NOVARTIS

Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Spartalizumab (PDR001) and canakinumab

Trial Indication(s)

Non-small-cell lung cancer (NSCLC)

Protocol Number

CPDR001C2101

Protocol Title

Phase Ib, multicenter, open label study of PDR001 in combination with platinum doublet chemotherapy and other immunooncology agents in PD-L1 unselected, metastatic NSCLS patients (ElevatION:NSCLC-101 trial)

Clinical Trial Phase

Phase 1

Phase of Drug Development

Phase III (spartalizumab) and Phase IV (canakinumab)

Study Start/End Dates

Study Start Date: May 2017 (Actual)
Primary Completion Date: July 2021 (Actual)
Study Completion Date: July 2021 (Actual)

Reason for Termination (If applicable)

Due to the competitive landscape for lung cancer therapies, the enrolment situation was carefully evaluated, and Novartis decided to halt the enrolment in this study. A letter was sent to investigators on 21-Jun-2019.

Study Design/Methodology

This was a multi-center, open-label, phase Ib trial investigating platinum-doublet chemotherapy regimens in combination with PDR001 and canakinumab in combination with PDR001 and platinum-doublet chemotherapy, in patients with squamous or non-squamous, stage IIIb or IV NSCLC. The study comprised of the dose confirmation and dose expansion parts.

- **Dose confirmation part**: The dose confirmation part consisted of two sub-parts.
    - The objective of the first dose confirmation sub-part was to establish the maximum tolerated dose (MTR) / recommended dose for expansion (RDE) of PDR001 in combination with 3 unique platinum-doublet chemotherapy regimens (Groups A, B, and C). In each treatment group, the first cohort of patients were treated with PDR001 at the starting dose of 300 mg every 3 weeks (intravenously) in combination with the assigned platinum-doublet chemotherapy, for up to four cycles in the induction period and followed by maintenance.
    - The second dose confirmation sub-part included canakinumab (at a starting dose of 200 mg every 3 weeks) with PDR001 (at a starting dose of 300 mg every 3 weeks) and platinum-doublet chemotherapy combination (Group E) to establish the MTD or RDE, and to assess the preliminary efficacy of this “triple” combination in patients with NSCLC. Treatment with this triple combination was to be followed by maintenance with pemetrexed, PDR001, and canakinumab.
- **Dose expansion part:** The expansion part was to start once MTD or RDE was established for the given treatment groups (Groups A, B and C). Participants were treated in each treatment indication group to further explore safety and preliminary antitumor activity of PDR001 in combination with platinum-doublet chemotherapy in treatment naïve patients.

In both parts, participants were treated up to 4 cycles in the induction period followed by maintenance period until disease progression or unacceptable toxicity, start of a new anti-neoplastic therapy, withdrawal of consent, physician’s decision, lost to follow-up, death or study is terminated by the sponsor.

Due to competitive landscape for lung cancer therapies, the enrollment situation was carefully evaluated, and Novartis decided to prematurely halt the enrollment in this study on 21-Jun-2019.

Centers

23 centers in 12 countries: United States(5), Belgium(2), Singapore(1), Spain(3), Italy(3), Korea, Republic of(1), Netherlands(1), Canada(1), Germany(2), Czech Republic(1), France(2), Hong Kong(1)

Objectives:

The primary objectives were:

- Dose confirmation part:
  - To establish the MTD and/or RDE of PDR001 with platinum-doublet chemotherapy as measured by incidence of dose limiting toxicities (DLTs) in the first 6 weeks of therapy
- Dose expansion part:
  - To assess the antitumor activity (as measured by overall response rate) of PDR001 with platinum-doublet chemotherapy based on RECIST 1.1 for groups A, B, C

The secondary objectives were:

- To assess other antitumor activity of PDR001 with platinum-doublet chemotherapy (Group A, B and C) and of canakinumab in combination with PDR001 and platinum-doublet chemotherapy (Group E) based on RECIST 1.1. The following related endpoints were assessed:
  - ORR- Group E
  - Progression-free survival (PFS), disease control rate (DCR), duration of response (DOR) and time to response (TTR)- Groups A, B, C and E
- To assess the overall survival (OS) of PDR001 with platinum-doublet chemotherapy (Groups A, B, and C) and of canakinumab in combination with PDR001 and platinum-doublet chemotherapy (Group E)
- To evaluate the PK of PDR001 and canakinumab (Group E only) in the presence of chemotherapy combination
- To evaluate the PK of chemotherapy combination in the presence of PDR001 with or without canakinumab.
- To characterize the prevalence and incidence of immunogenicity of PDR001 and canakinumab when given in combination with chemotherapy
- To assess the safety and tolerability profile of the combination of PDR001 with platinum-doublet chemotherapy (Groups A, B, and C) and of canakinumab in combination with PDR001 and platinum-doublet chemotherapy (Group E).

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

- PDR001 was supplied as powder in vial for solution for infusion and administered at a dose of 300 mg via intravenous infusion once every 3 weeks
- Canakinumab was administered at a dose of 200mg as a subcutaneous injection every 3 weeks.
- Pemetrexed was administered at a dose of 500 mg/m2 as an intravenous infusion every 3 weeks
- Gemcitabine was administered at a dose of 1250 mg/m² intravenous infusion for 4 cycles (induction period) on days 1 and 8 of each cycle (cycle=21 days).
- Cisplatin was administered at a dose of 75 mg/m2 as an intravenous infusion every 3 weeks for 4 cycles (induction period)
- Paclitaxel was administered at a dose of 200 mg/m2 as an intravenous infusion every 3 weeks for 4 cycles (induction period)
- Carboplatin was administered at a dose of AUC6 mg*min/mL as an intravenous infusion every 3 weeks for 4 cycles (induction period). If carboplatin was dosed with pemetrexed, carboplatin AUC5 might be used

Statistical Methods

Primary endpoints:

- Dose confirmation part: The percentage of participants with DLTs during the dose escalation part of the study for PDR001 in combination with platinum-doublet chemotherapy regimens (Groups A, B and C) and canakinumab in combination with PDR001 and platinum-doublet chemotherapy (Group E) was assessed. A dose-limiting toxicity (DLT) was defined as an adverse event or abnormal laboratory value assessed as unrelated to disease, disease progression, inter-current illness, or concomitant medications that occurred within the first 6 weeks of study treatment.
- Dose expansion part: ORR (per local investigator assessment) for treatment naive participants according to RECIST v 1.1 for groups A, B and C. ORR was defined as the percentage of participants with best overall response (BOR) of complete response (CR) or partial response (PR). BOR is defined as the best response recorded from the start of the treatment until disease progression as per RECIST v 1.1. The 95% CIs were calculated using exact binomial method

Secondary endpoints

- ORR, BOR and DCR were summarized by percent of participants and the corresponding 95% CI. DOR, TTR, PFS, and OS were analyzed using Kaplan-Meier method and presented along with their corresponding 95% CI.
- PK parameters were calculated using non-compartmental methods.

