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Sponsor

Novartis Pharmaceuticals

Generic Drug Name

NZV930, PDR001 (spartalizumab) and NIR178 (taminadenant)

Trial Indication(s)

Advanced malignancies

Protocol Number

CNZV930X2101

Protocol Title

A phase I/Ib, open-label, multi-center, study of NZV930 as a single agent and in combination with PDR001 and/or NIR178 in patients with advanced malignancies.

Clinical Trial Phase

Phase 1

Phase of Drug Development

NZV930 (phase 1), PDR001 (phase 3) and NIR178 (phase 2)

Study Start/End Dates

Study Start Date: July 18, 2018 (Actual)

Primary Completion Date: October 17, 2022 (Actual)

Study Completion Date: October 17, 2022 (Actual)

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Reason for Termination (If applicable)

After review of data which showed a low likelihood of achieving desired efficacy in the patient populations of the expansion arm, Novartis decided to terminate this trial early. Termination was not safety related.

Study Design/Methodology

This is a first in human (FIH) Phase I/Ib, open-label, multi-center study of NZV930 as a single agent and in combination with PDR001 and/or NIR178 in patients with advanced malignancies including non-small cell lung carcinoma (NSCLC), triple negative breast cancer (TNBC), pancreatic ductal adenocarcinoma (PDAC), renal cell carcinoma (RCC), ovarian cancer, microsatellite stable colorectal cancer (MSS CRC) and metastatic castration resistant prostate cancer (mCRPC).

The study consisted of two parts, dose escalation and dose expansion. The escalation part of the study evaluated NZV930 single agent and NZV930 in combination with PDR001 and/or NIR178.

The optimal dose and dosing frequency identified for NZV930 single agent and for the combinations with PDR001 and/or NIR178 were planned to be used in the corresponding dose expansion arms of the study.

Centers

10 centers in 7 countries: Australia(1), Canada(2), Singapore(1), United States(2), Japan(1), United Kingdom(1), Spain(2)

Objectives:

The primary objectives of the trial were:

- To characterize the safety and tolerability of NZV930 as a single agent and in combination with PDR001 and/or NIR178 in patients with advanced malignancies.
- To determine the recommended dose (RD) for expansion for single agent NZV930 and in combinations with PDR001 and/or NIR178.

The secondary objectives of the trial were:

- To assess the preliminary anti-tumor activity of NZV930 as a single agent and in combination with PDR001 and/or NIR178.
- To characterize the pharmacokinetics (PK) of NZV930 as a single agent and NZV930, PDR001 and/or NIR178 in combination.
- To assess the immunogenicity of NZV930 and PDR001

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

For this study, the study drugs are NZV930, PDR001 and NIR178. The study treatment is defined as NZV930 alone or in combination with PDR001, and/or NIR178.

NZV930 was administered via intravenous (i.v.) infusion over 1 hour every 2 weeks (Q2W). The infusions were given on Day 1 and 15 of each treatment cycle. The duration of one cycle was 28 days. NZV930 doses ranged between 60 mg and 1000 mg.

An alternative dosing schedule was investigated for NZV930. The step-up dosing schedule divided the first dose on NZV930 in two weekly infusions on C1D1 and C1D8, with the sum of the first two doses of NZV930 (day 1 and day 8) being equal to the dose use biweekly starting on C1D15. Dosing then continued at the C1D15 dose level on a Q2W regimen. The sum of the first two doses of NZV930 (day 1 and day 8) had to be equal to the highest dose level of NZV930 that had been previously tested in a Q2W regimen and had been determined to be well tolerated for the corresponding treatment (single agent, double or triplet.). This dosing schedule was tested only in the triple combination and it is the recommended dosing regimen for NZV930.

PDR001 was administered via intravenous (i.v.) infusion over 30 minutes every 4 weeks (Q4W). It was administered as a fixed dose infusion (400 mg) on Day 1 of each cycle.

NIR178 was administered as capsules taken orally twice daily (BID) and the doses ranged between 80 mg and 240 mg.

Patients could continue study treatment until the patient experienced unacceptable toxicity, disease progression per iRECIST (and as per PCWG3 guidance for mCRPC) and/or treatment was discontinued at the discretion of the investigator or the patient, or withdrawal of consent.

Statistical Methods

The dose escalation part of this study was guided by a Bayesian analysis of Cycle 1 dose limiting toxicities (DLT) data in each treatment arm. The relationship between dose and the probability of DLT was modelled using a Bayesian logistic regression model (BLRM) for single-agent NZV930 and each treatment combination. The Dose-Determining Set (DDS) was used in this analysis. No formal hypothesis was tested.

Evaluation of anti-tumor activity was based on local assessment of overall lesion response according to RECIST v1.1 and iRECIST. The endpoints used to evaluate anti-tumor activity were:

- Overall response rate (ORR) per RECIST v1.1 or iORR per iRECIST, defined as the proportion of subjects with best overall response of complete response (CR) or partial response (PR) (RECIST v1.1), or iCR and iPR (iRECIST).
- For RECIST v1.1, progression free survival (PFS) was defined as the time from the date of start of treatment to the date of the event defined as first documented progression or death due to any cause. If a subject had not had an event, PFS was censored at the date of the last adequate tumor evaluation. For iRECIST, date of event was defined as the date of first progression (iUPD) that was subsequently confirmed (iCPD) without intervening assessment of stable disease (iSD) or better, or death due to any cause. In the event that a subject's final efficacy assessment was iUPD without confirmation (iCPD) the date of the first assessment of iUPD that had no subsequent assessments of iSD or better were used as date of progression.
- Clinical benefit rate (CBR) per RECIST v1.1 or iCBR per iRECIST, defined as the proportion of subjects with best overall response of CR, PR or SD >= 16 weeks (RECIST) or iCR, iPR or iSD >= 16 weeks (iRECIST).

A Bayesian hierarchical model (BHM) was used to assess activity of treatment in terms of ORR and clinical benefit rate (CBR) across tumor types and treatment arms.

Pharmacokinetic parameters for free NZV930, PDR001, and NIR178 were estimated applying non-compartmental method(s), using Phoenix WinNonlin version 6.4 or above. The Pharmacokinetic analysis set (PAS) was used for all pharmacokinetic data analysis and PK summary statistics.

Immunogenicity of NZV930 and PDR001, assessed by the incidence of Anti-Drug Antibodies (ADA), anti-NZV930 and anti-PDR001 were summarized by treatment group.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

- Adult men & women ≥ 18 years of age
- Histologically confirmed advanced malignancies with documented progression following standard therapy, or for whom, in the opinion of the investigator, no appropriate standard therapy exists.
  - Escalation: Patients with advanced NSCLC, TNBC, PDAC, RCC, ovarian cancer, MSS CRC and mCRPC.
  - Expansion: Indications determined by observed clinical activity in the dose escalation part and/or available literature.
- Must have a site of disease amenable to biopsy and be a candidate for tumor biopsy according to the treating institution's guidelines. The patient must be willing to undergo a new tumor biopsy at screening and during treatment.
- ECOG performance status 0-2 and in the opinion of the investigator, likely to complete at least 56 days of treatment.

Exclusion Criteria:

- Symptomatic or uncontrolled brain metastases requiring concurrent treatment, inclusive of but not limited to surgery, radiation and/or corticosteroids. Patients with treated symptomatic brain metastases should be neurologically stable for 4 weeks post-treatment prior to study entry and at doses of <10 mg per day prednisolone or equivalent for at least 2 weeks before administration of any study treatment.

- Patients who required discontinuation of treatment due to treatment-related toxicities with prior immunotherapy.
- Patients previously treated with anti-CD73 treatment and/or adenosine receptor A2a (A2aR) inhibitors.
- Active, previously documented, or suspected autoimmune disease within the past 2 years.
  - Patients with vitiligo, type I diabetes, residual hypothyroidism only requiring hormone replacement, psoriasis not requiring systemic treatment or conditions not expected to recur should not be excluded. Additionally, patients previously exposed to anti-PD-1/PD-L1 treatment who are adequately treated for skin rash or with replacement therapy for endocrinopathies should not be excluded.
- History of or current drug-induced interstitial lung disease or pneumonitis grade ≥ 2.
- Impaired cardiovascular function or clinically significant cardiovascular disease, including any of the following:
  - Clinically significant and/or uncontrolled heart disease such as congestive heart failure requiring treatment (NYHA Grade ≥ 2), uncontrolled hypertension or clinically significant arrhythmia
  - Patients with corrected QT using the Fridericia's correction (QTcF) > 470 msec for females or >450 msec for males, on screening ECG or congenital long QT syndrome
  - Acute myocardial infarction or unstable angina < 3 months prior to study entry
  - History of stroke or transient ischemic event requiring medical therapy
  - Symptomatic claudication
- Infection:
  - HIV infection
  - Active HBV or HCV infection (per institutional guidelines). Patients with chronic HBV or HCV disease that is controlled under antiviral therapy are allowed in the expansion but not in the escalation
  - Known history of tuberculosis
  - Infection requiring systemic antibiotic therapy. Patients requiring systemic antibiotics for infection must have completed treatment before screening is initiated.

- Systemic anti-cancer therapy within 2 weeks of the first dose of study treatment. For cytotoxic agents that have major delayed toxicity, e.g. mitomycin C and nitrosoureas, 6 weeks is indicated as washout period. For patients receiving anticancer immunotherapies, 4 weeks is indicated as the washout period.
- Systemic chronic steroid therapy (≥ 10 mg/day prednisone or equivalent) or any immunosuppressive therapy, other than replacement dose steroids in the setting of adrenal insufficiency, within 7 days of the first dose of study treatment. Topical, inhaled, nasal, and ophthalmic steroids are allowed.

