg administered on day 1 of each 28-day cycle	and PDR001 400 mg administered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle	ered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	7	10	12	9	9	8	11	5	5	6	7	4	7	5
Maximum observed serum concentration (Cmax) of PDR001 (units: ug/mL) Geometric Mean (Geometric Coefficient of Variation)														
	101 (10.8%)	83.9 (32.9%)	93.5 (22.8%)	81.7 (111.4 %)	65.8 (112.2 %)	88.5 (29.3%)	94.7 (34.3%)	120 (6.9%)	89.4 (36.4%)	73.6 (25.1%)	84.0 (24.4%)	91.2 (36.0%)	77.8 (40.1%)	95.8 (5.9%)

Time to reach maximum serum concentration (Tmax) of PDR001

(Time Frame: pre dose, immediately after start of injection, 15 and 30 minutes, 1, 2 and 4 hours after start of PDR001 infusion on Cycle 1 Day 1.)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	**Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W**
Arm/Group Description	MIW815 50 ug administered on	MIW815 100 ug administered on	MIW815 200 ug administered on	MIW815 400 ug administered on	MIW815 800 ug administered on	MIW815 1600 ug administered on	MIW815 3200 ug administered on	MIW815 50 ug and PDR001	MIW815 100 ug and PDR001	MIW815 200 ug and PDR001	MIW815 400 ug and PDR001	MIW815 800 ug and PDR001	MIW815 1600 ug and PDR001	MIW815 3200 ug and PDR001

	days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	400 mg administered on day 1 of each 28-day cycle	400 mg administered on day 1 of each 28-day cycle	400 mg administered on day 1 of each 28-day cycle	400 mg administered on day 1 of each 28-day cycle	400 mg administered on day 1 of each 28-day cycle	400 mg administered on day 1 of each 28-day cycle	400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	7	10	12	9	9	8	11	5	5	6	7	4	7	5
Time to reach maximum serum concentration (Tmax) of PDR001 (units: hours) Median (Full Range)														
	1.20 (0.617 to 1.78)	1.49 (0.583 to 3.50)	0.900 (0.00 to 3.03)	1.22 (0.733 to 1.87)	1.88 (0.517 to 6.74)	1.03 (0.583 to 2.12)	0.950 (0.567 to 1.68)	1.08 (0.750 to 4.02)	1.75 (0.750 to 1.93)	1.63 (0.683 to 1.92)	2.33 (0.600 to 3.53)	1.36 (0.617 to 1.82)	1.65 (0.533 to 1.68)	0.917 (0.700 to 2.85)

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

(Time Frame: pre dose, immediately after start of injection, 15 and 30 minutes, 1, 2 and 4 hours after start of PDR001 infusion on Cycle 1 Day 1.)

Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W

Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	7	10	11	9	9	8	11	5	5	6	7	4	7	5
Area under the serum concentration-time curve from time zero to the time of last quantifiable concentration (AUClast) of PDR001 (units: day*ug/mL) Geometric Mean (Geometric Coefficient of Variation)														
	1050 (13.5%)	583 (731.2 %)	987 (43.2%)	851 (65.1%)	836 (100.2 %)	1020 (28.2%)	643 (360.2 %)	1260 (28.7%)	783 (45.7%)	990 (20.9%)	1200 (42.0%)	1050 (37.2%)	1010 (48.1%)	1040 (43.0%)

Area under the serum concentration-time curve from time zero to infinity (AUCinf) of PDR001

(Time Frame: pre dose, immediately after start of injection, 15 and 30 minutes, 1, 2 and 4 hours after start of PDR001 infusion on Cycle 1 Day 1.)

Group A – MIW815 50 ug Weekly 3W/1W + PDR001	Group A – MIW815 100 ug Weekly 3W/1W + PDR001	Group A – MIW815 200 ug Weekly 3W/1W + PDR001	Group A – MIW815 400 ug Weekly 3W/1W + PDR001	Group A – MIW815 800 ug Weekly 3W/1W + PDR001	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W

	400 mg Q4W	400 mg Q4W	400 mg Q4W	400 mg Q4W	400 mg Q4W	400 mg Q4W	400 mg Q4W							
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	0	1	0	1	2	1	1	1	0	0	0	1	0	2
Area under the serum concentration-time curve from time zero to infinity (AUCinf) of PDR001 (units: day*ug/mL) Geometric Mean (Geometric Coefficient of Variation)														
		1030 (NA%)[1]		2650 (NA%)[1]	991 (2.8%)	1550 (NA%)[1]	1310 (NA%)[1]	1180 (NA%)[1]				1420 (NA%)[1]		748 (6.3%)

[1] Insufficient number of participants with values.

Change from baseline of PD-L1 percent positive tumor

(Time Frame: Screening (baseline), Cycle 2 Day 15. The duration of each cycle was 28 days.)