- The number and percentage of participants with antidrug antibodies (ADA)-positive against PDR001 and canakinumab were summarized.

Study Population: Key Inclusion/Exclusion Criteria

Main Inclusion Criteria:

1. Patient has stage IIIB (and is not a candidate for definitive multimodality therapy) or has stage IV NSCLC or relapsed locally advanced or metastatic NSCLC as follows: Groups A (squamous cell only), B (non-squamous cell only), C (squamous cell or non-squamous cell), and E (non-squamous cell only): Patients not previously treated with any systemic anti-cancer therapy (e.g. cytotoxic drugs, targeted therapy, monoclonal antibody therapy including immunotherapy (e.g. PD-1/PD-L1 inhibitors) or targeted therapies, either experimental or not), with exception of neo-adjuvant or adjuvant therapy as depicted in inclusion criterion 4
2. Patient who received previous neo-adjuvant or adjuvant systemic therapy will be eligible for enrollment only if relapse has occurred more than 12 months from the end of the neoadjuvant or adjuvant systemic therapy. Patients must have recovered from all toxicities related to prior (neo-) adjuvant systemic therapy to grade ≤ 1 (CTCAE v 4.03). Exception to this criterion: patients with any grade of alopecia are allowed to enter the study.
3. Histologically or cytologically confirmed diagnosis of NSCLC that is EGFR Wild-type, ALK-negative rearrangement and ROS1-negative rearrangement
4. Eastern Cooperative Oncology Group (ECOG) performance status of 0-1
5. Patients with at least 1 measurable tumor lesion as assessed by Computed Tomography (CT) Scan or Magnetic Resonance Imaging (MRI) according to RECIST 1.1.

Main Exclusion Criteria:

1. Patient with a history of severe hypersensitivity reaction to the planned study treatment including gemcitabine, paclitaxel, cisplatin, carboplatin, pemetrexed or any known excipients of these drugs
2. History of severe hypersensitivity reactions to other monoclonal antibodies, which in the opinion of the investigator may pose an increased risk of serious infusion reaction.
3. Patient has history of interstitial lung disease or interstitial pneumonitis, including clinically significant radiation pneumonitis (i.e., affecting activities of daily living or requiring therapeutic intervention).
4. Any untreated central nervous system (CNS) lesion. However, patients are eligible if: a) all known CNS lesions have been treated with radiotherapy or surgery and b) patient remained without evidence of CNS disease progression ≥ 4 weeks after treatment and c) patients must be off corticosteroid therapy for ≥ 2 weeks
5. Patient who has received thoracic radiotherapy to lung fields ≤ 4 weeks prior to starting the study treatment or patients who have not recovered from radiotherapy-related toxicities. For all other anatomic sites (including radiotherapy to thoracic vertebrae and ribs) radiotherapy ≤ 2 weeks prior to starting the study treatment or has not recovered from radiotherapy-related toxicities. Palliative radiotherapy for bone lesions > 1 weeks prior to starting study treatment is allowed.

6. Patient has clinically significant, uncontrolled heart disease and/or recent cardiac event (within 6 months).
7. Active, known or suspected autoimmune disease or a documented history of autoimmune disease, including ulcerative colitis and Crohn's disease (Patients with vitiligo, type I diabetes mellitus, residual hypothyroidism due to autoimmune condition only requiring hormone replacement, psoriasis not requiring systemic treatment, or conditions not expected to recur in the absence of an external trigger are permitted to enroll).
8. Patients with active Hepatitis B infection (HBsAg positive).
9. Patients with positive test for hepatitis C ribonucleic acid (HCV RNA).
10. Known history of testing positive for Human Immunodeficiency Virus (HIV) infection.
11. Patients has other severe, acute, or chronic medical conditions, active infection,

Participant Flow Table

Overall Study

	Group A (squamous): PDR001 + gemcitabine/cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin	Group E (non-squamous): PDR001+ canakinumab + pemetrexed/cisplatin	Total
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed	
Started	33	38	33	7	111
Completed	0	0	0	0	0
Not Completed	33	38	33	7	111
Adverse Event	0	5	1	0	6
Death	2	3	0	1	6

Lost to Follow-up	0	0	1	0	1
Physician Decision	2	3	3	1	9
Progressive disease	24	18	26	4	72
Study terminated by sponsor	5	6	1	0	12
Patient/guardian decision	0	3	1	1	5

Baseline Characteristics

	Group A (squamous): PDR001 + gemcitabine/cisplatin	**Group B (non-squamous): PDR001 + pemetrexed/cisplatin**	**Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin**	**Group E (non-squamous): PDR001+ canakinumab + pemetrexed/cisplatin**	**Total**
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed	
Number of Participants [units: participants]	33	38	33	7	111

Age Continuous (units: Years) Mean ± Standard Deviation	63.6±7.44	62.9±8.60	60.3±8.95	64.7±9.69	62.45±8.46
Sex: Female, Male (units: Participants) Count of Participants (Not Applicable)					
Female	6	20	19	1	46
Male	27	18	14	6	65
Race/Ethnicity, Customized (units: Participants) Count of Participants (Not Applicable)					
Caucasian	26	26	28	5	85
Black	0	2	0	0	2
Asian	5	6	3	2	16
Native American	0	0	1	0	1
Other	1	3	1	0	5
Unknown	1	1	0	0	2

Primary Outcome Result(s)

Percentage of participants with dose limiting toxicities (DLTs) during the first 6 weeks of therapy

(Time Frame: Up to 6 weeks)

	Group A (squamous): PDR001 + gemcitabine/ cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin	Group E (non-squamous): PDR001+ canakinumab + pemetrexed/cisplatin

Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	27	31	28	7
Percentage of participants with dose limiting toxicities (DLTs) during the first 6 weeks of therapy (units: Participants) Count of Participants (Not Applicable)				
	0 (%)	2 (6.45%)	1 (3.57%)	0 (%)

Overall response rate (ORR) per local investigator assessment for groups A, B and C

(Time Frame: From baseline up to approximately 47 months)

	Group A (squamous): PDR001 + gemcitabine/ cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	Group C (squamous or non-squamous): PDR001 + paclitaxel/carboplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4

	maintenance with PDR001	maintenance with PDR001	cycles) followed by maintenance with PDR001
Number of Participants Analyzed [units: participants]	33	38	33
Overall response rate (ORR) per local investigator assessment for groups A, B and C (units: Percentage of participants) Number (95% Confidence Interval)			
	57.6 (39.2 to 74.5)	55.3 (38.3 to 71.4)	51.5 (33.5 to 69.2)

Secondary Outcome Result(s)

Overall Response Rate (ORR) per local investigator assessment for group E

(Time Frame: Up to approximately 21 months)