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Participant Flow Table

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

	NZV930 60 mg Q2W	NZV930 200 mg Q2W	NZV930 400 mg Q2W	NZV930 600 mg Q2W	NZV930 1000 mg Q2W	NZV930 200 mg Q2W + PDR001 400 mg Q4W	NZV930 400 mg Q2W + PDR001 400 mg Q4W	NZV930 600 mg Q2W + PDR001 400 mg Q4W	NZV930 200 mg Q2W + NIR178 80 mg BID	NZV930 200 mg Q2W + NIR178 160 mg BID	NZV930 400 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 240 mg BID
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID
Started	3	4	6	9	2	6	6	6	5	6	5	6	6
Completed	0	0	0	0	0	0	0	0	0	0	0	0	1*
Not Completed	3	4	6	9	2	6	6	6	5	6	5	6	5
Adverse Event	0	0	0	1	1	0	1	1	0	0	0	1	0
Death	0	0	0	1	0	0	0	1	0	0	0	0	1
Physician Decision	0	0	1	1	0	2	0	1	1	1	0	0	0

Progressive disease	3	4	5	6	1	4	5	3	3	5	5	4	3
Subject decision	0	0	0	0	0	0	0	0	1	0	0	1	1

* Treatment completed was selected incorrectly on the patient disposition eCRF

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID**	**NZV930 600mgQ2W (step-up) +PDR001 400mgQ4W +NIR178 240mgBID -E**	**Total**
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	All participants in the trial
Started	7	5	6	6	6	5	22	127
Completed	0	0	0	0	0	1*	0	2*
Not Completed	7	5	6	6	6	4	22	125
Adverse Event	1	0	1	0	1	0	5	13

Death	0	0	0	0	0	0	1	4
Physician Decision	0	0	0	0	0	0	2	9
Progressive disease	4	5	5	6	5	4	14	94
Subject decision	2	0	0	0	0	0	0	5

* Treatment completed was selected incorrectly on the patient disposition eCRF

Baseline Characteristics

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

	NZV930 60 mg Q2W	**NZV930 200 mg Q2W**	**NZV930 400 mg Q2W**	**NZV930 600 mg Q2W**	**NZV930 1000 mg Q2W**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W**	**NZV930 200 mg Q2W + NIR178 80 mg BID**	**NZV930 200 mg Q2W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + NIR178 240 mg BID**
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID

Number of Participants [units: participants]	3	4	6	9	2	6	6	6	5	6	5	6	6
Baseline Analysis Population Description													
Age Continuous (units: years) Analysis Population Type: Participants Mean ± Standard Deviation													
	71.7±7.23	55.5±4.36	56.7±10.21	59.1±8.30	48.0±0.00	52.3±16.54	54.3±10.78	56.5±11.47	59.6±4.83	52.8±15.61	53.6±12.97	51.8±12.16	65.5±9.93
Age, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)													
18 - <65 years	0	4	4	7	2	4	5	5	4	5	4	5	2
65 - <85 years	3	0	2	2	0	2	1	1	1	1	1	1	4
Sex: Female, Male (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)													
Female	3	1	4	4	0	3	5	3	3	5	1	6	2
Male	0	3	2	5	2	3	1	3	2	1	4	0	4

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

White	3	3	3	6	1	2	5	5	4	4	4	4	4
Black or African American	0	0	0	1	0	1	0	0	0	1	0	0	0
Asian	0	1	3	2	1	3	1	1	1	1	1	2	2
Multiple	0	0	0	0	0	0	0	0	0	0	0	0	0
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0

Study Specific Characteristic
Primary tumor types
(units: participants)
Analysis Population Type: Participants
Count of Participants (Not Applicable)

Colorectal cancer	1	4	4	6	1	2	5	3	4	1	5	4	2
Non-small cell lung cancer	0	0	0	1	0	1	0	1	1	1	0	0	2
Ovarian cancer	2	0	2	0	0	2	1	1	0	0	0	1	0
Pancreatic cancer	0	0	0	1	1	0	0	1	0	1	0	0	2

Prostate cancer	0	0	0	0	0	0	0	0	0	0	0	0	0
Renal cell carcinoma	0	0	0	1	0	0	0	0	0	0	0	0	0
Triple negative breast cancer	0	0	0	0	0	1	0	0	0	3	0	1	0

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID**	**NZV930 600mgQ2W (step-up) +PDR001 400mgQ4W +NIR178 240mgBID -E**	**Total**
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	All participants in the trial
Number of Participants [units: participants]	7	5	6	6	6	5	22	127

Baseline Analysis Population Description								
Age Continuous (units: years) Analysis Population Type: Participants Mean ± Standard Deviation								
	55.3±14.66	51.0±14.00	59.3±11.62	62.0±9.96	59.7±10.84	52.6±8.79	59.8±10.31	57.3±11.25
Age, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)								
18 - <65 years	5	4	4	4	4	5	14	91
65 - <85 years	2	1	2	2	2	0	8	36
Sex: Female, Male (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)								
Female	5	3	4	4	3	5	14	78
Male	2	2	2	2	3	0	8	49
Race/Ethnicity, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)								
White	6	3	6	4	4	4	15	90
Black or African American	0	0	0	0	0	0	0	3
Asian	1	2	0	1	2	1	6	32
Multiple	0	0	0	1	0	0	0	1

Missing	0	0	0	0	0	0	1	1
Study Specific Characteristic **Primary tumor types** (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)								
Colorectal cancer	3	4	3	4	5	2	0	63
Non-small cell lung cancer	0	0	1	0	0	0	0	8
Ovarian cancer	3	0	1	1	0	1	10	25
Pancreatic cancer	1	1	1	0	0	2	12	23
Prostate cancer	0	0	0	1	0	0	0	1
Renal cell carcinoma	0	0	0	0	1	0	0	2
Triple negative breast cancer	0	0	0	0	0	0	0	5

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Primary Outcome Result(s)

Number of participants with Dose-Limiting Toxicities (DLTs) in the dose escalation part

Description	A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 assessed as unrelated to disease, disease progression, inter-current illness or concomitant medications that occurs within the first cycle of treatment during the dose escalation part of the study. Other clinically significant toxicities may be considered to be DLTs, even if not CTCAE grade 3 or higher. The duration of one treatment cycle is 28 days.
Time Frame	28 days
Analysis Population Description	Patients who received at least one dose of study treatment and who either met the minimum exposure criterion defined in the protocol and had sufficient safety evaluations, or had experienced a DLT during cycle 1.

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

	NZV930 60 mg Q2W	**NZV930 200 mg Q2W**	**NZV930 400 mg Q2W**	**NZV930 600 mg Q2W**	**NZV930 1000 mg Q2W**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W**	**NZV930 200 mg Q2W + NIR178 80 mg BID**	**NZV930 200 mg Q2W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + NIR178 240 mg BID**
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID

Number of Participants Analyzed [units: participants]	3	4	6	8	2	5	6	6	4	6	4	5	5
Number of participants with Dose-Limiting Toxicities (DLTs) in the dose escalation part (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
	0 (%)	0 (%)	0 (%)	0 (%)	1 (50%)	0 (%)	1 (16.67%)	1 (16.67%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Dose escalation: NZV930+PDR001+NIR178

NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID**

Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	5	5	6	6	6	5
Number of participants with Dose-Limiting Toxicities (DLTs) in the dose escalation part (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
	1 (20%)	1 (20%)	1 (16.67%)	0 (%)	1 (16.67%)	0 (%)

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

Description	Number of participants with AEs (any AE regardless of seriousness) and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs. The on-treatment period is defined from the day of first administration of study treatment up to 30 days after the date of its last administration.
Time Frame	From first dose of study treatment to 30 days after last dose, up to approximately 36 weeks (NZV930), 46 weeks (NZV930+PDR001), 94 weeks (NZV930+NIR178) and 29 weeks (NZV930+PDR001+NIR178)

Analysis Population Description: All Patients who received at least one dose of study treatment

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

	NZV930 60 mg Q2W	NZV930 200 mg Q2W	NZV930 400 mg Q2W	NZV930 600 mg Q2W	NZV930 1000 mg Q2W	NZV930 200 mg Q2W + PDR001 400 mg Q4W	NZV930 400 mg Q2W + PDR001 400 mg Q4W	NZV930 600 mg Q2W + PDR001 400 mg Q4W	NZV930 200 mg Q2W + NIR178 80 mg BID	NZV930 200 mg Q2W + NIR178 160 mg BID	NZV930 400 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 240 mg BID
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	3	4	6	9	2	6	6	6	5	6	5	6	6
Number of participants with	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**

Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period (units: participants)	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**
AEs	3 (100%)	4 (100%)	6 (100%)	9 (100%)	2 (100%)	6 (100%)	6 (100%)	6 (100%)	5 (100%)	6 (100%)	5 (100%)	6 (100%)	6 (100%)
Treatment-related AEs	2 (66.67%)	3 (75%)	6 (100%)	8 (88.89%)	2 (100%)	3 (50%)	6 (100%)	4 (66.67%)	5 (100%)	5 (83.33%)	3 (60%)	6 (100%)	5 (83.33%)
SAEs	0 (%)	1 (25%)	3 (50%)	4 (44.44%)	1 (50%)	3 (50%)	2 (33.33%)	3 (50%)	3 (60%)	1 (16.67%)	3 (60%)	2 (33.33%)	3 (50%)
Treatment-related SAEs	0 (%)	0 (%)	3 (50%)	2 (22.22%)	1 (50%)	0 (%)	1 (16.67%)	1 (16.67%)	0 (%)	0 (%)	0 (%)	2 (33.33%)	0 (%)
Fatal SAEs	0 (%)	0 (%)	0 (%)	1 (11.11%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)
AEs leading to treatment discontinuation	0 (%)	0 (%)	0 (%)	2 (22.22%)	1 (50%)	0 (%)	1 (16.67%)	1 (16.67%)	1 (20%)	0 (%)	0 (%)	1 (16.67%)	1 (16.67%)
Treatment-related AEs leading to	0 (%)	0 (%)	0 (%)	2 (22.22%)	1 (50%)	0 (%)	1 (16.67%)	1 (16.67%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

discontinuation													
AEs requiring additional therapy	3 (100%)	3 (75%)	6 (100%)	9 (100%)	2 (100%)	6 (100%)	6 (100%)	6 (100%)	5 (100%)	6 (100%)	5 (100%)	6 (100%)	6 (100%)

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID**	**NZV930 600mgQ2W (step-up) +PDR001 400mgQ4W +NIR178 240mgBID -E**
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	7	5	6	6	6	5	22
Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**

on-treatment period
(units: participants)

AEs	7 (100%)	5 (100%)	6 (100%)	6 (100%)	6 (100%)	5 (100%)	22 (100%)
Treatment-related AEs	6 (85.71%)	5 (100%)	5 (83.33%)	5 (83.33%)	6 (100%)	5 (100%)	21 (95.45%)
SAEs	5 (71.43%)	2 (40%)	2 (33.33%)	3 (50%)	1 (16.67%)	1 (20%)	11 (50%)
Treatment-related SAEs	1 (14.29%)	1 (20%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	4 (18.18%)
Fatal SAEs	1 (14.29%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4.55%)
AEs leading to treatment discontinuation	2 (28.57%)	1 (20%)	2 (33.33%)	0 (%)	1 (16.67%)	0 (%)	6 (27.27%)
Treatment-related AEs leading to discontinuation	1 (14.29%)	1 (20%)	1 (16.67%)	0 (%)	1 (16.67%)	0 (%)	3 (13.64%)
AEs requiring additional therapy	7 (100%)	4 (80%)	5 (83.33%)	6 (100%)	5 (83.33%)	5 (100%)	21 (95.45%)

Number of participants with dose reductions and dose interruptions of NZV930

Description	Number of participants with at least one dose reduction of NZV930 and number of participants with at least one dose interruption of NZV930.
Time Frame	From first dose of NZV930 to last dose, up to 32 weeks (NZV930), 42 weeks (NZV930+PDR001), 90 weeks (NZV930+NIR178) and 25 weeks (NZV930+PDR001+NIR178)
Analysis Population Description	All Patients who received at least one dose of NZV930