Group A – MIW815 50 ug	Group A – MIW815 100 ug	Group A – MIW815 200 ug	Group A – MIW815 400 ug	Group A – MIW815 800 ug	Group A – MIW815 1600 ug	Group A – MIW815 3200 ug	Group B – MIW815 50 ug	Group B – MIW815 100 ug	Group B – MIW815 200 ug	Group B – MIW815 400 ug	Group B – MIW815 800 ug	Group B – MIW815 1600 ug	Group B – MIW815 3200 ug

	Weekly 3W/1W + PDR001 400 mg Q4W	Weekly 3W/1W + PDR001 400 mg Q4W	Weekly 3W/1W + PDR001 400 mg Q4W	Weekly 3W/1W + PDR001 400 mg Q4W	Weekly 3W/1W + PDR001 400 mg Q4W	Weekly 3W/1W + PDR001 400 mg Q4W	Weekly 3W/1W + PDR001 400 mg Q4W	Q4W + PDR001 400 mg Q4W	Q4W + PDR001 400 mg Q4W	Q4W + PDR001 400 mg Q4W	Q4W + PDR001 400 mg Q4W	Q4W + PDR001 400 mg Q4W	Q4W + PDR001 400 mg Q4W	Q4W + PDR001 400 mg Q4W
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	4 (I), 3 (NI)	4 (I), 3 (NI)	3 (I), 5 (NI)	2 (I), 1 (NI)	5 (I), 3 (NI)	7 (I), 4 (NI)	0 (I), 2 (NI)	2 (I), 2 (NI)	2 (I), 1 (NI)	3 (I), 4 (NI)	2 (I), 3 (NI)	3 (I), 3 (NI)	2 (I), 3 (NI)	2 (I), 1 (NI)
Change from baseline of PD-L1 percent positive tumor (units: PD-L1 percent positive tumor) Median (Full Range)														
Injected tumor (I)	0.00 (0.0 to 4.0)	0.00 (-10.0 to 40.0)	14.50 (5.0 to 40.0)	5.00 (0.0 to 10.0)	1.00 (-5.0 to 2.5)	-3.00 (-40.0 to 50.0)		30.25 (0.5 to 60.0)	0.25 (0.0 to 0.5)	0.00 (-19.5 to 35.0)	0.00 (0.0 to 0.0)	-5.00 (-15.0 to 4.0)	-32.25 (-67.0 to 2.5)	0.25 (0.0 to 0.5)
Non-injected tumor (NI)	60.00 (5.0 to 75.0)	0.00 (0.0 to 0.0)	0.00 (-4.5 to 100.0)	0.00 (0.0 to 0.0)	0.00 (-10.0 to 0.5)	-7.5 (-15.0 to 14.5)	-0.50 (-0.5 to -0.5)	2.50 (0.0 to 5.0)	0.00 (0.0 to 0.0)	0.00 (-1.0 to 20.0)	0.00 (-1.5 to 38.0)	0.00 (-15.0 to 0.0)	0.00 (-10.0 to 69.0)	0.00 (0.0 to 0.0)

Change from baseline of CD8 percent marker area

(Time Frame: Screening (baseline), Cycle 2 Day 15. The duration of each cycle was 28 days.)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	4 (I), 4 (NI)	3 (I), 2 (NI)	3 (I), 4 (NI)	2 (I), 2 (NI)	6 (I), 3 (NI)	6 (I), 3 (NI)	0 (I), 2 (NI)	2 (I), 2 (NI)	2 (I), 1 (NI)	2 (I), 4 (NI)	2 (I), 3 (NI)	3 (I), 3 (NI)	2 (I), 3 (NI)	2 (I), 3 (NI)
Change from baseline of CD8 percent marker area (units: CD8 percent marker area) Median (Full Range)														
Injected tumor (I)	5.83 (-2.3 to 11.5)	0.22 (-2.2 to 10.2)	-0.10 (-0.5 to 0.2)	0.23 (-7.7 to 8.2)	-0.24 (-5.8 to 8.0)	3.16 (-12.0 to 7.3)		6.60 (-0.5 to 13.7)	0.16 (-0.1 to 0.4)	0.63 (-0.9 to 2.2)	3.61 (0.1 to 7.1)	0.21 (-0.4 to 1.6)	2.77 (1.8 to 3.7)	0.32 (0.2 to 0.5)

Non-injected tumor (NI)	9.10 (0.3 to 12.6)	3.72 (-0.4 to 7.9)	0.03 (-0.6 to 0.1)	-3.51 (-3.7 to -3.4)	-0.01 (-0.7 to 2.6)	0.38 (-1.5 to 0.8)	0.84 (0.2 to 1.5)	1.14 (0.3 to 2.0)	-0.33 (-0.33 to -0.33)	-0.03 (-1.1 to 0.2)	0.54 (-0.1 to 2.3)	0.20 (-0.1 to 0.8)	0.08 (-0.2 to 22.0)	0.58 (0.1 to 3.2)