	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed

Number of Participants Analyzed [units: participants]	7
Overall Response Rate (ORR) per local investigator assessment for group E (units: Percentage of participants) Number (95% Confidence Interval)	
	57.1 (18.4 to 90.1)

Progression Free Survival (PFS) per local investigator assessment

(Time Frame: From start of treatment to the date of the first documented progression or death due to any cause, whichever comes first, assessed up to approximately 50 months)

	Group A (squamous): PDR001 + gemcitabine/cisplatin	**Group B (non-squamous): PDR001 + pemetrexed/cisplatin**	**Group C (squamous or non-squamous): PDR001 + paclitaxel/carboplatin**	**Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin**
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	33	38	33	7
Progression Free Survival (PFS) per local				

investigator assessment (units: Months) Median (95% Confidence Interval)				
	6.2 (4.2 to 8.7)	10.4 (5.4 to 26.4)	6.3 (4.1 to 10.2)	7.5 (4.1 to 12.4)

Disease Control Rate (DCR) per local investigator assessment

(Time Frame: Up to approximately 47 months)

	Group A (squamous): PDR001 + gemcitabine/cisplatin	Group B (non-squamous): PDR001+ pemetrexed/cisplatin	Group C (squamous or non-squamous): PDR001 + paclitaxel/carboplatin	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	33	38	33	7
Disease Control Rate (DCR) per local investigator assessment (units: Percentage of participants) Number (95% Confidence Interval)				
	90.9 (75.7 to 98.1)	81.6 (65.7 to 92.3)	81.8 (64.5 to 93.0)	100 (59.0 to 100)

Duration of Response (DOR) per local investigator assessment

(Time Frame: From date of first documented response to the first documented progression or death due to any cause, whichever comes first, assessed up to approximately 43 months)

	Group A (squamous): PDR001 + gemcitabine/cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	Group C (squamous or non-squamous): PDR001 + paclitaxel/carboplatin	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	19	21	17	4
Duration of Response (DOR) per local investigator assessment (units: Months) Number (95% Confidence Interval)				
	6.0 (3.0 to 18.0)	30.1 (9.0 to NA)[12]	8.2 (5.1 to 23.1)	7.1 (1.4 to NA)[12]

[1] Upper limit was not reached (NA) due to insufficient number of participants with events
[2] Upper limit was not reached (NA) due to insufficient number of participants with events

Time to Response (TTR) per local investigator assessment

(Time Frame: From start of treatment to the date of the first documented reponse (CR or PR), assessed up to approximately 47 months)

	Group A (squamous): PDR001	Group B (non-squamous): PDR001	Group C (squamous or non-squamous):	Group E (non-squamous): PDR001

	+ gemcitabine/cisplatin	+ pemetrexed/cisplatin	PDR001 + paclitaxel/carboplatin	+ canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	33	38	33	7
Time to Response (TTR) per local investigator assessment (units: Months) Median (95% Confidence Interval)				
	2.7 (1.3 to NA)[1234]	6.2 (1.4 to NA)[1234]	3.9 (1.3 to NA)[1234]	5.0 (1.3 to NA)[1234]

[1] Upper limit was not reached (NA) due to insufficient number of participants with events
[2] Upper limit was not reached (NA) due to insufficient number of participants with events
[3] Upper limit was not reached (NA) due to insufficient number of participants with events
[4] Upper limit was not reached (NA) due to insufficient number of participants with events

Overall survival (OS)

(Time Frame: From date of start of treatment to date of death due to any cause (assessed up to approximately 50 months))

	Group A (squamous): PDR001 + gemcitabine/cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	Group C (squamous or non-squamous): PDR001 + paclitaxel/carboplatin	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with	Participants with non-squamous NSCLC treated with	Participants with squamous or non-squamous NSCLC	Participants with non-squamous NSCLC treated with PDR001

	gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	+ canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	33	38	33	7
Overall survival (OS) (units: Months) Median (95% Confidence Interval)				
	16.1 (10.0 to 21.7)	29.7 (17.8 to 39.9)	17.6 (9.4 to 23.3)	21.0 (4.8 to NA)[1]

[1] Upper limit was not reached (NA) due to insufficient number of participants with events

Trough plasma Concentration (Ctrough) of PDR001

(Time Frame: Pre-infusion on Day 1 of Cycle 1, Cycle 3 and Cycle 4 of induction period (Cycle = 21 Days))

	Group A (squamous): PDR001 + gemcitabine/cisplatin	**Group B (non-squamous): PDR001 + pemetrexed/cisplatin**	**Group C (squamous or non-squamous): PDR001 + paclitaxel/carboplatin**	**Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin**
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	33	38	33	7

Trough plasma Concentration (Ctrough) of PDR001 (units: microgram/mililiter (ug/mL)) Mean ± Standard Deviation				
Cycle 1 Day 1 (induction period)	16.1 ± 4.45	19.4 ± 6.44	17.8 ± 8.06	20.9 ± 7.08
Cycle 3 Day 1 (induction period)	38.7 ± 11.8	38.6 ± 16.7	37.8 ± 14.2	47.3 ± 8.08
Cycle 4 Day 1 (induction period)	44.1 ± 12.8	52.7 ± 14.5	42.7 ± 16.9	48.8 ± 16.4

Trough plasma Concentration (Ctrough) of canakinumab

(Time Frame: Pre-infusion on Day 1 of Cycle 1 of induction period. Cycle = 21 Days)

	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	7
Trough plasma Concentration (Ctrough) of canakinumab (units: nanogram (ng)/mililiter (mL))	

Mean ± Standard Deviation	
Cycle 1 Day 1 (induction period)	12100 ± 3960

Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of PDR001

(Time Frame: Pre-infusion, end of infusion, 168 hours (h) and 336h after the beginning of the infusion on Cycle 1 Day 1, Cycle 3 Day 1 and Cycle 4 Day 1 of induction period (Cycle = 21 Days))

	Group A (squamous): PDR001 + gemcitabine/cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	Group C (squamous or non-squamous): PDR001 + paclitaxel/carboplatin	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	33	38	33	7
Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of PDR001 (units: hour*microgram/mililiter (h*ug/mL)) Mean ± Standard Deviation				
Cycle 1 Day 1 (induction period)	14000 ± 3710	16000 ± 4970	16000 ± 4670	16400 ± 3920
Cycle 3 Day 1 (induction period)	26300 ± 7610	28300 ± 9100	23400 ± 9700	31100 ± 11500

Cycle 4 Day 1 (induction period)	27200 ± 10600	34100 ± 11300	26200 ± 11500	30000 ± 12900

Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of canakinumab

(Time Frame: Pre-dose, 168 and 336 h post-dose on Cycle 1 Day 1 of induction period (Cycle = 21 Days))

	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	7
Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of canakinumab (units: hour*nanogram/mililiter (h*ng/mL)) Mean ± Standard Deviation	
Cycle 1 Day 1 (induction period)	6430000 ± 2420000

Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of gemcitabine

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 30 min and 1h, 2h, 4h and 6h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group A (squamous): PDR001 + gemcitabine/ cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001
Number of Participants Analyzed [units: participants]	31
Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of gemcitabine (units: hour*nanogram/mililiter (h*ng/mL)) Mean ± Standard Deviation	
Cycle 1 Day 1 (induction period)	7800 ± 5200
Cycle 3 Day 1 (induction period)	9190 ± 5090

Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of cisplatin

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 15 min, 30 min, 1h and 2h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group A (squamous): PDR001 + gemcitabine/ cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed
Number of Participants Analyzed [units: participants]	32	36
Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of cisplatin (units: hour*nanogram/mililiter (h*ng/mL)) Mean ± Standard Deviation		
Cycle 1 Day 1 (induction period)	2900 ± 625	3200 ± 708
Cycle 3 Day 1 (induction period)	2700 ± 581	3340 ± 665

Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of pemetrexed

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 1h, 2h, 4h and 6h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	Group E (non-squamous): PDR001+ canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with non-squamous NSCLC	Participants with non-squamous NSCLC

	treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	38	7
Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of pemetrexed (units: hour*nanogram/mililiter (h*ng/mL)) Mean ± Standard Deviation		
Cycle 1 Day 1 (induction period)	158000 ± 37100	163000 ± 21100
Cycle 3 Day 1 (induction period)	143000 ± 33000	157000 ± 27400

Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of paclitaxel

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 2 h, 4 h and 6 h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin
Arm/Group Description	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4

	cycles) followed by maintenance with PDR001
Number of Participants Analyzed [units: participants]	33
Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of paclitaxel (units: hour*nanogram/mililiter (h*ng/mL)) Mean ± Standard Deviation	
Cycle 1 Day 1 (induction period)	17900 ± 7340
Cycle 3 Day 1 (induction period)	18300 ± 11100

Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of carboplatin

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 1 h, 2 h and 3 h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin
Arm/Group Description	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001

Number of Participants Analyzed [units: participants]	33
Area under the plasma concentration-time curve from time 0 to the time of the last quantifiable concentration (AUClast) of carboplatin (units: hour*nanogram/mililiter (h*ng/mL)) Mean ± Standard Deviation	
Cycle 1 Day 1 (induction period)	37000 ± 7220
Cycle 3 Day 1 (induction period)	41000 ± 10200

Maximum concentration (Cmax) of PDR001

(Time Frame: Pre-infusion, end of infusion, 168 hours (h) and 336h after the beginning of the infusion on Cycle 1 Day 1, Cycle 3 Day 1 and Cycle 4 Day 1 of induction period (Cycle = 21 Days))

	Group A (squamous): PDR001 + gemcitabine/cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	Group C (squamous or non-squamous): PDR001 + paclitaxel/carboplatin	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	33	38	33	7

Maximum concentration (Cmax) of PDR001 (units: microgram/milliliter (ug/mL)) Mean ± Standard Deviation				
Cycle 1 Day 1 (induction period)	61.8 ± 17.1	65.7 ± 19.3	68.4 ± 21.6	69.9 ± 17.2
Cycle 3 Day 1 (induction period)	88.0 ± 24.5	94.3 ± 25.1	84.1 ± 23.2	92.7 ± 24.6
Cycle 4 Day 1 (induction period)	98.0 ± 21.0	108 ± 30.2	98.2 ± 28.2	94.9 ± 31.6

Maximum concentration (Cmax) of canakinumab

(Time Frame: Pre-dose, 168 and 336 h post-dose on Cycle 1 Day 1 of induction period (Cycle = 21 Days))

	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	7
Maximum concentration (Cmax) of canakinumab (units: nanogram/milliliter (ng/mL)) Mean ± Standard Deviation	

Cycle 1 Day 1 (induction period)	18100 ± 7220

Maximum concentration (Cmax) of gemcitabine

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 30 min and 1h, 2h, 4h and 6h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group A (squamous): PDR001 + gemcitabine/ cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001
Number of Participants Analyzed [units: participants]	31
Maximum concentration (Cmax) of gemcitabine (units: nanogram/mililiter (ng/mL)) Mean ± Standard Deviation	
Cycle 1 Day 1 (induction period)	13000 ± 8880
Cycle 3 Day 1 (induction period)	14600 ± 8080

Maximum concentration (Cmax) of cisplatin

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 15 min, 30 min, 1h and 2h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group A (squamous): PDR001 + gemcitabine/ cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed
Number of Participants Analyzed [units: participants]	32	36
Maximum concentration (Cmax) of cisplatin (units: nanogram/mililiter (ng/mL)) Mean ± Standard Deviation		
Cycle 1 Day 1 (induction period)	2160 ± 597	2350 ± 784
Cycle 3 Day 1 (induction period)	2030 ± 583	2360 ± 676

Maximum concentration (Cmax) of pemetrexed

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 1h, 2h, 4h and 6h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	Group E (non-squamous): PDR001+ canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin	Participants with non-squamous NSCLC treated with PDR001 + canakinumab +

	+ PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	38	7
Maximum concentration (Cmax) of pemetrexed (units: nanogram/mililiter (h*ng/mL)) Mean ± Standard Deviation		
Cycle 1 Day 1 (induction period)	86500 ± 20700	92300 ± 15800
Cycle 3 Day 1 (induction period)	87200 ± 23800	84200 ± 24200

Maximum concentration (Cmax) of paclitaxel

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 2 h, 4 h and 6 h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin
Arm/Group Description	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001

Number of Participants Analyzed [units: participants]	33
Maximum concentration (Cmax) of paclitaxel (units: nanogram/mililiter (ng/mL)) Mean ± Standard Deviation	
Cycle 1 Day 1 (induction period)	5720 ± 2460
Cycle 3 Day 1 (induction period)	5950 ± 4250

Maximum concentration (Cmax) of carboplatin

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 1 h, 2 h and 3 h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin
Arm/Group Description	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001
Number of Participants Analyzed [units: participants]	33
Maximum concentration (Cmax) of carboplatin (units: nanogram/mililiter (ng/mL)) Mean ± Standard Deviation	

Cycle 1 Day 1 (induction period)	19600 ± 6340
Cycle 3 Day 1 (induction period)	23300 ± 5020

Time to reach the maximum concentration after drug administration (Tmax) of PDR001

(Time Frame: Pre-infusion, end of infusion, 168 hours (h) and 336h after the beginning of the infusion on Cycle 1 Day 1, Cycle 3 Day 1 and Cycle 4 Day 1 of induction period (Cycle = 21 Days))