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

	NZV930 60 mg Q2W	NZV930 200 mg Q2W	NZV930 400 mg Q2W	NZV930 600 mg Q2W	NZV930 1000 mg Q2W	NZV930 200 mg Q2W + PDR001 400 mg Q4W	NZV930 400 mg Q2W + PDR001 400 mg Q4W	NZV930 600 mg Q2W + PDR001 400 mg Q4W	NZV930 200 mg Q2W + NIR178 80 mg BID	NZV930 200 mg Q2W + NIR178 160 mg BID	NZV930 400 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 240 mg BID
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	3	4	6	9	2	6	6	6	5	6	5	6	6
Number of participants with dose reductions and dose interruptions of NZV930	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**

(units: participants)													
At least one dose reduction	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
At least one dose interruption	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67%)

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID**	**NZV930 600mgQ2W (step-up) +PDR001 400mgQ4W +NIR178 240mgBID -E**
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID
Number of Participants Analyzed	7	5	6	6	6	5	22

[units: participants]							
Number of participants with dose reductions and dose interruptions of NZV930 (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
At least one dose reduction	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
At least one dose interruption	0 (%)	1 (20%)	1 (16.67%)	1 (16.67%)	0 (%)	1 (20%)	3 (13.64%)

Number of participants with dose reductions and dose interruptions of PDR001

Description	Number of participants with at least one dose reduction of PDR001 and number of participants with at least one dose interruption of PDR001. Dose reductions were not allowed for PDR001.
Time Frame	From first dose of PDR001 to last dose, up to 42 weeks (NZV930+PDR001) and 25 weeks (NZV930+PDR001+NIR178)
Analysis Population Description	All Patients who received at least one dose of PDR001

NZV930+PDR001 (Dose escalation) and NZV930+PDR001+NIR178 (Dose escalation and expansion)

NZV930 200 mg Q2W + PDR001 400 mg Q4W	**NZV930 400 mg Q2W + PDR001 400 mg Q4W**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W +**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W +**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W +**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W +**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W +**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W**	**NZV930 600mgQ2W (step-up) +PDR001 400mgQ4W +NIR178**

				NIR178 80 mg BID	NIR178 160 mg BID	NIR178 160 mg BID	NIR178 160 mg BID	NIR178 240 mg BID	+NIR178 240mg BID	240mgBID -E
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	6	6	6	7	5	6	6	6	5	22
Number of participants with dose reductions and dose interruptions of PDR001 (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
At least one dose reduction	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

At least one dose interruption	0 (%)	0 (%)	1 (16.67%)	0 (%)	1 (20%)	1 (16.67%)	1 (16.67%)	0 (%)	1 (20%)	2 (9.09%)

Number of participants with dose reductions and dose interruptions of NIR178

Description	Number of participants with at least one dose reduction of NIR178 and number of participants with at least one dose interruption of NIR178.
Time Frame	From first dose of NIR178 to last dose, up to 90 weeks (NZV930+NIR178) and 25 weeks (NZV930+PDR001+NIR178)
Analysis Population Description	All Patients who received at least one dose of NIR178

NZV930+NIR178 (Dose escalation) and NZV930+PDR001+NIR178 (Dose escalation and expansion)

	NZV930 200 mg Q2W + NIR178 80 mg BID	**NZV930 200 mg Q2W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + NIR178 240 mg BID**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID**	**NZV930 600mgQ 2W (step-up) +PDR001 400mgQ 4W +NIR178 240mgBI D -E**
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W

						80 mg BID	160 mg BID	160 mg BID	160 mg BID	240 mg BID	and NIR178 240 mg BID	and NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	5	6	5	6	6	7	5	6	6	6	5	22
Number of participants with dose reductions and dose interruptions of NIR178 (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
At least one dose reduction	0 (%)	1 (16.67%)	0 (%)	1 (16.67%)	1 (16.67%)	1 (14.29%)	0 (%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	0 (%)
At least one dose interruption	0 (%)	1 (16.67%)	1 (20%)	3 (50%)	1 (16.67%)	1 (14.29%)	2 (40%)	3 (50%)	3 (50%)	1 (16.67%)	0 (%)	6 (27.27%)

Dose intensity of NZV930

Description Dose intensity of NZV930 was calculated as cumulative actual dose in milligrams divided by duration of exposure in days and then multiplied by 28 days.

Time Frame	From first dose of NZV930 to last dose, up to 32 weeks (NZV930), 42 weeks (NZV930+PDR001), 90 weeks (NZV930+NIR178) and 25 weeks (NZV930+PDR001+NIR178)
Analysis Population Description	All Patients who received at least one dose of NZV930

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

	NZV930 60 mg Q2W	**NZV930 200 mg Q2W**	**NZV930 400 mg Q2W**	**NZV930 600 mg Q2W**	**NZV930 1000 mg Q2W**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W**	**NZV930 200 mg Q2W + NIR178 80 mg BID**	**NZV930 200 mg Q2W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + NIR178 240 mg BID**
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	3	4	6	9	2	6	6	6	5	6	5	6	6
Dose intensity	**Mean ±**	**Mean ±**	**Mean ±**	**Mean ±**	**Mean ±**	**Mean ±**	**Mean ±**	**Mean ±**	**Mean ±**	**Mean ±**	**Mean ±**	**Mean ±**	**Mean ±**

of NZV930 (units: mg/28 days)	Standard Deviation	Standard Deviation	Standard Deviation	Standard Deviation	Standard Deviation	Standard Deviation	Standard Deviation	Standard Deviation	Standard Deviation	Standard Deviation	Standard Deviation	Standard Deviation
	120.6 ± 1.00	396.3 ± 11.36	781.1 ± 34.82	1223.5 ± 97.86	2000.0 ± 0.00	387.3 ± 22.32	765.5 ± 38.75	1193.1 ± 15.83	457.8 ± 135.43	382.6 ± 28.27	791.9 ± 18.19	1142.5 ± 92.49	1153.9 ± 102.04

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID	NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID	NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID	NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID	NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID	NZV930 600mgQ2W (step-up) +PDR001 400mgQ4W +NIR178 240mgBID -E
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	7	5	6	6	6	5	22
Dose intensity of NZV930 (units: mg/28 days)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**

400.0 ± 0.00	341.9 ± 78.63	789.8 ± 18.92	1160.1 ± 69.02	1161.7 ± 63.38	1133.1 ± 110.92	981.9 ± 280.07	

Dose intensity of PDR001

Description	Dose intensity of PDR001 was calculated as cumulative actual dose in milligrams divided by duration of exposure in days and then multiplied by 28 days.
Time Frame	From first dose of PDR001 to last dose, up to 42 weeks (NZV930+PDR001) and 25 weeks (NZV930+PDR001+NIR178)
Analysis Population Description	All Patients who received at least one dose of PDR001

NZV930+PDR001 (Dose escalation) and NZV930+PDR001+NIR178 (Dose escalation and expansion)

	NZV930 200 mg Q2W + PDR001 400 mg Q4W	**NZV930 400 mg Q2W + PDR001 400 mg Q4W**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID**	**NZV930 600mgQ2W (step-up) +PDR001 400mgQ4W +NIR178 240mgBID -E**
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and

									NIR178 240 mg BID	NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	6	6	6	7	5	6	6	6	5	22
Dose intensity of PDR001 (units: mg/28 days)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
	389.7 ± 17.29	392.1 ± 10.64	400.7 ± 8.07	422.4 ± 42.19	354.5 ± 63.35	394.9 ± 9.46	381.8 ± 17.51	400.0 ± 0.00	379.4 ± 54.36	392.1 ± 34.45

Dose intensity of NIR178

Description	Dose intensity of NIR178 was calculated as cumulative actual dose in milligrams divided by duration of exposure in days.
Time Frame	From first dose of NIR178 to last dose, up to 90 weeks (NZV930+NIR178) and 25 weeks (NZV930+PDR001+NIR178)
Analysis Population Description	All Patients who received at least one dose of NIR178

NZV930+NIR178 (Dose escalation) and NZV930+PDR001+NIR178 (Dose escalation and expansion)

NZV930 200 mg Q2W + NIR178 80 mg BID	**NZV930 200 mg Q2W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + NIR178 240 mg BID**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178**	**NZV930 600mgQ2W (step-up) +PDR001 400mgQ4W +NIR178**

						80 mg BID	160 mg BID	160 mg BID	160 mg BID	240 mg BID	240mg BID	240mgBID -E
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	5	6	5	6	6	7	5	6	6	6	5	22
Dose intensity of NIR178 (units: mg/day)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
	160.0 ± 0.00	314.3 ± 8.04	318.9 ± 2.56	324.6 ± 63.04	397.4 ± 138.45	150.7 ± 18.56	288.3 ± 64.15	304.7 ± 26.54	303.3 ± 27.56	440.2 ± 61.69	480.0 ± 0.00	449.9 ± 76.92

NOVARTIS

Secondary Outcome Result(s)

Overall Response Rate (ORR) per RECIST v1.1

Description	Tumor response was based on local investigator assessment as per Response Evaluation Criteria In Solid Tumors (RECIST) v1.1. ORR per RECIST v1.1 is defined as the percentage of participants with a best overall response of Complete Response (CR) or Partial Response (PR). For RECIST v1.1, CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters.
Time Frame	From start of treatment until end of treatment, assessed up to 32 weeks (NZV930), 42 weeks (NZV930+PDR001), 90 weeks (NZV930+NIR178) and 25 weeks (NZV930+PDR001+NIR178)
Analysis Population Description	All Patients who received at least one dose of study treatment

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

	NZV930 60 mg Q2W	NZV930 200 mg Q2W	NZV930 400 mg Q2W	NZV930 600 mg Q2W	NZV930 1000 mg Q2W	NZV930 200 mg Q2W + PDR001 400 mg Q4W	NZV930 400 mg Q2W + PDR001 400 mg Q4W	NZV930 600 mg Q2W + PDR001 400 mg Q4W	NZV930 200 mg Q2W + NIR178 80 mg BID	NZV930 200 mg Q2W + NIR178 160 mg BID	NZV930 400 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 240 mg BID
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID

						4 weeks (Q4W)			day (BID)				
Number of Participants Analyzed [units: participants]	3	4	6	9	2	6	6	6	5	6	5	6	6
Overall Response Rate (ORR) per RECIST v1.1 (units: percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	0 (0.0 to 70.8)	0 (0.0 to 60.2)	0 (0.0 to 45.9)	0 (0.0 to 33.6)	0 (0.0 to 84.2)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 45.9)	0 (0.0 to 45.9)

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID**	**NZV930 + PDR001 + NIR178 PDAC**	**NZV930 + PDR001 + NIR178 OVA**
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose expansion part. NZV930 600 mg Q2W (step-up) in	Dose expansion part. NZV930 600 mg Q2W

	in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	(step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID in pancreatic ductal adenocarcinoma (PDAC)	(step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID in ovarian cancer (OVA)
Number of Participants Analyzed [units: participants]	7	5	6	6	6	5	12	10
Overall Response Rate (ORR) per RECIST v1.1 (units: percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	0 (0.0 to 41.0)	0 (0.0 to 52.2)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 26.5)	0 (0.0 to 30.8)