Change from baseline of CD68 percent marker area

(Time Frame: Screening (baseline), Cycle 2 Day 15. The duration of each cycle was 28 days.)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of Participants Analyzed [units: participants]	4 (I), 4 (NI)	3 (I), 2 (NI)	3 (I), 4 (NI)	2 (I), 2 (NI)	4 (I), 3 (NI)	5 (I), 3 (NI)	0 (I), 2 (NI)	2 (I), 2 (NI)	2 (I), 1 (NI)	2 (I), 4 (NI)	2 (I), 3 (NI)	2 (I), 2 (NI)	2 (I), 3 (NI)	3 (I), 2 (NI)

Change from baseline of CD68 percent marker area
(units: CD68 percent marker area)
Median (Full Range)

Injected tumor (I)	3.70 (-4.1 to 5.4)	0.58 (0.4 to 28.9)	0.26 (-1.0 to 0.5)	0.46 (-0.7 to 1.6)	0.33 (-1.7 to 2.6)	1.23 (-3.5 to 5.1)		2.41 (-1.0 to 5.9)	-0.21 (-0.3 to -0.2)	0.85 (-0.3 to 2.0)	2.26 (-0.3 to 4.8)	0.46 (0.4 to 0.5)	10.21 (-0.3 to 20.7)	-0.45 (-2.1 to 0.3)
Non-injected tumor (NI)	1.85 (-1.0 to 17.2)	-1.24 (-1.5 to -1.0)	0.16 (-0.4 to 1.5)	-5.90 (-13.0 to 1.2)	1.98 (-0.0 to 2.1)	-1.73 (-9.1 to 1.1)	-1.05 (-2.3 to 0.2)	1.35 (-0.7 to 3.4)	0.22 (0.22 to 0.22)	0.04 (-0.9 to 3.8)	1.40 (-1.3 to 4.0)	-1.81 (-3.2 to -0.5)	0.54 (0.0 to 21.2)	0.47 (-0.7 to 1.7)

Change from baseline of FOXP3 percent marker area

(Time Frame: Screening (baseline), Cycle 2 Day 15. The duration of each cycle was 28 days.)

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W	**Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W**	**Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W**	**Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W**
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle
Number of	4 (I), 4 (NI)	3 (I), 2 (NI)	3 (I), 4 (NI)	2 (I), 2 (NI)	5 (I), 3 (NI)	5 (I), 3 (NI)	0 (I), 2 (NI)	2 (I), 2 (NI)	2 (I), 1 (NI)	2 (I), 4 (NI)	2 (I), 3 (NI)	3 (I), 3 (NI)	1 (I), 3 (NI)	1 (I), 2 (NI)

Participants Analyzed [units: participants]														
Change from baseline of FOXP3 percent marker area (units: FOXP3 percent marker area) Median (Full Range)														
Injected tumor (I)	-0.14 (-0.6 to 1.0)	0.03 (-0.8 to 1.1)	-0.01 (-0.1 to 0.1)	1.64 (0.6 to 2.7)	-0.03 (-1.2 to 2.7)	0.21 (-1.3 to 2.6)		0.17 (-0.2 to 0.5)	-0.03 (-0.1 to 0.0)	0.15 (0.0 to 0.3)	0.51 (0.0 to 1.0)	0.00 (-0.1 to 0.6)	0.43 (0.43 to 0.43)	0.02 (-0.0 to 0.1)
Non-injected tumor (NI)	0.15 (-0.4 to 2.1)	0.28 (-0.1 to 0.6)	0.01 (-0.1 to 0.1)	-0.02 (-0.2 to 0.1)	0.00 (-0.1 to 0.8)	0.21 (-0.0 to 0.7)	0.08 (0.0 to 0.1)	-1.16 (-2.4 to 0.0)	-0.05 (-0.05 to -0.05)	0.13 (-0.1 to 0.4)	-0.02 (-0.1 to 0.2)	-0.01 (-0.01 to 0.1)	0.11 (0.0 to 1.9)	0.24 (0.0 to 0.5)

Safety Results

All-Cause Mortality

	Group A – MIW815 50 ug Weekly 3W/1W + PDR001 400 mg Q4W N = 7	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W N = 10	Group A – MIW815 200 ug Weekly 3W/1W + PDR001 400 mg Q4W N = 13	Group A – MIW815 400 ug Weekly 3W/1W + PDR001 400 mg Q4W N = 9	Group A – MIW815 800 ug Weekly 3W/1W + PDR001 400 mg Q4W N = 9	Group A – MIW815 1600 ug Weekly 3W/1W + PDR001 400 mg Q4W N = 8	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W N = 11	Group B – MIW815 50 ug Q4W + PDR001 400 mg Q4W N = 5	Group B – MIW815 100 ug Q4W + PDR001 400 mg Q4W N = 5	Group B – MIW815 200 ug Q4W + PDR001 400 mg Q4W N = 6	Group B – MIW815 400 ug Q4W + PDR001 400 mg Q4W N = 7	Group B – MIW815 800 ug Q4W + PDR001 400 mg Q4W N = 4	Group B – MIW815 1600 ug Q4W + PDR001 400 mg Q4W N = 7	Group B – MIW815 3200 ug Q4W + PDR001 400 mg Q4W N = 5	All Patients N = 106
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR001 400 mg administered on day 1 of each 28-day cycle	All Patients in Groups A and B
Total participants affected	1 (14.29 %)	2 (20.00 %)	2 (15.38 %)	1 (11.11 %)	1 (11.11 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	2 (40.00 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (40.00 %)	13 (12.26%)