	Group A (squamous): PDR001 + gemcitabine/cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	Group C (squamous or non-squamous): PDR001 + paclitaxel/carboplatin	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	33	38	33	7
Time to reach the maximum concentration after drug administration (Tmax) of PDR001 (units: hours) Median (Full Range)				
Cycle 1 Day 1 (induction period)	0.567 (0.00 to 167)	0.767 (0.5 to 172)	0.7 (0.450 to 2.50)	0.617 (0.550 to 2.63)
Cycle 3 Day 1 (induction period)	0.633 (0.467 to 337)	0.667 (0.467 to 2.38)	0.683 (0.333 to 168)	0.558 (0.467 to 0.750)
Cycle 4 Day 1 (induction period)	0.850 (0.00 to 24.2)	0.975 (0.533 to 146)	0.750 (0.467 to 23.0)	1.00 (0.5 to 145)

Time to reach the maximum concentration after drug administration (Tmax) of canakinumab

(Time Frame: Pre-dose, 168 and 336 h post-dose on Cycle 1 Day 1 of induction period (Cycle = 21 Days))

	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	7
Time to reach the maximum concentration after drug administration (Tmax) of canakinumab (units: hours) Median (Full Range)	
Cycle 1 Day 1 (induction period)	168 (144 to 336)

Time to reach the maximum concentration after drug administration (Tmax) of gemcitabine

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 30 min and 1h, 2h, 4h and 6h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group A (squamous): PDR001 +

	gemcitabine/ cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001
Number of Participants Analyzed [units: participants]	31
Time to reach the maximum concentration after drug administration (Tmax) of gemcitabine (units: hours) Median (Full Range)	
Cycle 1 Day 1 (induction period)	0.467 (0.433 to 1.15)
Cycle 3 Day 1 (induction period)	0.525 (0.417 to 1.50)

Time to reach the maximum concentration after drug administration (Tmax) of cisplatin

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 15 min, 30 min, 1h and 2h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group A (squamous): PDR001 + gemcitabine/ cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4

	cycles) followed by maintenance with PDR001	cycles) followed by maintenance with PDR001+ pemetrexed
Number of Participants Analyzed [units: participants]	32	36
Time to reach the maximum concentration after drug administration (Tmax) of cisplatin (units: hours) Median (Full Range)		
Cycle 1 Day 1 (induction period)	1.01 (0.967 to 4.50)	1.03 (0.883 to 4.78)
Cycle 3 Day 1 (induction period)	1.07 (0.967 to 4.62)	1.25 (0.967 to 1.98)

Time to reach the maximum concentration after drug administration (Tmax) of pemetrexed

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 1h, 2h, 4h and 6h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	**Group E (non-squamous): PDR001+ canakinumab + pemetrexed/cisplatin**
Arm/Group Description	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	38	7

Time to reach the maximum concentration after drug administration (Tmax) of pemetrexed (units: hours) Median (Full Range)		
Cycle 1 Day 1 (induction period)	0.133 (0.133 to 1.17)	0.133 (0.133 to 0.283)
Cycle 3 Day 1 (induction period)	0.133 (0.00 to 0.3)	0.133 (0.133 to 0.217)

Time to reach the maximum concentration after drug administration (Tmax) of paclitaxel

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 2 h, 4 h and 6 h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin
Arm/Group Description	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001
Number of Participants Analyzed [units: participants]	33
Time to reach the maximum concentration after drug administration (Tmax) of paclitaxel (units: hours) Median (Full Range)	

Cycle 1 Day 1 (induction period)	3.08 (2.78 to 4.58)
Cycle 3 Day 1 (induction period)	2.97 (2.92 to 4.67)

Time to reach the maximum concentration after drug administration (Tmax) of carboplatin

(Time Frame: 30 min pre-infusion, 2 min prior to end of infusion, 1 h, 2 h and 3 h post end of infusion on Cycle 1 Day 1 and Cycle 3 Day 1 of induction phase (Cycle = 21 Days))

	Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin
Arm/Group Description	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001
Number of Participants Analyzed [units: participants]	33
Time to reach the maximum concentration after drug administration (Tmax) of carboplatin (units: hours) Median (Full Range)	
Cycle 1 Day 1 (induction period)	1.02 (0.467 to 2.83)
Cycle 3 Day 1 (induction period)	0.967 (0.00 to 1.12)

PDR001 Antidrug antibodies (ADA) prevalence at baseline

(Time Frame: Baseline)

	Group A (squamous): PDR001 + gemcitabine/cisplatin	Group B (non-squamous): PDR001 + pemetrexed/cisplatin	Group C (squamous or non-squamous): PDR001 + paclitaxel/carboplatin	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	29	32	30	4
PDR001 Antidrug antibodies (ADA) prevalence at baseline (units: Participants) Count of Participants (Not Applicable)				
	1 (3.45%)	3 (9.38%)	0 (%)	0 (%)

Canakinumab ADA prevalence at baseline

(Time Frame: Baseline)

	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with non-squamous NSCLC

	treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	7
Canakinumab ADA prevalence at baseline (units: Participants) Count of Participants (Not Applicable)	0 (%)

PDR001 ADA incidence during treatment

(Time Frame: Pre-infusion on Day 1 of Cycle 1 to 4 of induction phase, pre-infusion on Day 1 of Cycle 1, 2, 3, 4, 6, 8 and every 6 cycle afterwards of maintenance phase, end of treatment and 30 and 150-day post-treatment, assessed up to approximately 30 months)

	Group A (squamous): PDR001 + gemcitabine/cisplatin	**Group B (non-squamous): PDR001 + pemetrexed/cisplatin**	**Group C (squamous or non-squamous): PDR001 + paclitaxel/carboplatin**	**Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin**
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed

Number of Participants Analyzed [units: participants]	32	38	33	7
PDR001 ADA incidence during treatment (units: Participants) Count of Participants (Not Applicable)				
	10 (31.25%)	9 (23.68%)	10 (30.3%)	2 (28.57%)

Canakinumab ADA incidence during treatment

(Time Frame: Pre-infusion on Day 1 of Cycle 1 and 4 of induction phase, pre-infusion on Day 1 of Cycle 6, 14 and 20 of maintenance phase, end of treatment and 30 and 150-day post-treatment, assessed up to approximately 30 month)

	Group E (non-squamous): PDR001 + canakinumab + pemetrexed/cisplatin
Arm/Group Description	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	7
Canakinumab ADA incidence during treatment (units: Participants)	

Count of Participants (Not Applicable)
0 (%)

Post-hoc: All collected deaths

(Time Frame: Pre-treatment deaths: from screening visit up to the first day of treatment, for a maximum of 28 days. On-treatment deaths: from first dose of study medication to 30 days after the last dose of study medication for a maximum duration of 40 months. Extended safety follow-up deaths: from day 31 post treatment up to 150 days post-treatment, for a maximum duration of approx. 50 months. Post-treatment deaths: after 150 days post-treatment, up to 50 months.)