Clinical Benefit Rate (CBR) per RECIST v1.1

Description	Tumor response was based on local investigator assessment per RECIST v1.1. CBR per RECIST v1.1 is defined as the percentage of participants with a best overall response of Complete Response (CR), Partial Response (PR) or Stable Disease (SD) ≥ 16 weeks. For RECIST v1.1, CR=Disappearance of all non-nodal target lesions. In addition, any pathological lymph nodes assigned as target lesions must have a reduction in short axis to < 10 mm; PR= At least a 30% decrease in the sum of diameter of all target lesions, taking as reference the baseline sum of diameters; SD= Neither sufficient shrinkage to qualify for PR or CR nor an increase in lesions which would qualify for progression).
Time Frame	From start of treatment until end of treatment, assessed up to 32 weeks (NZV930), 42 weeks (NZV930+PDR001), 90 weeks (NZV930+NIR178) and 25 weeks (NZV930+PDR001+NIR178)

Analysis Population Description: All Patients who received at least one dose of study treatment

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

	NZV930 60 mg Q2W	NZV930 200 mg Q2W	NZV930 400 mg Q2W	NZV930 600 mg Q2W	NZV930 1000 mg Q2W	NZV930 200 mg Q2W + PDR001 400 mg Q4W	NZV930 400 mg Q2W + PDR001 400 mg Q4W	NZV930 600 mg Q2W + PDR001 400 mg Q4W	NZV930 200 mg Q2W + NIR178 80 mg BID	NZV930 200 mg Q2W + NIR178 160 mg BID	NZV930 400 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 240 mg BID
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	3	4	6	9	2	6	6	6	5	6	5	6	6
Clinical Benefit Rate (CBR) per	**Number (95% Confidence**	**Number (95% Confidence**	**Number (95% Confidence**	**Number (95% Confidence**	**Number (95% Confidence**	**Number (95% Confiden**	**Number (95% Confiden**	**Number (95% Confiden**	**Number (95% Confidence**	**Number (95% Confidence**	**Number (95% Confidence**	**Number (95% Confidence**	**Number (95% Confidence**

RECIST v1.1 (units: percentage of participants)	**Interval)**	**Interval)**	**Interval)**	**Interval)**	**Interval)**	**ce Interval)**	**ce Interval)**	**ce Interval)**	**Interval)**	**Interval)**	**Interval)**	**Interval)**	**Interval)**
	0 (0.0 to 70.8)	0 (0.0 to 60.2)	0 (0.0 to 45.9)	0 (0.0 to 33.6)	0 (0.0 to 84.2)	0 (0.0 to 45.9)	16.7 (0.4 to 64.1)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	16.7 (0.4 to 64.1)	16.7 (0.4 to 64.1)

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID**	**NZV930 + PDR001 + NIR178 PDAC**	**NZV930 + PDR001 + NIR178 OVA**
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID in pancreatic ductal adenocarcinoma (PDAC)	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID in ovarian cancer (OVA)
Number of Participants Analyzed [units: participants]	7	5	6	6	6	5	12	10

Clinical Benefit Rate (CBR) per RECIST v1.1 (units: percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	0 (0.0 to 41.0)	0 (0.0 to 52.2)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 26.5)	10.0 (0.3 to 44.5)

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

Description	PFS is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause. If a patient did not have an event, PFS was censored at the date of the last adequate tumor assessment. Tumor response was based on local investigator assessment per RECIST v1.1. PFS was analyzed using Kaplan-Meier estimates.
Time Frame	From start of treatment until end of treatment, assessed up to 25 weeks
Analysis Population Description	All Patients who received at least one dose of study treatment in the dose expansion part

	NZV930 + PDR001 + NIR178 PDAC	**NZV930 + PDR001 + NIR178 OVA**
Arm/Group Description	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID in pancreatic ductal adenocarcinoma (PDAC)	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID in ovarian cancer (OVA)
Number of Participants Analyzed [units: participants]	12	10
Progression-Free Survival (PFS) per RECIST v1.1 for dose expansion (units: months)	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**
	1.7 (1.3 to NA)[1]	3.5 (1.9 to 3.7)

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

Overall Response Rate (ORR) per iRECIST

Description	Tumor response was based on local investigator assessment per immune-related RECIST (iRECIST). ORR per iRECIST is defined as the percentage of participants with a best overall response of Complete Response (iCR) or Partial Response (iPR).
Time Frame	From start of treatment until end of treatment, assessed up to 32 weeks (NZV930), 42 weeks (NZV930+PDR001), 90 weeks (NZV930+NIR178) and 25 weeks (NZV930+PDR001+NIR178)
Analysis Population Description	All Patients who received at least one dose of study treatment

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

	NZV930 60 mg Q2W	NZV930 200 mg Q2W	NZV930 400 mg Q2W	NZV930 600 mg Q2W	NZV930 1000 mg Q2W	NZV930 200 mg Q2W + PDR001 400 mg Q4W	NZV930 400 mg Q2W + PDR001 400 mg Q4W	NZV930 600 mg Q2W + PDR001 400 mg Q4W	NZV930 200 mg Q2W + NIR178 80 mg BID	NZV930 200 mg Q2W + NIR178 160 mg BID	NZV930 400 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 240 mg BID
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID
Number of Participants	3	4	6	9	2	6	6	6	5	6	5	6	6

Analyzed [units: participants]													
Overall Response Rate (ORR) per iRECIST (units: percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	0 (0.0 to 70.8)	0 (0.0 to 60.2)	0 (0.0 to 45.9)	0 (0.0 to 33.6)	0 (0.0 to 84.2)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 45.9)	0 (0.0 to 45.9)

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID**	**NZV930 + PDR001 + NIR178 PDAC**	**NZV930 + PDR001 + NIR178 OVA**
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID in pancreatic	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID

							ductal adenocarcinoma (PDAC)	in ovarian cancer (OVA)
Number of Participants Analyzed [units: participants]	7	5	6	6	6	5	12	10
Overall Response Rate (ORR) per iRECIST (units: percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	0 (0.0 to 41.0)	0 (0.0 to 52.2)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 26.5)	0 (0.0 to 30.8)

Clinical Benefit Rate (CBR) per iRECIST

Description	Tumor response was based on local investigator assessment per iRECIST. CBR per iRECIST is defined as the percentage of participants with a best overall response of Complete Response (iCR), Partial Response (iPR) or Stable Disease (iSD) ≥ 16 weeks.
Time Frame	From start of treatment until end of treatment, assessed up to 32 weeks (NZV930), 42 weeks (NZV930+PDR001), 90 weeks (NZV930+NIR178) and 25 weeks (NZV930+PDR001+NIR178)
Analysis Population Description	All Patients who received at least one dose of study treatment

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

NZV930 60 mg Q2W	**NZV930 200 mg Q2W**	**NZV930 400 mg Q2W**	**NZV930 600 mg Q2W**	**NZV930 1000 mg Q2W**	**NZV930 200 mg Q2W + PDR001**	**NZV930 400 mg Q2W + PDR001**	**NZV930 600 mg Q2W + PDR001**	**NZV930 200 mg Q2W + NIR178**	**NZV930 200 mg Q2W + NIR178**	**NZV930 400 mg Q2W + NIR178**	**NZV930 600 mg Q2W + NIR178**	**NZV930 600 mg Q2W + NIR178**

						400 mg Q4W	400 mg Q4W	400 mg Q4W	80 mg BID	160 mg BID	160 mg BID	160 mg BID	240 mg BID
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	3	4	6	9	2	6	6	6	5	6	5	6	6
Clinical Benefit Rate (CBR) per iRECIST (units: percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	0 (0.0 to 70.8)	0 (0.0 to 60.2)	0 (0.0 to 45.9)	0 (0.0 to 33.6)	0 (0.0 to 84.2)	0 (0.0 to 45.9)	16.7 (0.4 to 64.1)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	16.7 (0.4 to 64.1)	16.7 (0.4 to 64.1)

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID	NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID	NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID	NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID	NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID	NZV930 + PDR001 + NIR178 PDAC	NZV930 + PDR001 + NIR178 OVA
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID in pancreatic ductal adenocarcinoma (PDAC)	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID in ovarian cancer (OVA)
Number of Participants Analyzed [units: participants]	7	5	6	6	6	5	12	10
Clinical Benefit Rate (CBR) per iRECIST (units: percentage of participants)	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**	**Number (95% Confidence Interval)**
	0 (0.0 to 41.0)	0 (0.0 to 52.2)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 26.5)	10.0 (0.3 to 44.5)

Best percentage change from baseline in PSA

Description	Prostate-specific antigen (PSA) tests were only performed in patients with metastatic castration resistant prostate cancer (mCRPC). Rising PSA is generally an indication of recurring disease.
Time Frame	From start of treatment until lost to follow-up, assessed up 1 month
Analysis Population Description	Patients with mCRPC who received at least one dose of study treatment

	NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID
Arm/Group Description	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID
Number of Participants Analyzed [units: participants]	1
Best percentage change from baseline in PSA (units: Percentage change from baseline)	
	0.5917

Number of participants with anti-NZV930 antibodies

Description	Immunogenicity was evaluated in serum in a validated three-tiered assay approach. Samples were screened for potential anti-NZV930 antibodies and positive screen results were confirmed using a confirmatory assay. For confirmed anti-drug antibodies (ADA) positive samples, titers were determined. Patient ADA status was defined as follows: • ADA-negative at baseline: ADA-negative sample at baseline • ADA-positive at baseline: ADA-positive sample at baseline • ADA-negative post-baseline: patient with ADA-negative sample at baseline and at least 1 post baseline determinant sample, all of which are ADA-negative samples • ADA-inconclusive post-baseline = patient who does not qualify as ADA-positive or ADA-negative • Treatment-induced ADA-positive = ADA-negative sample at baseline and at least 1 treatment-induced ADA-positive sample • Treatment-boosted ADA-positive = ADA-positive sample at baseline and at least 1 treatment-boosted ADA-positive sample
Time Frame	Baseline (before first dose) and post-baseline (assessed throughout the treatment up to 32 weeks (NZV930), 42 weeks (NZV930+PDR001), 90 weeks (NZV930+NIR178) and 25 weeks (NZV930+PDR001+NIR178))

Analysis Population Description	All patients who received at least one dose of NZV930 and had a determinant baseline immunogenicity (IG) sample and at least one determinant post-baseline IG sample for assessing anti-NZV930 antibodies. Determinant samples are defined as samples which are not unevaluable (where unevaluable = sample where assay is not available).