Serious Adverse Events by System Organ Class

Time Frame	From the day of the first dose of any study drug up to 150 days after the last dose, up to maximum duration of 94 weeks.
Additional Description	Any sign or symptom that occurs during the study treatment plus the 150 days post treatment.
Source Vocabulary for Table Default	MedDRA (23.1)
Assessment Type for Table Default	Systematic Assessment

	Group A – MIW815 50 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 7	**Group A – MIW815 100 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 10**	**Group A – MIW815 200 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 13**	**Group A – MIW815 400 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 9**	**Group A – MIW815 800 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 9**	**Group A – MIW815 1600 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 8**	**Group A – MIW815 3200 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 11**	**Group B – MIW815 50 ug Q4W + PDR00 1 400 mg Q4W N = 5**	**Group B – MIW815 100 ug Q4W + PDR00 1 400 mg Q4W N = 5**	**Group B – MIW815 200 ug Q4W + PDR00 1 400 mg Q4W N = 6**	**Group B – MIW815 400 ug Q4W + PDR00 1 400 mg Q4W N = 7**	**Group B – MIW815 800 ug Q4W + PDR00 1 400 mg Q4W N = 4**	**Group B – MIW815 1600 ug Q4W + PDR00 1 400 mg Q4W N = 7**	**Group B – MIW815 3200 ug Q4W + PDR00 1 400 mg Q4W N = 5**	**All Patients N = 106**
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	All Patients in Groups A and B

Total participants affected	5 (71.43%)	4 (40.00%)	6 (46.15%)	3 (33.33%)	3 (33.33%)	2 (25.00%)	1 (9.09%)	1 (20.00%)	2 (40.00%)	1 (16.67%)	1 (14.29%)	2 (50.00%)	3 (42.86%)	3 (60.00%)	37 (34.91%)
Blood and lymphatic system disorders															
Anaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (2.83%)
Leukocytosis	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Cardiac disorders															
Atrial fibrillation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Right ventricular dysfunction	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Endocrine disorders															
Hyperthyroidism	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Gastrointestinal disorders															
Abdominal pain	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	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 (1.89%)
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%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Diarrhoea	0 (0.00%)	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%)	1 (25.00%)	0 (0.00%)	1 (20.00%)	3 (2.83%)

Incarcerated umbilical hernia	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.0 0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Intussusception	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.0 0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Subileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.0 0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
General disorders and administration site conditions															
Chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.0 0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Fatigue	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.0 0%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (2.83%)
Pyrexia	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.0 0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	3 (2.83%)
Infections and infestations															
Bacteraemia	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.0 0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.0 0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	2 (1.89%)
Epiglottitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.0 0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Localised infection	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.0 0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.0 9%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)

Sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Skin infection	1 (14.2 9%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Injury, poisoning and procedural complications															
Procedural haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.2 9%)	0 (0.00 %)	1 (0.94 %)
Investigations															
Amylase increased	1 (14.2 9%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Blood creatine increased	1 (14.2 9%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Lipase increased	1 (14.2 9%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Metabolism and nutrition disorders															
Failure to thrive	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Musculoskeletal and connective tissue disorders															

Back pain	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (1.89 %)
Flank pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Muscular weaknes s	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.0 0%)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Pain in extremity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Pain in jaw	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.2 9%)	0 (0.00 %)	1 (0.94 %)
Neoplasms benign, malignant and unspecifie d (incl cysts and polyps)															
Metastas es to central nervous system	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (12.5 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Oesopha geal adenocar cinoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (14.2 9%)	0 (0.00 %)	1 (0.94 %)
Skin neoplasm bleeding	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Squamou s cell carcinom a	0 (0.00 %)	0 (0.00 %)	1 (7.69 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)

Nervous system disorders															
Headache	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Partial seizures	0 (0.00%)	0 (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%)	0 (0.00%)	1 (0.94%)
Renal and urinary disorders															
Acute kidney injury	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
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%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Respiratory, thoracic and mediastinal disorders															
Dysphonia	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)
Dyspnoea	0 (0.00%)	1 (10.00%)	2 (15.38%)	0 (0.00%)	1 (11.11%)	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%)	5 (4.72%)
Immune-mediated pneumonitis	0 (0.00%)	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%)	0 (0.00%)	1 (0.94%)
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%)	0 (0.00%)	1 (20.00%)	1 (0.94%)
Pneumothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.94%)