	Group A (squamous): PDR001 + gemcitabine/ cisplatin	**Group B (non-squamous): PDR001 + pemetrexed/cisplatin**	**Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin**	**Group E (non-squamous): PDR001+ canakinumab + pemetrexed/cisplatin**
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Number of Participants Analyzed [units: participants]	33	39	33	7
All collected deaths (units: Participants) Count of Participants (Not Applicable)				
Pre-treatment deaths	0 (%)	1 (2.56%)	0 (%)	0 (%)
On-treatment deaths	3 (9.09%)	3 (7.89%)	1 (3.03%)	1 (14.29%)

Extended safety follow-up deaths	8 (24.24%)	8 (21.05%)	11 (33.33%)	2 (28.57%)
Post-treatment deaths	12 (36.36%)	11 (28.95%)	14 (42.42%)	3 (42.86%)
All deaths	23 (69.7%)	23 (58.97%)	26 (78.79%)	6 (85.71%)

Safety Results

All-Cause Mortality

	Group A (squamous): PDR001 + gemcitabine/ cisplatin (on-treatment period) N = 33	**Group A (squamous): PDR001 + gemcitabine/ cisplatin (extended safety follow-up period) N = 33**	**Group B (non-squamous): PDR001 + pemetrexed/cisplatin (on-treatment period) N = 38**	**Group B (non-squamous): PDR001 + pemetrexed/cisplatin (extended safety follow-up period) N = 38**	**Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin (on-treatment period) N = 33**	**Group C (squamous or non-squamous): PDR001+paclitaxel/carboplatin (extended safety follow-up period) N = 33**	**Group E (non-squamous): PDR001+ canakinumab + pemetrexed/cisplatin (on-treatment period) N = 7**	**Group E (non-squamous): PDR001+canakinumab+ pemetrexed/cisplatin (extended safety follow-up period) N = 7**
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with squamous NSCLC treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 +	Participants with non-squamous NSCLC treated with PDR001 +canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed

			with PDR001+ pemetrexed	with PDR001+ pemetrexed	maintenance with PDR001		canakinumab + pemetrexed	
Total participants affected	3 (9.09%)	8 (24.24%)	3 (7.89%)	8 (21.05%)	1 (3.03%)	11 (33.33%)	1 (14.29%)	2 (28.57%)

Serious Adverse Events by System Organ Class

Time Frame	In the on-treatment period, adverse events (AEs) and serious AEs (including the All-Cause Mortality data table) are presented from first dose of study treatment until last dose of study treatment plus 30 days post treatment, up to 40 months. In the extended safety follow-up period, AEs and serious AEs (including the All-Cause Mortality data table) are presented from day 31 to day 150 after last administration of study treatment, up to 50 months
Additional Description	In the on-treatment period, any sign or symptom that occurs during the study treatment plus 30 days post treatment. In the extended safety follow-up period, any sign or symptom that occurs between 31 and 150 days post treatment.
Source Vocabulary for Table Default	MedDRA (24.0)
Assessment Type for Table Default	Systematic Assessment

	Group A (squamous): PDR001 + gemcitabine/ cisplatin (on-treatment period) N = 33	**Group A (squamous): PDR001 + gemcitabine/ cisplatin (extended safety follow-up period) N = 33**	**Group B (non-squamous): PDR001 + pemetrexed/cisplatin (on-treatment period) N = 38**	**Group B (non-squamous): PDR001 + pemetrexed/cisplatin (extended safety follow-up period) N = 38**	**Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin (on-treatment period) N = 33**	**Group C (squamous or non-squamous): PDR001+paclitaxel/ carboplatin (extended safety follow-up period) N = 33**	**Group E (non-squamous): PDR001+ canakinumab + pemetrexed/cisplatin (on-treatment period) N = 7**	**Group E (non-squamous): PDR001+canakinumab+ pemetrexed/cisplatin (extended safety follow-up period) N = 7**
Arm/Group Description	Participants with squamous NSCLC	Participants with squamous NSCLC	Participants with non-squamous NSCLC	Participants with non-squamous NSCLC	Participants with squamous or non-	Participants with squamous or non-squamous NSCLC treated with	Participants with non-squamous NSCLC	Participants with non-squamous NSCLC treated with PDR001

	treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	treated with gemcitabine/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001+ pemetrexed	squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed	+canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed
Total participants affected	15 (45.45%)	2 (6.06%)	22 (57.89%)	3 (7.89%)	13 (39.39%)	3 (9.09%)	4 (57.14%)	0 (0.00%)
Blood and lymphatic system disorders								
Anaemia	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Febrile neutropenia	1 (3.03%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukopenia	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pancytopenia	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders								
Acute myocardial infarction	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Atrioventricular	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

block complete								
Cardiac arrest	0 (0.00%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiogenic shock	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiotoxicity	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myocardial infarction	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericardial effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders								
Abdominal pain	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	0 (0.00%)	0 (0.00%)	2 (5.26%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Enterocolitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Gastric ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intestinal perforation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenic colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vomiting	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

General disorders and administration site conditions								
Chest pain	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Condition aggravated	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
General physical health deterioration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Mucosal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	3 (9.09%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatobiliary disorders								
Autoimmune hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Cholecystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Hepatitis	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations								

Gastroenteritis viral	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Orchitis	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	2 (6.06%)	0 (0.00%)	1 (2.63%)	1 (2.63%)	2 (6.06%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Pneumonia bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory tract infection	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Scrotal abscess	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sepsis	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Septic shock	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications								
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Postoperative ileus	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal fracture	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations								

Lipase increased	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders								
Hyponatraemia	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders								
Back pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Bone pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neck pain	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
Lung neoplasm malignant	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.63%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metastases to spine	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders								
Aphasia	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Cerebral haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Cerebrovascular accident	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cerebrovascular disorder	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hemiparesis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lethargy	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Partial seizures	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Polyneuropathy	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Posterior reversible encephalopathy syndrome	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seizure	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders								
Suicide attempt	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders								
Acute kidney injury	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Haematuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nephropathy	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders								
Acute respiratory failure	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis chronic	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonitis	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary embolism	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	1 (3.03%)	1 (3.03%)	1 (14.29%)	0 (0.00%)
Vascular disorders								
Peripheral artery occlusion	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Subclavian steal syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Other Adverse Events by System Organ Class

Time Frame	In the on-treatment period, adverse events (AEs) and serious AEs (including the All-Cause Mortality data table) are presented from first dose of study treatment until last dose of study treatment plus 30 days post treatment, up to 40 months. In the extended safety follow-up period, AEs and serious AEs (including the All-Cause Mortality data table) are presented from day 31 to day 150 after last administration of study treatment, up to 50 months
Additional Description	In the on-treatment period, any sign or symptom that occurs during the study treatment plus 30 days post treatment. In the extended safety follow-up period, any sign or symptom that occurs between 31 and 150 days post treatment.
Source Vocabulary for Table Default	MedDRA (24.0)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