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

	NZV930 60 mg Q2W	NZV930 200 mg Q2W	NZV930 400 mg Q2W	NZV930 600 mg Q2W	NZV930 1000 mg Q2W	NZV930 200 mg Q2W + PDR001 400 mg Q4W	NZV930 400 mg Q2W + PDR001 400 mg Q4W	NZV930 600 mg Q2W + PDR001 400 mg Q4W	NZV930 200 mg Q2W + NIR178 80 mg BID	NZV930 200 mg Q2W + NIR178 160 mg BID	NZV930 400 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 160 mg BID	NZV930 600 mg Q2W + NIR178 240 mg BID
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg twice a day (BID)	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	3	3	6	9	1	5	6	5	4	6	3	6	5
Number of participants with	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**

anti-NZV930 antibodies (units: participants)	(Percentage)	(Percentage)	(Percentage)	(Percentage)	(Percentage)	(Percentage)	(Percentage)	(Percentage)	(Percentage)	(Percentage)	(Percentage)	(Percentage)	(Percentage)
ADA-negative at baseline	3 (100%)	3 (100%)	6 (100%)	9 (100%)	1 (100%)	5 (100%)	6 (100%)	5 (100%)	4 (100%)	6 (100%)	3 (100%)	6 (100%)	5 (100%)
ADA-positive at baseline	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
ADA-inconclusive post-baseline	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
ADA-negative post-baseline	2 (66.67%)	3 (100%)	6 (100%)	8 (88.89%)	1 (100%)	5 (100%)	5 (83.33%)	5 (100%)	3 (75%)	6 (100%)	3 (100%)	6 (100%)	5 (100%)
Treatment-induced ADA-positive	1 (33.33%)	0 (%)	0 (%)	1 (11.11%)	0 (%)	0 (%)	1 (16.67%)	0 (%)	1 (25%)	0 (%)	0 (%)	0 (%)	0 (%)
Treatment-boosted ADA-positive	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID	NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID	NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID	NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID	NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID	NZV930 600mgQ2W (step-up) +PDR001 400mgQ4W +NIR178 240mgBID -E
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	5	3	5	6	6	5	17
Number of participants with anti-NZV930 antibodies (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
ADA-negative at baseline	5 (100%)	3 (100%)	5 (100%)	6 (100%)	6 (100%)	5 (100%)	17 (100%)
ADA-positive at baseline	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
ADA-inconclusive post-baseline	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
ADA-negative post-baseline	4 (80%)	2 (66.67%)	5 (100%)	5 (83.33%)	6 (100%)	5 (100%)	16 (94.12%)

Treatment-induced ADA-positive	1 (20%)	1 (33.33%)	0 (%)	1 (16.67%)	0 (%)	0 (%)	1 (5.88%)
Treatment-boosted ADA-positive	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Number of participants with anti-PDR001 antibodies

Description	Immunogenicity was evaluated in serum in a validated three-tiered assay approach. Samples were screened for potential anti-PDR001 antibodies and positive screen results were confirmed using a confirmatory assay. For confirmed anti-drug antibodies (ADA) positive samples, titers were determined. Patient ADA status was defined as follows: • ADA-negative at baseline: ADA-negative sample at baseline • ADA-positive at baseline: ADA-positive sample at baseline • ADA-negative post-baseline: patient with ADA-negative sample at baseline and at least 1 post baseline determinant sample, all of which are ADA-negative samples • ADA-inconclusive post-baseline = patient who does not qualify as ADA-positive or ADA-negative • Treatment-induced ADA-positive = ADA-negative sample at baseline and at least 1 treatment-induced ADA-positive sample • Treatment-boosted ADA-positive = ADA-positive sample at baseline and at least 1 treatment-boosted ADA-positive sample
Time Frame	Baseline (before first dose) and post-baseline (assessed throughout the treatment up to 42 weeks (NZV930+PDR001) and 25 weeks (NZV930+PDR001+NIR178))
Analysis Population Description	All patients who received at least one dose of PDR001 and had a determinant baseline immunogenicity (IG) sample and at least one determinant post-baseline IG sample for assessing anti-PDR001 antibodies. Determinant samples are defined as samples which are not unevaluable (where unevaluable = sample where assay is not available).

NZV930+PDR001 (Dose escalation) and NZV930+PDR001+NIR178 (Dose escalation and expansion)

	NZV930 200 mg Q2W + PDR001 400 mg Q4W	**NZV930 400 mg Q2W + PDR001 400 mg Q4W**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID**	**NZV930 600mgQ2W (step-up) +PDR001 400mgQ4W +NIR178 240mgBID -E**
Arm/Group	Dose escalation	Dose escalation	Dose escalation	Dose escalation	Dose escalation	Dose escalation	Dose escalation	Dose escalation	Dose escalation	Dose expansion

Description	part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID
Number of Participants Analyzed [units: participants]	5	6	5	3	4	5	5	5	5	20
Number of participants with anti-PDR001 antibodies (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
ADA-negative at baseline	4 (80%)	6 (100%)	5 (100%)	3 (100%)	4 (100%)	5 (100%)	5 (100%)	5 (100%)	5 (100%)	19 (95%)
ADA-positive at baseline	1 (20%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (5%)
ADA-inconclusive post-baseline	1 (20%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (5%)

ADA-negative post-baseline	4 (80%)	5 (83.33%)	4 (80%)	2 (66.67%)	4 (100%)	5 (100%)	5 (100%)	5 (100%)	4 (80%)	18 (90%)
Treatment-induced ADA-positive	0 (%)	1 (16.67%)	1 (20%)	1 (33.33%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (20%)	1 (5%)
Treatment-boosted ADA-positive	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Maximum observed serum concentration (Cmax) of NZV930

Description	Pharmacokinetic (PK) parameters were calculated based on NZV930 serum concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed serum concentration following a dose.
Time Frame	pre-infusion and 1, 24, 48, 72, 168, 240 and 336 hours after completion of the NZV930 infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was approximately 1 hour. The duration of one cycle was 28 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) with an available value for the outcome measure in each timepoint. PAS consists of all patients who received the planned treatment, provided at least one primary PK parameter and did not vomit within 4 hours after the dosing of NIR178.

	NZV930 60 mg Q2W	**NZV930 200 mg Q2W**	**NZV930 400 mg Q2W**	**NZV930 600 mg Q2W**	**NZV930 1000 mg Q2W**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W**	**NZV930 200 mg Q2W + NIR178**	**NZV930 400 mg Q2W + NIR178**	**NZV930 600 mg Q2W + NIR178**	**NZV930 200 mg Q2W + PDR001 + NIR178**	**NZV930 400 mg Q2W + PDR001 + NIR178**	**NZV930 600 mg Q2W + PDR001 + NIR178**
Arm/Group Description	Dose escalation part. NZV930 60 mg	Dose escalation part. NZV930	Dose escalation part. NZV930 400	Dose escalation part. NZV930 600	Dose escalation part. NZV930 1000	Dose escalation part. NZV930 200 mg	Dose escalation part. NZV930 400	Dose escalation part. NZV930 600	Dose escalation part. NZV930 200 mg	Dose escalation part. NZV930 400 mg	Dose escalation part. NZV930 600	Dose escalation part. NZV930 200 mg	Dose escalation part. NZV930 400	Dose escalation part. NZV930 600

	every 2 weeks (Q2W)	200 mg Q2W	mg Q2W	mg Q2W	mg Q2W	Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	mg Q2W in combination with spartalizumab 400 mg Q4W	mg Q2W in combination with spartalizumab 400 mg Q4W	Q2W in combination with any dose level of NIR178	Q2W in combination with any dose level of NIR178	mg Q2W in combination with any dose level of NIR178	Q2W in combination with any dose level of spartalizumab and NIR178	mg Q2W in combination with any dose level of spartalizumab and NIR178	mg Q2W in combination with any dose level of spartalizumab and NIR178
Number of Participants Analyzed [units: participants]	3	4	6	9	2	6	6	6	11	5	11	10	5	11
Maximum observed serum concentration (Cmax) of NZV930 (units: µg/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
Cycle 1 Day 1 (n=3,4,6,9,2,6,6,6,11,5,11,10,5,11)	14.8 (46.4%)	39.7 (18.3%)	115 (12.3%)	147 (19.2%)	268 (95.4%)	45.3 (47.8%)	108 (33.7%)	140 (50.3%)	48.7 (36.5%)	86.7 (30.3%)	174 (20.3%)	50.3 (29.4%)	147 (58.4%)	155 (38.7%)
Cycle 3 Day 1 (n=1,1,3,3,0,1,3,2,4,1,4,1,2,3)	21.3	59.5	149 (3.8%)	228 (3.6%)		60.5	165 (40.5%)	162 (11.3%)	83.6 (13.3%)	132	239 (28.0%)	68.6	123 (21.4%)	197 (25.5%)

Time to reach maximum serum concentration (Tmax) of NZV930

Description PK parameters were calculated based on NZV930 serum concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) serum concentration following a dose. Actual recorded sampling times were considered for the calculations.

Time Frame	pre-infusion and 1, 24, 48, 72, 168, 240 and 336 hours after completion of the NZV930 infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was approximately 1 hour. The duration of one cycle was 28 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) with an available value for the outcome measure in each timepoint. PAS consists of all patients who received the planned treatment, provided at least one primary PK parameter and did not vomit within 4 hours after the dosing of NIR178.

	NZV930 60 mg Q2W	**NZV930 200 mg Q2W**	**NZV930 400 mg Q2W**	**NZV930 600 mg Q2W**	**NZV930 1000 mg Q2W**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W**	**NZV930 200 mg Q2W + NIR178**	**NZV930 400 mg Q2W + NIR178**	**NZV930 600 mg Q2W + NIR178**	**NZV930 200 mg Q2W + PDR001 + NIR178**	**NZV930 400 mg Q2W + PDR001 + NIR178**	**NZV930 600 mg Q2W + PDR001 + NIR178**
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg every 4 weeks (Q4W)	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with any dose level of NIR178	Dose escalation part. NZV930 400 mg Q2W in combination with any dose level of NIR178	Dose escalation part. NZV930 600 mg Q2W in combination with any dose level of NIR178	Dose escalation part. NZV930 200 mg Q2W in combination with any dose level of spartalizumab and NIR178	Dose escalation part. NZV930 400 mg Q2W in combination with any dose level of spartalizumab and NIR178	Dose escalation part. NZV930 600 mg Q2W in combination with any dose level of spartalizumab and NIR178
Number of Participants Analyzed [units: participants]	3	4	6	9	2	6	6	6	11	5	11	10	5	11
Time to reach maximum serum concentration (Tmax) of NZV930 (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**

Cycle 1 Day 1 (n=3,4,6,9,2,6,6,6,11,5,11,10,5,11)	2.12 (2.10 to 23.2)	2.05 (2.00 to 2.08)	2.08 (2.00 to 2.28)	2.10 (2.00 to 25.1)	2.08 (2.08 to 2.08)	2.07 (2.00 to 45.6)	2.03 (1.00 to 51.1)	2.06 (2.00 to 26.5)	2.03 (0.867 to 24.9)	2.33 (2.00 to 23.9)	2.00 (1.00 to 23.7)	2.00 (0.983 to 23.4)	2.00 (1.90 to 3.00)	2.00 (1.00 to 341)
Cycle 3 Day 1 (n=1,1,3,3,0,1,3,2,4,1,4,1,2,3)	2.00 (2.00 to 2.00)	2.00 (2.00 to 2.00)	2.05 (2.02 to 2.15)	2.70 (1.95 to 24.9)		1.98 (1.98 to 1.98)	2.68 (1.12 to 26.0)	2.98 (2.95 to 3.00)	2.00 (1.83 to 2.08)	2.00 (2.00 to 2.00)	2.09 (1.13 to 2.83)	3.02 (3.02 to 3.02)	1.58 (1.22 to 1.93)	1.97 (1.97 to 2.15)

Area under the serum concentration-time curve from time zero to 15 days (AUC0-15day) of NZV930

Description	PK parameters were calculated based on NZV930 serum concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUC0-15day calculation.
Time Frame	pre-infusion and 1, 24, 48, 72, 168, 240 and 336 hours after completion of the NZV930 infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was approximately 1 hour. The duration of one cycle was 28 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) with an available value for the outcome measure in each timepoint. PAS consists of all patients who received the planned treatment, provided at least one primary PK parameter and did not vomit within 4 hours after the dosing of NIR178.