Pulmonary embolism	0 (0.00 %)	1 (10.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Respiratory failure	1 (14.29%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Tracheal stenosis	0 (0.00 %)	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 %)	0 (0.00 %)	1 (0.94 %)
Vocal cord disorder	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 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Vascular disorders															
Hypertension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (25.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (1.89 %)
Hypotension	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 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)
Orthostatic hypotension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (0.94 %)

Other Adverse Events by System Organ Class

Time Frame	From the day of the first dose of any study drug up to 150 days after the last dose, up to maximum duration of 94 weeks.
Additional Description	Any sign or symptom that occurs during the study treatment plus the 150 days post treatment.
Source Vocabulary for Table Default	MedDRA (23.1)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

	Group A – MIW815 50 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 7	Group A – MIW815 100 ug Weekly 3W/1W + PDR001 400 mg Q4W N = 10	Group A – MIW815 200 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 13	Group A – MIW815 400 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 9	Group A – MIW815 800 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 9	Group A – MIW815 1600 ug Weekly 3W/1W + PDR00 1 400 mg Q4W N = 8	Group A – MIW815 3200 ug Weekly 3W/1W + PDR001 400 mg Q4W N = 11	Group B – MIW815 50 ug Q4W + PDR00 1 400 mg Q4W N = 5	Group B – MIW815 100 ug Q4W + PDR00 1 400 mg Q4W N = 5	Group B – MIW815 200 ug Q4W + PDR00 1 400 mg Q4W N = 6	Group B – MIW81 5 400 ug Q4W + PDR00 1 400 mg Q4W N = 7	Group B – MIW815 800 ug Q4W + PDR00 1 400 mg Q4W N = 4	Group B – MIW81 5 1600 ug Q4W + PDR00 1 400 mg Q4W N = 7	Group B – MIW815 3200 ug Q4W + PDR00 1 400 mg Q4W N = 5	All Patients N = 106
Arm/Group Description	MIW815 50 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 400 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 1600 ug administered on days 1, 8 and 15 and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug administered on days 1, 8 and 15 and PDR001 400 mg administered on day 1 of each 28-day cycle	MIW815 50 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 100 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 200 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW81 5 400 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 800 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW81 5 1600 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	MIW815 3200 ug and PDR00 1 400 mg administered on day 1 of each 28-day cycle	All Patients in Groups A and B
Total participants affected	7 (100.00%)	10 (100.00%)	12 (92.31%)	9 (100.00%)	9 (100.00%)	8 (100.00%)	11 (100.00%)	5 (100.00%)	5 (100.00%)	6 (100.00%)	6 (85.71%)	4 (100.00%)	5 (71.43%)	5 (100.00%)	102 (96.23%)
Blood and lymphatic system disorders															
Anaemia	4 (57.14%)	3 (30.00%)	3 (23.08%)	2 (22.22%)	2 (22.22%)	3 (37.50%)	2 (18.18%)	1 (20.00%)	2 (40.00%)	2 (33.33%)	0 (0.0 0%)	1 (25.00%)	2 (28.57%)	1 (20.00%)	28 (26.42%)
Leukocytosis	1 (14.29%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89%)
Lymph node pain	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25.00%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94%)

Lymphopenia	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Neutropenia	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Thrombocytopenia	0 (0.0 0%)	0 (0.00 %)	2 (15. 38%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Cardiac disorders															
Bradycardia	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Tachycardia	1 (14. 29%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	3 (2.83 %)
Ear and labyrinth disorders															
Deafness	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Tympanic membrane perforation	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Endocrine disorders															
Hyperthyroidism	1 (14. 29%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Hypothyroidism	1 (14. 29%)	0 (0.00 %)	2 (15. 38%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	4 (3.77 %)
Eye disorders															
Conjunctival haemorrhage	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)

Dry eye	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Ocular hyperaemia	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Gastrointestinal disorders															
Abdominal distension	0 (0.0 0%)	1 (10.0 0%)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	4 (3.77 %)
Abdominal pain	0 (0.0 0%)	1 (10.0 0%)	1 (7.6 9%)	2 (22. 22%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	6 (5.66 %)
Abdominal pain lower	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Abdominal pain upper	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	3 (2.83 %)
Anal haemorrhage	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Ascites	0 (0.0 0%)	2 (20.0 0%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	3 (2.83 %)
Constipation	2 (28. 57%)	2 (20.0 0%)	1 (7.6 9%)	0 (0.0 0%)	2 (22. 22%)	0 (0.0 0%)	2 (18.1 8%)	1 (20. 00%)	2 (40. 00%)	0 (0.0 0%)	3 (42. 86%)	1 (25. 00%)	0 (0.0 0%)	1 (20. 00%)	17 (16. 04%)
Diarrhoea	3 (42. 86%)	0 (0.00 %)	2 (15. 38%)	2 (22. 22%)	2 (22. 22%)	1 (12. 50%)	1 (9.09 %)	1 (20. 00%)	1 (20. 00%)	1 (16. 67%)	1 (14. 29%)	2 (50. 00%)	2 (28. 57%)	2 (40. 00%)	21 (19. 81%)
Dry mouth	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	2 (28. 57%)	0 (0.0 0%)	4 (3.77 %)
Enteritis	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Enterocolitis	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)