	Group A (squamous) : PDR001 + gemcitabine / cisplatin (on-treatment period) N = 33	**Group A (squamous) : PDR001 + gemcitabine / cisplatin (extended safety follow-up period) N = 33**	**Group B (non-squamous): PDR001 + pemetrexed/ cisplatin (on-treatment period) N = 38**	**Group B (non-squamous): PDR001 + pemetrexed/ cisplatin (extended safety follow-up period) N = 38**	**Group C (squamous or non-squamous): PDR001 + paclitaxel/ carboplatin (on-treatment period) N = 33**	**Group C (squamous or non-squamous): PDR001+paclitaxel/ carboplatin (extended safety follow-up period) N = 33**	**Group E (non-squamous): PDR001+ canakinumab + pemetrexed/ cisplatin (on-treatment period) N = 7**	**Group E (non-squamous): PDR001+canakinumab+ pemetrexed/cisplatin (extended safety follow-up period) N = 7**
Arm/Group Description	Participants with squamous NSCLC treated with gemcitabine/ cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with squamous NSCLC treated with gemcitabine/ cisplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with	Participants with non-squamous NSCLC treated with pemetrexed/cisplatin + PDR001 (up to 4 cycles) followed by maintenance with	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by	Participants with squamous or non-squamous NSCLC treated with paclitaxel/carboplatin + PDR001 (up to 4 cycles) followed by maintenance with PDR001	Participants with non-squamous NSCLC treated with PDR001 + canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 +	Participants with non-squamous NSCLC treated with PDR001 +canakinumab + pemetrexed/cisplatin followed by maintenance with PDR001 + canakinumab + pemetrexed

			PDR001+ pemetrexed	PDR001+ pemetrexed	maintenance with PDR001		canakinumab + pemetrexed	
Total participants affected	33 (100.00%)	4 (12.12%)	38 (100.00%)	9 (23.68%)	33 (100.00%)	5 (15.15%)	7 (100.00%)	0 (0.00%)
Blood and lymphatic system disorders								
Anaemia	20 (60.61%)	1 (3.03%)	16 (42.11%)	0 (0.00%)	18 (54.55%)	1 (3.03%)	4 (57.14%)	0 (0.00%)
Leukocytosis	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukopenia	2 (6.06%)	0 (0.00%)	4 (10.53%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphopenia	2 (6.06%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenia	19 (57.58%)	0 (0.00%)	19 (50.00%)	0 (0.00%)	19 (57.58%)	0 (0.00%)	3 (42.86%)	0 (0.00%)
Thrombocytopenia	11 (33.33%)	0 (0.00%)	4 (10.53%)	0 (0.00%)	8 (24.24%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombocytosis	3 (9.09%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders								
Angina pectoris	2 (6.06%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ear and labyrinth disorders								
Tinnitus	3 (9.09%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Vertigo	0 (0.00%)	0 (0.00%)	4 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endocrine disorders								
Hyperthyroidism	2 (6.06%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hypothyroidism	1 (3.03%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders								
Cataract	0 (0.00%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lacrimation increased	0 (0.00%)	0 (0.00%)	8 (21.05%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Vision blurred	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders								
Abdominal pain	3 (9.09%)	0 (0.00%)	6 (15.79%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain lower	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Abdominal pain upper	2 (6.06%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	10 (30.30%)	0 (0.00%)	12 (31.58%)	1 (2.63%)	12 (36.36%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Diarrhoea	8 (24.24%)	0 (0.00%)	10 (26.32%)	1 (2.63%)	12 (36.36%)	0 (0.00%)	2 (28.57%)	0 (0.00%)
Dyspepsia	1 (3.03%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphagia	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	1 (3.03%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Gastrooesophageal reflux disease	1 (3.03%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	13 (39.39%)	0 (0.00%)	28 (73.68%)	0 (0.00%)	12 (36.36%)	0 (0.00%)	2 (28.57%)	0 (0.00%)
Stomatitis	2 (6.06%)	0 (0.00%)	4 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Vomiting	4 (12.12%)	0 (0.00%)	14 (36.84%)	0 (0.00%)	7 (21.21%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
General disorders and								

administration site conditions								
Asthenia	13 (39.39%)	0 (0.00%)	13 (34.21%)	1 (2.63%)	14 (42.42%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest pain	1 (3.03%)	0 (0.00%)	4 (10.53%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Chills	3 (9.09%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Face oedema	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	9 (27.27%)	0 (0.00%)	8 (21.05%)	0 (0.00%)	9 (27.27%)	0 (0.00%)	4 (57.14%)	0 (0.00%)
Influenza like illness	2 (6.06%)	0 (0.00%)	1 (2.63%)	1 (2.63%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malaise	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mucosal inflammation	1 (3.03%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	1 (3.03%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Non-cardiac chest pain	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	5 (15.15%)	0 (0.00%)	15 (39.47%)	0 (0.00%)	3 (9.09%)	1 (3.03%)	1 (14.29%)	0 (0.00%)
Pain	3 (9.09%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral swelling	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	6 (18.18%)	1 (3.03%)	9 (23.68%)	1 (2.63%)	8 (24.24%)	1 (3.03%)	1 (14.29%)	0 (0.00%)
Swelling	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Hepatobiliary disorders								
Cholecystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Cholestasis	0 (0.00%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune system disorders								

Contrast media reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Infections and infestations								
Conjunctivitis	0 (0.00%)	0 (0.00%)	6 (15.79%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infection	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasopharyngitis	2 (6.06%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral candidiasis	1 (3.03%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Perichondritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Pharyngitis	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Respiratory tract infection	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (12.12%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinitis	2 (6.06%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinusitis	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	3 (9.09%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Urinary tract infection	3 (9.09%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications								
Infusion related reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lumbar vertebral fracture	0 (0.00%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Investigations