	NZV930 60 mg Q2W	**NZV930 200 mg Q2W**	**NZV930 400 mg Q2W**	**NZV930 600 mg Q2W**	**NZV930 1000 mg Q2W**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W**	**NZV930 200 mg Q2W + NIR178**	**NZV930 400 mg Q2W + NIR178**	**NZV930 600 mg Q2W + NIR178**	**NZV930 200 mg Q2W + PDR001 + NIR178**	**NZV930 400 mg Q2W + PDR001 + NIR178**	**NZV930 600 mg Q2W + PDR001 + NIR178**
Arm/Group Description	Dose escalation part. NZV930 60 mg every 2 weeks (Q2W)	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartali	Dose escalation part. NZV930 400 mg Q2W in combination with spartali	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab	Dose escalation part. NZV930 200 mg Q2W in combination with any	Dose escalation part. NZV930 400 mg Q2W in combination with any	Dose escalation part. NZV930 600 mg Q2W in combination with any dose	Dose escalation part. NZV930 200 mg Q2W in combination with any	Dose escalation part. NZV930 400 mg Q2W in combination with any	Dose escalation part. NZV930 600 mg Q2W in combination with any dose level of

						zumab 400 mg every 4 weeks (Q4W)	zumab 400 mg Q4W	400 mg Q4W	dose level of NIR178	dose level of NIR178	level of NIR178	dose level of spartali zumab and NIR178	dose level of spartali zumab and NIR178	spartaliz umab and NIR178
Number of Participants Analyzed [units: participants]	2	4	6	9	2	6	5	6	10	5	11	10	5	11
Area under the serum concentration-time curve from time zero to 15 days (AUC0-15day) of NZV930 (units: day*µg/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
Cycle 1 Day 1 (n=2,4,6,9,2,6,5,6,10,5,11,10,5,11)	27.9 (77.4%)	108 (18.5%)	488 (16.4%)	674 (27.0%)	811 (42.6%)	150 (30.3%)	513 (54.6%)	707 (28.0%)	162 (36.9%)	352 (32.9%)	850 (25.7%)	166 (36.5%)	433 (21.2%)	722 (50.2%)
Cycle 3 Day 1 (n=1,1,3,3,0,1,3,2,4,1,3,1,2,3)	38.4	268	853 (7.5%)	1620 (21.7%)		244	889 (25.4%)	1000 (30.3%)	393 (31.9%)	1000	1440 (58.6%)	431	469 (31.1%)	1360 (27.7%)

Maximum observed serum concentration (Cmax) of PDR001

Description	Pharmacokinetic (PK) parameters were calculated based on PDR001 serum concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed serum concentration following a dose.
Time Frame	pre-infusion and 1, 168, 336 and 672 hours after completion of the PDR001 infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was approximately 30 minutes. The duration of one cycle was 28 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) with an available value for the outcome measure in each timepoint. PAS consists of all patients who received the planned treatment, provided at least one primary PK parameter and did not vomit within 4 hours after the dosing of NIR178.

	PDR001 400 mg Q4W
Arm/Group Description	Dose escalation and expansion. All patients who received spartalizumab 400 mg Q4W in combination with any of the other study drugs
Number of Participants Analyzed [units: participants]	60
Maximum observed serum concentration (Cmax) of PDR001 (units: µg/mL)	**Geometric Mean** **(Geometric Coefficient of Variation)**
Cycle 1 Day 1 (n=60)	95.3 (33.4%)
Cycle 3 Day 1 (n=20)	127 (26.8%)

Time to reach maximum serum concentration (Tmax) of PDR001

Description	PK parameters were calculated based on PDR001 serum concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) serum concentration following a dose. Actual recorded sampling times were considered for the calculations.
Time Frame	pre-infusion and 1, 168, 336 and 672 hours after completion of the PDR001 infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was approximately 30 minutes. The duration of one cycle was 28 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) with an available value for the outcome measure in each timepoint. PAS consists of all patients who received the planned treatment, provided at least one primary PK parameter and did not vomit within 4 hours after the dosing of NIR178.

	PDR001 400 mg Q4W
Arm/Group Description	Dose escalation and expansion. All patients who received spartalizumab 400 mg Q4W in combination with any of the other study drugs
Number of Participants Analyzed [units: participants]	60
Time to reach maximum serum concentration (Tmax) of PDR001 (units: hours)	**Median** **(Full Range)**
Cycle 1 Day 1 (n=60)	1.50 (0.417 to 433)

Cycle 3 Day 1 (n=20)	1.49 (0.50 to 1.80)

Area under the serum concentration-time curve from time zero to 28 days (AUC0-28day) of PDR001

Description	PK parameters were calculated based on PDR001 serum concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUC0-28day calculation.
Time Frame	pre-infusion and 1, 168, 336 and 672 hours after completion of the PDR001 infusion on Cycle 1 Day 1 and Cycle 3 Day 1. The duration of the infusion was approximately 30 minutes. The duration of one cycle was 28 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) with an available value for the outcome measure in each timepoint. PAS consists of all patients who received the planned treatment, provided at least one primary PK parameter and did not vomit within 4 hours after the dosing of NIR178.

	PDR001 400 mg Q4W
Arm/Group Description	Dose escalation and expansion. All patients who received spartalizumab 400 mg Q4W in combination with any of the other study drugs
Number of Participants Analyzed [units: participants]	37
Area under the serum concentration-time curve from time zero to 28 days (AUC0-28day) of PDR001 (units: hr*µg/mL)	**Geometric Mean** **(Geometric Coefficient of Variation)**
Cycle 1 Day 1 (n=37)	29000 (28.7%)
Cycle 3 Day 1 (n=6)	50400 (38.9%)

Maximum observed plasma concentration (Cmax) of NIR178

Description	Pharmacokinetic (PK) parameters were calculated based on NIR178 plasma concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed plasma concentration following a dose.
Time Frame	pre-dose, 15 minutes, 30 minutes and 1, 1.5, 2, 3, 4 and 6 hours after morning dose and 12 hours after evening dose on Cycle 1 Day 1 and Cycle 2 Day 1. The duration of one cycle was 28 days.

Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) with an available value for the outcome measure in each timepoint. PAS consists of all patients who received the planned treatment, provided at least one primary PK parameter and did not vomit within 4 hours after the dosing of NIR178.

	NIR178 80 mg BID	NIR178 160 mg BID	NIR178 240 mg BID
Arm/Group Description	Dose escalation part. All patients who received NIR178 80 mg BID in combination with any of the other study drugs	Dose escalation part. All patients who received NIR178 160 mg BID in combination with any of the other study drugs	Dose escalation and expansion. All patients who received NIR178 240 mg BID in combination with any of the other study drugs
Number of Participants Analyzed [units: participants]	11	29	37
Maximum observed plasma concentration (Cmax) of NIR178 (units: ng/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
Cycle 1 Day 1 (n=11,29,37)	88.7 (599.4%)	131 (324.3%)	261 (243.3%)
Cycle 2 Day 1 (n=7,24,24)	312 (555.0%)	341 (269.9%)	636 (181.6%)

Time to reach maximum plasma concentration (Tmax) of NIR178

Description	PK parameters were calculated based on NIR178 plasma concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) plasma concentration following a dose. Actual recorded sampling times were considered for the calculations.
Time Frame	pre-dose, 15 minutes, 30 minutes and 1, 1.5, 2, 3, 4 and 6 hours after morning dose and 12 hours after evening dose on Cycle 1 Day 1 and Cycle 2 Day 1. The duration of one cycle was 28 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) with an available value for the outcome measure in each timepoint. PAS consists of all patients who received the planned treatment, provided at least one primary PK parameter and did not vomit within 4 hours after the dosing of NIR178.

	NIR178 80 mg BID	NIR178 160 mg BID	NIR178 240 mg BID

Arm/Group Description	Dose escalation part. All patients who received NIR178 80 mg BID in combination with any of the other study drugs	Dose escalation part. All patients who received NIR178 160 mg BID in combination with any of the other study drugs	Dose escalation and expansion. All patients who received NIR178 240 mg BID in combination with any of the other study drugs
Number of Participants Analyzed [units: participants]	11	29	37
Time to reach maximum plasma concentration (Tmax) of NIR178 (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 Day 1 (n=11,29,37)	2.00 (1.08 to 5.93)	2.20 (0.50 to 5.55)	2.05 (0.50 to 6.38)
Cycle 2 Day 1 (n=7,24,24)	3.58 (1.50 to 4.65)	2.08 (1.00 to 6.03)	2.00 (0.250 to 5.13)

Area under the plasma concentration-time curve from time zero to 12 hours (AUC0-12hr) of NIR178

Description	PK parameters were calculated based on NIR178 plasma concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUC0-12hr calculation.
Time Frame	pre-dose, 15 minutes, 30 minutes and 1, 1.5, 2, 3, 4 and 6 hours after morning dose and 12 hours after evening dose on Cycle 1 Day 1 and Cycle 2 Day 1. The duration of one cycle was 28 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) with an available value for the outcome measure in each timepoint. PAS consists of all patients who received the planned treatment, provided at least one primary PK parameter and did not vomit within 4 hours after the dosing of NIR178.