Gastritis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Gastrointestinal haemorrhage	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Gastrooesophageal reflux disease	0 (0.0 0%)	1 (10.0 0%)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Haemorrhoids	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Hiatus hernia	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Hyperaesthesia teeth	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Intussusception	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Melaena	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Nausea	4 (57. 14%)	0 (0.00 %)	2 (15. 38%)	1 (11. 11%)	2 (22. 22%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	13 (12. 26%)
Oral pain	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Overflow diarrhoea	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Stomatitis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Subileus	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Toothache	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)

Trichoglossia	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Vomiting	4 (57. 14%)	0 (0.00 %)	2 (15. 38%)	1 (11. 11%)	1 (11. 11%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	2 (33. 33%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	2 (40. 00%)	15 (14. 15%)
General disorders and administration site conditions															
Asthenia	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (40. 00%)	5 (4.72 %)
Axillary pain	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Chest pain	0 (0.0 0%)	2 (20.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	3 (2.83 %)
Chills	0 (0.0 0%)	2 (20.0 0%)	2 (15. 38%)	0 (0.0 0%)	1 (11. 11%)	2 (25. 00%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	1 (25. 00%)	0 (0.0 0%)	1 (20. 00%)	10 (9.4 3%)
Facial pain	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Fatigue	1 (14. 29%)	4 (40.0 0%)	1 (7.6 9%)	0 (0.0 0%)	1 (11. 11%)	2 (25. 00%)	2 (18.1 8%)	0 (0.0 0%)	1 (20. 00%)	1 (16. 67%)	1 (14. 29%)	1 (25. 00%)	2 (28. 57%)	0 (0.0 0%)	17 (16. 04%)
Impaired healing	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Influenza like illness	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Infusion site erythema	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Infusion site swelling	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)

Injection site discharge	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Injection site erythema	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	2 (1.89 %)
Injection site pain	1 (14. 29%)	1 (10.0 0%)	2 (15. 38%)	2 (22. 22%)	2 (22. 22%)	2 (25. 00%)	7 (63.6 4%)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	2 (28. 57%)	1 (20. 00%)	21 (19. 81%)
Injection site rash	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Injection site reaction	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	3 (27.2 7%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	4 (3.77 %)
Localised oedema	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Malaise	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Mucosal inflammation	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Oedema	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Oedema peripheral	0 (0.0 0%)	2 (20.0 0%)	0 (0.0 0%)	1 (11. 11%)	1 (11. 11%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	6 (5.66 %)
Pain	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Pyrexia	1 (14. 29%)	1 (10.0 0%)	3 (23. 08%)	1 (11. 11%)	3 (33. 33%)	4 (50. 00%)	7 (63.6 4%)	1 (20. 00%)	0 (0.0 0%)	2 (33. 33%)	1 (14. 29%)	0 (0.0 0%)	1 (14. 29%)	3 (60. 00%)	28 (26. 42%)
Hepatobiliary disorders															
Hyperbilirubinaemia	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)

Infections and infestations															
Cellulitis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	3 (2.83 %)
Ear infection viral	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Empyema	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Gastroent eritis	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Gastroent eritis viral	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	1 (0.94 %)
Gastrointe stinal infection	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Hordeolu m	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (0.94 %)
Infection	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Injection site infection	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Nasophar yngitis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	1 (0.94 %)
Oral candidiasi s	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Otitis media	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Pharyngiti s	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)

Pneumonia	0 (0.0 0%)	0 (0.00 %)	2 (15. 38%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	3 (2.83 %)
Post procedural infection	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Rhinitis	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Sepsis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Sinusitis	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Skin infection	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Tinea versicolour	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Upper respiratory tract infection	0 (0.0 0%)	1 (10.0 0%)	2 (15. 38%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	8 (7.55 %)
Urinary tract infection	1 (14. 29%)	1 (10.0 0%)	0 (0.0 0%)	2 (22. 22%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	4 (3.77 %)
Viral upper respiratory tract infection	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Vulval cellulitis	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Wound infection	0 (0.0 0%)	1 (10.0 0%)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Injury, poisoning															

and procedural complications															
Ankle fracture	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Contusion	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Fall	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Foot fracture	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Infusion related reaction	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Neurological procedural complication	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Post procedural discharge	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Procedural pain	1 (14. 29%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	5 (4.72 %)
Radiation associated pain	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Radiation fibrosis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Seroma	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (0.94 %)
Thermal burn	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)

Urostomy complication	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Wound complication	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Wound secretion	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Investigations															
Alanine aminotransferase increased	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	2 (40. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	6 (5.66 %)
Amylase decreased	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Amylase increased	1 (14. 29%)	1 (10.0 0%)	1 (7.6 9%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	1 (20. 00%)	7 (6.60 %)
Aspartate aminotransferase increased	1 (14. 29%)	1 (10.0 0%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	2 (40. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	6 (5.66 %)
Blood alkaline phosphatase increased	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	1 (20. 00%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	6 (5.66 %)
Blood bilirubin increased	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Blood creatine increased	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)