Alanine aminotransferase increased	7 (21.21%)	0 (0.00%)	5 (13.16%)	1 (2.63%)	7 (21.21%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Amylase increased	1 (3.03%)	0 (0.00%)	6 (15.79%)	0 (0.00%)	1 (3.03%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Aspartate aminotransferase increased	3 (9.09%)	0 (0.00%)	5 (13.16%)	1 (2.63%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood albumin decreased	3 (9.09%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood alkaline phosphatase increased	4 (12.12%)	0 (0.00%)	7 (18.42%)	1 (2.63%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatine phosphokinase increased	2 (6.06%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	4 (12.12%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatinine increased	5 (15.15%)	0 (0.00%)	12 (31.58%)	1 (2.63%)	2 (6.06%)	0 (0.00%)	3 (42.86%)	0 (0.00%)
Blood thyroid stimulating hormone decreased	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	1 (3.03%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Blood thyroid stimulating hormone increased	2 (6.06%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood urea increased	1 (3.03%)	0 (0.00%)	4 (10.53%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Blood uric acid increased	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
C-reactive protein increased	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gamma-glutamyltransferase increased	2 (6.06%)	0 (0.00%)	4 (10.53%)	2 (5.26%)	7 (21.21%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	2 (6.06%)	0 (0.00%)	5 (13.16%)	1 (2.63%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphocyte count decreased	1 (3.03%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutrophil count decreased	3 (9.09%)	0 (0.00%)	4 (10.53%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Platelet count decreased	3 (9.09%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Protein total decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight decreased	1 (3.03%)	0 (0.00%)	3 (7.89%)	1 (2.63%)	4 (12.12%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight increased	1 (3.03%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White blood cell count decreased	1 (3.03%)	0 (0.00%)	6 (15.79%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders								
Cell death	0 (0.00%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Decreased appetite	7 (21.21%)	0 (0.00%)	8 (21.05%)	0 (0.00%)	11 (33.33%)	1 (3.03%)	4 (57.14%)	0 (0.00%)
Dehydration	2 (6.06%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diabetes mellitus	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Hypercalcaemia	0 (0.00%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypercholesterolaemia	1 (3.03%)	0 (0.00%)	5 (13.16%)	0 (0.00%)	1 (3.03%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Hyperglycaemia	0 (0.00%)	0 (0.00%)	5 (13.16%)	0 (0.00%)	1 (3.03%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Hyperkalaemia	3 (9.09%)	0 (0.00%)	5 (13.16%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Hyperphosphataemia	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperuricaemia	1 (3.03%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoalbuminaemia	5 (15.15%)	0 (0.00%)	6 (15.79%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypokalaemia	2 (6.06%)	0 (0.00%)	5 (13.16%)	0 (0.00%)	5 (15.15%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Hypomagnesaemia	5 (15.15%)	0 (0.00%)	4 (10.53%)	0 (0.00%)	10 (30.30%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	4 (12.12%)	0 (0.00%)	4 (10.53%)	0 (0.00%)	4 (12.12%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypophosphataemia	5 (15.15%)	0 (0.00%)	6 (15.79%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Musculoskeletal and connective tissue disorders								

Arthralgia	9 (27.27%)	0 (0.00%)	7 (18.42%)	1 (2.63%)	13 (39.39%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Back pain	4 (12.12%)	0 (0.00%)	11 (28.95%)	1 (2.63%)	5 (15.15%)	2 (6.06%)	1 (14.29%)	0 (0.00%)
Bone pain	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (12.12%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle spasms	2 (6.06%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Muscle swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Muscular weakness	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal chest pain	1 (3.03%)	1 (3.03%)	2 (5.26%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myalgia	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	9 (27.27%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Neck pain	4 (12.12%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteoarthritis	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in extremity	3 (9.09%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	5 (15.15%)	1 (3.03%)	1 (14.29%)	0 (0.00%)
Nervous system disorders								
Dizziness	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	6 (18.18%)	1 (3.03%)	1 (14.29%)	0 (0.00%)
Dysaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysgeusia	4 (12.12%)	0 (0.00%)	6 (15.79%)	0 (0.00%)	4 (12.12%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Headache	7 (21.21%)	0 (0.00%)	4 (10.53%)	0 (0.00%)	4 (12.12%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoaesthesia	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neuropathy peripheral	4 (12.12%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	7 (21.21%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Paraesthesia	3 (9.09%)	0 (0.00%)	5 (13.16%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Peripheral motor neuropathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral sensory neuropathy	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Restless legs syndrome	0 (0.00%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Somnolence	1 (3.03%)	0 (0.00%)	2 (5.26%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders								
Anxiety	5 (15.15%)	0 (0.00%)	2 (5.26%)	1 (2.63%)	3 (9.09%)	1 (3.03%)	0 (0.00%)	0 (0.00%)
Depression	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Insomnia	6 (18.18%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	8 (24.24%)	1 (3.03%)	1 (14.29%)	0 (0.00%)
Renal and urinary disorders								
Acute kidney injury	0 (0.00%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nephritis	0 (0.00%)	0 (0.00%)	3 (7.89%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pollakiuria	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal failure	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary retention	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders								
Chronic obstructive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)

pulmonary disease								
Cough	5 (15.15%)	1 (3.03%)	11 (28.95%)	0 (0.00%)	7 (21.21%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphonia	1 (3.03%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	3 (9.09%)	0 (0.00%)	11 (28.95%)	1 (2.63%)	5 (15.15%)	2 (6.06%)	0 (0.00%)	0 (0.00%)
Dyspnoea exertional	2 (6.06%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Epistaxis	2 (6.06%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemoptysis	1 (3.03%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hiccups	3 (9.09%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Oropharyngeal pain	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Pleural effusion	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonitis	4 (12.12%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	4 (12.12%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Productive cough	4 (12.12%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary embolism	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinorrhoea	2 (6.06%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	2 (28.57%)	0 (0.00%)
Skin and subcutaneous tissue disorders								
Alopecia	4 (12.12%)	0 (0.00%)	6 (15.79%)	0 (0.00%)	10 (30.30%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry skin	2 (6.06%)	0 (0.00%)	5 (13.16%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Erythema	0 (0.00%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperkeratosis	2 (6.06%)	0 (0.00%)	1 (2.63%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Pigmentation disorder	0 (0.00%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pruritus	6 (18.18%)	0 (0.00%)	10 (26.32%)	0 (0.00%)	8 (24.24%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash	5 (15.15%)	1 (3.03%)	11 (28.95%)	0 (0.00%)	9 (27.27%)	0 (0.00%)	1 (14.29%)	0 (0.00%)
Rash maculo-papular	3 (9.09%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	4 (12.12%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders								
Deep vein thrombosis	1 (3.03%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertension	4 (12.12%)	0 (0.00%)	3 (7.89%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypotension	1 (3.03%)	0 (0.00%)	2 (5.26%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Other Relevant Findings

None

Conclusion:

The MTDs/RDEs was established for PDR001 as 300 mg Q3W in combination with platinum-doublet chemotherapy (Groups A, B and C), and canakinumab as 200 mg Q3W in combination with PDR001 and platinum-doublet chemotherapy (Group E).

The antitumor activity as measured by ORR, DCR, PFS, OS and DOR observed in PDR001 with platinum-doublet chemotherapy (Group A, B and C) and PDR001 in combination with canakinumab and platinum-doublet chemotherapy (Group E) was comparable with that of pembrolizumab (another PD-1 checkpoint inhibitor) in combination with pemetrexed.

The addition of canakinumab to the regimen of PDR001 with pemetrexed and cisplatin does not improve its antitumor activity and does not affect the PK parameters of PDR001 as well.

The tolerability of PDR001 in combination with canakinumab, and chemotherapy agents (paclitaxel, pemetrexed, gemcitabine and cisplatin) was acceptable across the treatment groups.

Date of Clinical Trial Report

11-Mar-2022