	NIR178 80 mg BID	NIR178 160 mg BID	NIR178 240 mg BID
Arm/Group Description	Dose escalation part. All patients who received NIR178 80 mg BID in combination with any of the other study drugs	Dose escalation part. All patients who received NIR178 160 mg BID in combination with any of the other study drugs	Dose escalation and expansion. All patients who received NIR178 240 mg BID in combination with any of the other study drugs
Number of Participants Analyzed [units: participants]	6	16	21

Area under the plasma concentration-time curve from time zero to 12 hours (AUC0-12hr) of NIR178 (units: hr*µg/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
Cycle 1 Day 1 (n=6,16,21)	0.207 (884.8%)	0.507 (211.1%)	0.609 (272.2%)
Cycle 2 Day 1 (n=2,14,16)	0.386 (107.5%)	0.557 (109.9%)	2.53 (138.1%)

Safety Results

Time Frame	From first dose of study treatment to 90 days after last dose (NZV930 single agent and NZV930+NIR178) and to 150 days after last dose (NZV930+PDR001 and NZV930+PDR001+NIR178), up to approximately 45 weeks (NZV930), 64 weeks (NZV930+PDR001), 103 weeks (NZV930+NIR178) and 47 weeks (NZV930+PDR001+NIR178).
Source Vocabulary for Table Default	MedDRA (25.1)
Collection Approach for Table Default	Systematic Assessment

All-Cause Mortality

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

NZV930 60 mg Q2W N = 3	**NZV930 200 mg Q2W N = 4**	**NZV930 400 mg Q2W N = 6**	**NZV930 600 mg Q2W N = 9**	**NZV930 1000 mg Q2W N = 2**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W N = 6**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W N = 6**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W N = 6**	**NZV930 200 mg Q2W + NIR178 80 mg BID N = 5**	**NZV930 200 mg Q2W + NIR178 160 mg BID N = 6**	**NZV930 400 mg Q2W + NIR178 160 mg BID N = 5**	**NZV930 600 mg Q2W + NIR178 160 mg BID N = 6**	**NZV930 600 mg Q2W + NIR178 240 mg BID N = 6**

Arm/Group Description	Dose escalation part. NZV930 60 mg Q2W	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID
Total Number Affected	0	1	2	4	2	2	4	4	2	4	3	3	4
Total Number At Risk	3	4	6	9	2	6	6	6	5	6	5	6	6

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID N = 7	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID N = 5**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID N = 6**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID N = 6**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID N = 6**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID N = 27**	**All patients N = 127**
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part and dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab	All patients in the trial

	and NIR178 80 mg BID	and NIR178 160 mg BID	and NIR178 160 mg BID	and NIR178 160 mg BID	and NIR178 240 mg BID	400 mg Q4W and NIR178 240 mg BID	
Total Number Affected	4	3	3	2	2	9	58
Total Number At Risk	7	5	6	6	6	27	127

Serious Adverse Events

Time Frame	From first dose of study treatment to 90 days after last dose (NZV930 single agent and NZV930+NIR178) and to 150 days after last dose (NZV930+PDR001 and NZV930+PDR001+NIR178), up to approximately 45 weeks (NZV930), 64 weeks (NZV930+PDR001), 103 weeks (NZV930+NIR178) and 47 weeks (NZV930+PDR001+NIR178).
Source Vocabulary for Table Default	MedDRA (25.1)
Collection Approach for Table Default	Systematic Assessment

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

NZV930 60 mg Q2W N = 3	**NZV930 200 mg Q2W N = 4**	**NZV930 400 mg Q2W N = 6**	**NZV930 600 mg Q2W N = 9**	**NZV930 1000 mg Q2W N = 2**	**NZV930 200 mg Q2W + PDR001 400 mg**	**NZV930 400 mg Q2W + PDR001 400 mg**	**NZV930 600 mg Q2W + PDR001 400 mg**	**NZV930 200 mg Q2W + NIR178 80 mg**	**NZV930 200 mg Q2W + NIR178 160 mg**	**NZV930 400 mg Q2W + NIR178 160 mg**	**NZV930 600 mg Q2W + NIR178 160 mg**	**NZV930 600 mg Q2W + NIR178 240 mg**

						Q4W N = 6	Q4W N = 6	Q4W N = 6	BID N = 5	BID N = 6	BID N = 5	BID N = 6	BID N = 6
Arm/Group Description	Dose escalation part. NZV930 60 mg Q2W	Dose escalation part. NZV930 200 mg Q2W	Dose escalation part. NZV930 400 mg Q2W	Dose escalation part. NZV930 600 mg Q2W	Dose escalation part. NZV930 1000 mg Q2W	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with NIR178 240 mg BID
Total # Affected by any Serious Adverse Event	0	2	3	4	1	3	3	3	3	1	3	2	3
Total # at Risk by any Serious Adverse Event	3	4	6	9	2	6	6	6	5	6	5	6	6
Blood and lymphatic system disorders													
Febrile neutropenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neutropenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thrombocytopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cardiac disorders													

Cardiac arrest	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (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 %)
Myocardial infarction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Supraventricular tachycardia	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear and labyrinth disorders													
Vertigo positional	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal disorders													
Abdominal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Abdominal pain upper	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Anal incontinence	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ascites	0 (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 %)	1 (16.67 %)	0 (0.00 %)
Constipation	0 (0.00 %)	0 (0.00 %)	0 (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 %)
Duodenal obstruction	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastric haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ileus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nausea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)

Rectal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vomiting	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	1 (50.00%)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
General disorders and administration site conditions													
Chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Disease progression	0 (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 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)
Generalised oedema	0 (0.00 %)	1 (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 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Non-cardiac chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oedema peripheral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pyrexia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	1 (50.00%)	1 (16.67 %)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00 %)
Hepatobiliary disorders													
Autoimmune hepatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cholecystitis chronic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cholestasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Hyperbilirubinaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (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 %)
Immune-mediated cholangitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infections and infestations													
Biliary tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Periorbital cellulitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.67 %)	2 (40.00 %)	0 (0.00 %)	0 (0.00 %)
Sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Upper respiratory tract infection	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 %)
Urinary tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Investigations													
Blood creatine phosphokinase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (22.22%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metabolism and nutrition disorders													
Dehydration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)
Diabetic ketoacidosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Failure to thrive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperkalaemia	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 %)
Hyperuricaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypervolaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal and connective tissue disorders													
Arthralgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Back pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)
Myopathy	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neck pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)													
Paraneoplastic syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tumour pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nervous system disorders													

Cerebrovascular accident	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haemorrhage intracranial	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (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 %)
Headache	0 (0.00 %)	0 (0.00 %)	2 (33.33%)	0 (0.00 %)	1 (50.00%)	0 (0.00%)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (33.33 %)	0 (0.00 %)
Lethargy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (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 %)
Spinal cord compression	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Psychiatric disorders													
Anxiety	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal and urinary disorders													
Acute kidney injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hydronephrosis	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 %)	0 (0.00 %)
Renal failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal impairment	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory, thoracic and mediastinal disorders													
Dyspnoea	0 (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 %)
Haemoptysis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)

Pleural effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pulmonary embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory distress	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (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 %)
Respiratory failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin and subcutaneous tissue disorders													
Rash maculo-papular	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vascular disorders													
Deep vein thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (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 %)
Embolism	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 %)	0 (0.00 %)
Vasospasm	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID N = 7	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID N = 5**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID N = 6**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID N = 6**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID N = 6**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178 240mg BID N = 27**	**All patients N = 127**

Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part and dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	All patients in the trial
Total # Affected by any Serious Adverse Event	5	2	2	3	1	12	56
Total # at Risk by any Serious Adverse Event	7	5	6	6	6	27	127
Blood and lymphatic system disorders							
Febrile neutropenia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Neutropenia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Cardiac disorders							
Cardiac arrest	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Myocardial infarction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.79%)
Supraventricular tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Ear and labyrinth disorders							
Vertigo positional	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)

Gastrointestinal disorders							
Abdominal pain	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (2.36%)
Abdominal pain upper	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Anal incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Constipation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Duodenal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Gastric haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.79%)
Ileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.79%)
Nausea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	4 (3.15%)
Rectal haemorrhage	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (2.36%)
General disorders and administration site conditions							
Chest pain	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Disease progression	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (2.36%)
Generalised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Non-cardiac chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Oedema peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.79%)
Pyrexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	7 (5.51%)

Hepatobiliary disorders							
Autoimmune hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.79%)
Cholecystitis chronic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Cholestasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Hyperbilirubinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Immune-mediated cholangitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.79%)
Infections and infestations							
Biliary tract infection	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Periorbital cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Pneumonia	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (3.70%)	8 (6.30%)
Sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Urinary tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.79%)
Investigations							
Blood creatine phosphokinase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Metabolism and nutrition disorders							
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Diabetic ketoacidosis	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)

Failure to thrive	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Hyperkalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Hyperuricaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Hypervolaemia	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Musculoskeletal and connective tissue disorders							
Arthralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Back pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Myopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Neck pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Paraneoplastic syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Tumour pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Nervous system disorders							
Cerebrovascular accident	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.79%)
Haemorrhage intracranial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Headache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	8 (6.30%)
Lethargy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Spinal cord compression	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Psychiatric disorders							

Anxiety	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Renal and urinary disorders							
Acute kidney injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Hydronephrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Renal failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Renal impairment	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.79%)
Respiratory, thoracic and mediastinal disorders							
Dyspnoea	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Haemoptysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Pleural effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	3 (2.36%)
Pulmonary embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.79%)
Respiratory distress	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Respiratory failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (0.79%)
Skin and subcutaneous tissue disorders							
Rash maculo-papular	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Vascular disorders							
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Vasospasm	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (0.79%)

Other (Not Including Serious) Adverse Events

Time Frame	From first dose of study treatment to 90 days after last dose (NZV930 single agent and NZV930+NIR178) and to 150 days after last dose (NZV930+PDR001 and NZV930+PDR001+NIR178), up to approximately 45 weeks (NZV930), 64 weeks (NZV930+PDR001), 103 weeks (NZV930+NIR178) and 47 weeks (NZV930+PDR001+NIR178).
Source Vocabulary for Table Default	MedDRA (25.1)
Collection Approach for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

Dose escalation: NZV930 single agent, NZV930+PDR001 and NZV930+NIR178

	NZV930 60 mg Q2W N = 3	**NZV930 200 mg Q2W N = 4**	**NZV930 400 mg Q2W N = 6**	**NZV930 600 mg Q2W N = 9**	**NZV930 1000 mg Q2W N = 2**	**NZV930 200 mg Q2W + PDR001 400 mg Q4W N = 6**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W N = 6**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W N = 6**	**NZV930 200 mg Q2W + NIR178 80 mg BID N = 5**	**NZV930 200 mg Q2W + NIR178 160 mg BID N = 6**	**NZV930 400 mg Q2W + NIR178 160 mg BID N = 5**	**NZV930 600 mg Q2W + NIR178 160 mg BID N = 6**	**NZV930 600 mg Q2W + NIR178 240 mg BID N = 6**
Arm/Group Description	Dose escalation part. NZV93	Dose escalation part. NZV93	Dose escalation part. NZV93	Dose escalation part. NZV93 0 600	Dose escalation part. NZV93	Dose escalation part. NZV930 200 mg	Dose escalation part. NZV930 400 mg	Dose escalation part. NZV930 600 mg	Dose escalation part. NZV93 0 200	Dose escalation part. NZV93 0 200	Dose escalation part. NZV93 0 400	Dose escalation part. NZV93 0 600	Dose escalation part. NZV93 0 600