Blood creatinine increased	2 (28.57%)	0 (0.00%)	1 (7.69%)	0 (0.0 0%)	0 (0.0 0%)	1 (12.50%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25.00%)	0 (0.0 0%)	0 (0.0 0%)	5 (4.72%)
Blood lactate dehydrogenase increased	0 (0.0 0%)	0 (0.00%)	1 (7.69%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94%)
Blood potassium decreased	1 (14.29%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94%)
Blood thyroid stimulating hormone increased	1 (14.29%)	0 (0.00%)	1 (7.69%)	0 (0.0 0%)	1 (11.11%)	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	3 (2.83%)
Blood urea increased	1 (14.29%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94%)
Blood uric acid increased	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25.00%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94%)
C-reactive protein increased	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	1 (11.11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94%)
Electrocardiogram QT prolonged	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	1 (11.11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94%)
Eosinophil count increased	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	1 (16.67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94%)
Gamma-glutamyltr	1 (14.29%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94%)

ansferase increased															
Human chorionic gonadotropin increased	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Lipase increased	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	2 (22. 22%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	6 (5.66 %)
Liver function test increased	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
SARS-CoV-2 test negative	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Transaminases increased	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	1 (0.94 %)
Weight decreased	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	2 (22. 22%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	4 (3.77 %)
White blood cell count decreased	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Metabolism and nutrition disorders															
Decreased appetite	0 (0.0 0%)	1 (10.0 0%)	1 (7.6 9%)	0 (0.0 0%)	1 (11. 11%)	2 (25. 00%)	3 (27.2 7%)	1 (20. 00%)	1 (20. 00%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	12 (11. 32%)
Dehydration	1 (14. 29%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	3 (2.83 %)
Hyperamylasaemia	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	1 (0.94 %)

Hypercalcaemia	1 (14.29%)	1 (10.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.89%)
Hyperkalaemia	0 (0.0%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.29%)	0 (0.0%)	0 (0.0%)	1 (20.00%)	2 (1.89%)
Hypermagnesaemia	0 (0.0%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.50%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.94%)
Hyperuricaemia	1 (14.29%)	0 (0.00%)	1 (7.69%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.00%)	3 (2.83%)
Hypoalbuminaemia	1 (14.29%)	0 (0.00%)	0 (0.0%)	1 (11.11%)	0 (0.0%)	0 (0.0%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.89%)
Hypocalcaemia	0 (0.0%)	0 (0.00%)	0 (0.0%)	1 (11.11%)	0 (0.0%)	0 (0.0%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.94%)
Hypokalaemia	0 (0.0%)	0 (0.00%)	2 (15.38%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.09%)	0 (0.0%)	1 (20.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.00%)	5 (4.72%)
Hypomagnesaemia	0 (0.0%)	0 (0.00%)	2 (15.38%)	0 (0.0%)	1 (11.11%)	0 (0.0%)	1 (9.09%)	2 (40.00%)	0 (0.0%)	0 (0.0%)	1 (14.29%)	1 (25.00%)	0 (0.0%)	0 (0.0%)	8 (7.55%)
Hyponatraemia	0 (0.0%)	1 (10.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.09%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.00%)	3 (2.83%)
Hypophosphataemia	1 (14.29%)	0 (0.00%)	1 (7.69%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.00%)	0 (0.0%)	0 (0.0%)	3 (2.83%)
Vitamin D deficiency	1 (14.29%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.94%)
Musculoskeletal and connective tissue disorders															
Arthralgia	2 (28.57%)	2 (20.00%)	1 (7.69%)	1 (11.11%)	0 (0.0%)	0 (0.0%)	2 (18.18%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (7.55%)
Arthritis	0 (0.0%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.50%)	0 (0.00%)	0 (0.0%)	0 (0.0%)	1 (16.67%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.89%)

Back pain	0 (0.0 0%)	0 (0.00 %)	2 (15. 38%)	0 (0.0 0%)	2 (22. 22%)	1 (12. 50%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	8 (7.55 %)
Fistula	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Flank pain	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Groin pain	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	2 (1.89 %)
Joint range of motion decreased	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Joint stiffness	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Metatarsal gia	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	1 (0.94 %)
Muscle spasms	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Musculoskeletal chest pain	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Musculoskeletal pain	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Myalgia	1 (14. 29%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (28. 57%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	5 (4.72 %)
Neck pain	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Osteoporosis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Pain in extremity	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	1 (11. 11%)	1 (11. 11%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	4 (3.77 %)

Pain in jaw	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (0.94 %)
Tendonitis	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)															
Basal cell carcinoma	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Brain cancer metastatic	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Cancer pain	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	2 (1.89 %)
Dysplastic naevus	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Gastrointestinal tract adenoma	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Infected neoplasm	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Malignant ascites	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Metastases to skin	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Neoplasm skin	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Oncologic complication	0 (0.0 0%)	1 (10.0 0%)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)

Tumour haemorrhage	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Tumour inflammation	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Tumour pain	1 (14. 29%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	4 (3.77 %)
Nervous system disorders															
Balance disorder	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Cognitive disorder	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Dizziness	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	3 (2.83 %)
Dysgeusia	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	1 (11. 11%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Epilepsy	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (0.94 %)
Headache	2 (28. 57%)	1 (10.0 0%)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	6 (5.66 %)
Hypotonia	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Memory impairment	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Neuropathy peripheral	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Paraesthesia	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)

Restless legs syndrome	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (0.94 %)
Somnolence	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Syncope	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Tremor	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	3 (2.83 %)
Psychiatric disorders															
Agitation	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Anxiety	1 (14. 29%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Depression	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Insomnia	0 (0.0 0%)	0 (0.00 %)	2 (15. 38%)	1 (11. 11%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	5 (4.72 %)
Renal and urinary disorders															
Acute kidney injury	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	1 (0.94 %)
Chronic kidney disease	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Haematuria	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Hydronephrosis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)

Pelvi-ureteric obstruction	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Pollakiuria	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Renal impairment	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Reproductive system and breast disorders															
Dysmenorrhoea	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Scrotal pain	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	1 (0.94 %)
Vaginal haemorrhage	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Vaginal oedema	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Vulvovaginal pain	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Respiratory, thoracic and mediastinal disorders															
Atelectasis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (0.94 %)
Cough	2 (28. 57%)	0 (0.00 %)	3 (23. 08%)	1 (11. 11%)	2 (22. 22%)	0 (0.0 0%)	2 (18.1 8%)	0 (0.0 0%)	2 (40. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	3 (60. 00%)	15 (14. 15%)

Dysphonia	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Dyspnoea	2 (28. 57%)	2 (20.0 0%)	3 (23. 08%)	1 (11. 11%)	1 (11. 11%)	0 (0.0 0%)	3 (27.2 7%)	1 (20. 00%)	2 (40. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	1 (20. 00%)	17 (16. 04%)
Dyspnoea exertional	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (11. 11%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	3 (2.83 %)
Haemoptysis	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Hiccups	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	1 (0.94 %)
Immune-mediated pneumonitis	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Nasal congestion	0 (0.0 0%)	1 (10.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Oropharyngeal pain	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Pleural effusion	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	2 (18.1 8%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	1 (20. 00%)	7 (6.60 %)
Pneumonitis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Pneumothorax	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	1 (0.94 %)
Productive cough	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Pulmonary amyloidosis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Pulmonary embolism	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (25. 00%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)

Rhinorrhoea	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Wheezing	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Skin and subcutaneous tissue disorders															
Actinic keratosis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Alopecia	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Dermatitis bullous	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Dermatitis contact	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	1 (0.94 %)
Dry skin	1 (14. 29%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Eczema	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Eczema nummular	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Erythema	0 (0.0 0%)	1 (10.0 0%)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	3 (2.83 %)
Night sweats	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Pain of skin	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Pruritus	1 (14. 29%)	1 (10.0 0%)	3 (23. 08%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	1 (9.09 %)	1 (20. 00%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	9 (8.49 %)
Psoriasis	0 (0.0 0%)	0 (0.00 %)	1 (7.6 9%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)

Rash	0 (0.0 0%)	2 (20.0 0%)	2 (15. 38%)	2 (22. 22%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	1 (20. 00%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (40. 00%)	11 (10. 38%)
Rash macular	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (16. 67%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Rash maculo-papular	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Rash pruritic	1 (14. 29%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Skin irritation	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Skin lesion	0 (0.0 0%)	0 (0.00 %)	2 (15. 38%)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	4 (3.77 %)
Skin lesion inflammation	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Skin necrosis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	1 (9.09 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)
Vitiligo	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	2 (1.89 %)
Vascular disorders															
Deep vein thrombosis	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (0.94 %)
Hypertension	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	1 (11. 11%)	0 (0.0 0%)	2 (25. 00%)	1 (9.09 %)	1 (20. 00%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	5 (4.72 %)
Hypotension	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	1 (14. 29%)	0 (0.0 0%)	0 (0.0 0%)	1 (20. 00%)	2 (1.89 %)
Lymphoedema	0 (0.0 0%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	1 (11. 11%)	1 (12. 50%)	0 (0.00 %)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	0 (0.0 0%)	2 (1.89 %)

Conclusion:

- The safety and tolerability of MIW815 was generally favorable across all studied treatment groups.
- The MTD was not reached and no RDE was declared for MIW815 in combination with PDR001.
- Plasma exposure of MIW815 increased with dose. The variability of PK exposure was moderate to high.
- Limited anti-tumor activity was noted in dose escalation cohorts. Based on a review of the totality of data generated during the dose escalation part, the study was terminated early and the expansion part was not conducted.

Date of Clinical Trial Report

19-Aug-2021