	0 60 mg Q2W	0 200 mg Q2W	0 400 mg Q2W	mg Q2W	0 1000 mg Q2W	Q2W in combination with spartalizumab 400 mg Q4W	Q2W in combination with spartalizumab 400 mg Q4W	Q2W in combination with spartalizumab 400 mg Q4W	mg Q2W in combination with NIR178 80 mg BID	mg Q2W in combination with NIR178 160 mg BID	mg Q2W in combination with NIR178 160 mg BID	mg Q2W in combination with NIR178 160 mg BID	mg Q2W in combination with NIR178 240 mg BID
Total # Affected by any Other Adverse Event	3	4	6	9	2	6	6	6	5	6	5	6	6
Total # at Risk by any Other Adverse Event	3	4	6	9	2	6	6	6	5	6	5	6	6
Blood and lymphatic system disorders													
Anaemia	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	1 (11.11%)	0 (0.00 %)	2 (33.33 %)	2 (33.33 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Iron deficiency anaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Leukocytosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lymph node pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thrombocytopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cardiac disorders													
Atrial fibrillation	0 (0.00 %)	0 (0.00 %)	0 (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 %)
Bradycardia	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 %)

Sinus tachycardia	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tachycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	2 (33.33 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear and labyrinth disorders													
Ear pain	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	1 (50.0 0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoacusis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Tinnitus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vertigo	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Endocrine disorders													
Hyperthyroidism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypothyroidism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eye disorders													
Diplopia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vision blurred	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 %)	0 (0.00 %)
Gastrointestinal disorders													
Abdominal distension	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.0 0%)	0 (0.00 %)	1 (20.0 0%)	2 (33.3 3%)	0 (0.00 %)

Abdominal pain	1 (33.33%)	0 (0.00%)	2 (33.33%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (40.00%)	1 (16.67%)	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 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain upper	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (16.67%)
Anal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal incontinence	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anorectal discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ascites	1 (33.33%)	1 (25.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (20.00%)	1 (16.67%)	0 (0.00%)
Constipation	1 (33.33%)	0 (0.00%)	1 (16.67%)	2 (22.22%)	1 (50.00%)	1 (16.67%)	3 (50.00%)	1 (16.67%)	2 (40.00%)	1 (16.67%)	2 (40.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	0 (0.00%)	1 (25.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (16.67%)	1 (16.67%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	2 (33.33%)
Dry mouth	0 (0.00%)	1 (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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspepsia	0 (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%)	1 (16.67%)	1 (16.67%)
Epigastric discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Flatulence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Frequent bowel movements	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrooesophageal reflux disease	1 (33.33%)	0 (0.00%)	1 (16.67%)	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%)

Haematochezia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haemorrhoids	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperaesthesia teeth	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Intestinal dilatation	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mouth ulceration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nausea	2 (66.67%)	0 (0.00 %)	4 (66.67%)	5 (55.56%)	0 (0.00 %)	1 (16.67 %)	3 (50.00 %)	2 (33.33 %)	3 (60.00%)	4 (66.67%)	5 (100.00%)	4 (66.67%)	1 (16.67%)
Obstruction gastric	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Proctalgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rectal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Stomatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tongue discolouration	0 (0.00 %)	1 (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 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tongue ulceration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vomiting	2 (66.67%)	1 (25.00%)	5 (83.33%)	4 (44.44%)	1 (50.00%)	1 (16.67 %)	2 (33.33 %)	1 (16.67 %)	1 (20.00%)	3 (50.00%)	4 (80.00%)	3 (50.00%)	2 (33.33%)
General disorders and administration site conditions													
Asthenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	1 (50.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	2 (40.00%)	3 (50.00%)	1 (20.00%)	1 (16.67%)	2 (33.33%)

Chest discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Chest pain	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Chills	0 (0.00 %)	1 (25.0 0%)	1 (16.6 7%)	1 (11.1 1%)	1 (50.0 0%)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Fatigue	1 (33.3 3%)	2 (50.0 0%)	1 (16.6 7%)	3 (33.3 3%)	0 (0.00 %)	2 (33.33 %)	2 (33.33 %)	1 (16.67 %)	1 (20.0 0%)	0 (0.00 %)	1 (20.0 0%)	1 (16.6 7%)	3 (50.0 0%)
Gait disturbance	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypothermia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Influenza like illness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infusion site reaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)
Localised oedema	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Malaise	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mucosal inflammation	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oedema peripheral	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (16.67 %)	2 (33.33 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Pain	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Peripheral swelling	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pyrexia	0 (0.00 %)	2 (50.0 0%)	2 (33.3 3%)	4 (44.4 4%)	1 (50.0 0%)	2 (33.33 %)	5 (83.33 %)	0 (0.00%)	2 (40.0 0%)	2 (33.3 3%)	1 (20.0 0%)	2 (33.3 3%)	3 (50.0 0%)
Hepatobiliary disorders													

Hepatic pain	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 %)	0 (0.00 %)
Hyperbilirubinaemia	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 %)	1 (16.67%)	0 (0.00 %)
Hypertransaminasaemia	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 %)	0 (0.00 %)
Jaundice	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)
Immune system disorders													
Cytokine release syndrome	0 (0.00 %)	1 (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 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Drug hypersensitivity	0 (0.00 %)	0 (0.00 %)	0 (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 %)
Infections and infestations													
Herpes virus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Histoplasmosis disseminated	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nasopharyngitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oral herpes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Otitis externa	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Perirectal abscess	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	1 (16.67%)	1 (20.00%)	0 (0.00 %)	1 (16.67%)

Tooth infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Upper respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Viral upper respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vulvovaginal candidiasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injury, poisoning and procedural complications													
Infusion related reaction	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Post procedural complication	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Post procedural haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Procedural pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Procedural pneumothorax	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tooth fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Investigations													

Activated partial thromboplastin time prolonged	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Alanine aminotransfera se increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (22.2 2%)	0 (0.00 %)	1 (16.67 %)	2 (33.33 %)	1 (16.67 %)	0 (0.00 %)	1 (16.6 7%)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)
Amylase increased	1 (33.3 3%)	0 (0.00 %)	1 (16.6 7%)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Aspartate aminotransfera se increased	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	3 (33.3 3%)	0 (0.00 %)	1 (16.67 %)	2 (33.33 %)	1 (16.67 %)	0 (0.00 %)	1 (16.6 7%)	1 (20.0 0%)	1 (16.6 7%)	0 (0.00 %)
Bilirubin conjugated increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood alkaline phosphatase increased	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	2 (33.3 3%)
Blood bilirubin increased	0 (0.00 %)	2 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood creatine phosphokinase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (33.3 3%)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)
Blood creatinine increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood lactate dehydrogenase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood thyroid stimulating hormone decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood thyroid stimulating	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)

hormone increased													
Creatinine renal clearance decreased	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Electrocardiogram QT prolonged	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gamma-glutamyltransferase increased	1 (33.33%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00%)	0 (0.00 %)	1 (16.67%)
International normalised ratio increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lipase increased	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	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 %)	1 (16.67%)
Lymphocyte count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
SARS-CoV-2 test negative	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Weight decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
White blood cell count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metabolism and nutrition disorders													
Abnormal loss of weight	0 (0.00 %)	0 (0.00 %)	0 (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 %)
Appetite disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	2 (33.33 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)

Cachexia	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Decreased appetite	0 (0.00 %)	3 (75.00%)	0 (0.00 %)	4 (44.44%)	0 (0.00 %)	1 (16.67 %)	2 (33.33 %)	1 (16.67 %)	3 (60.00%)	1 (16.67%)	2 (40.00%)	2 (33.33%)	1 (16.67%)
Dehydration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypercalcaemia	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 %)	1 (16.67%)
Hyperglycaemia	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 %)	0 (0.00 %)
Hyperkalaemia	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 %)
Hyperphosphataemia	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 %)	0 (0.00 %)
Hyperuricaemia	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypervolaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoalbuminaemia	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	1 (16.67 %)	1 (20.00%)	1 (16.67%)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)
Hypocalcaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypokalaemia	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.00%)	2 (33.33%)	0 (0.00 %)
Hypomagnesaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	1 (16.67 %)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyponatraemia	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	1 (16.67 %)	1 (20.00%)	0 (0.00 %)	1 (20.00%)	1 (16.67%)	0 (0.00 %)
Hypophosphataemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)
Lactic acidosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Malnutrition	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Type 1 diabetes mellitus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal and connective tissue disorders													
Arthralgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	3 (50.0 0%)
Back pain	1 (33.3 3%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	1 (50.0 0%)	0 (0.00%)	1 (16.67 %)	1 (16.67 %)	0 (0.00 %)	1 (16.6 7%)	1 (20.0 0%)	0 (0.00 %)	2 (33.3 3%)
Flank pain	1 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Muscle spasms	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Muscle twitching	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Muscular weakness	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal stiffness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Myalgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Myositis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neck pain	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.0 0%)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	1 (16.6 7%)

Pain in extremity	0 (0.00 %)	1 (25.0 0%)	2 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Spinal disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tendon pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)													
Cancer pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lymphangiosis carcinomatosa	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Metastases to central nervous system	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Paraneoplastic syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tumour obstruction	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 %)	0 (0.00 %)
Tumour pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	2 (33.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nervous system disorders													
Amnesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dizziness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	2 (33.3 3%)
Dizziness postural	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)

Dysarthria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysgeusia	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Headache	1 (33.33%)	3 (75.00%)	2 (33.33%)	9 (100.00%)	1 (50.00%)	2 (33.33 %)	4 (66.67 %)	5 (83.33 %)	3 (60.00%)	4 (66.67%)	2 (40.00%)	5 (83.33%)	4 (66.67%)
Hypoaesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)
Memory impairment	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Migraine	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neuralgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neuropathy peripheral	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Paraesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Peripheral sensory neuropathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Presyncope	0 (0.00 %)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Restless legs syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Subarachnoid haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tardive dyskinesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Taste disorder	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 %)

Psychiatric disorders													
Anxiety	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Delirium	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Depression	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hallucination, auditory	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Insomnia	1 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (33.3 3%)
Mental status changes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal and urinary disorders													
Acute kidney injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dysuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haematuria	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Hydronephrosis	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary incontinence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary tract obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)

Reproductive system and breast disorders													
Breast inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.67%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pelvic pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Penile pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Testicular oedema	0 (0.00 %)	1 (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 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Testicular pain	0 (0.00 %)	1 (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 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vaginal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Respiratory, thoracic and mediastinal disorders													
Aphonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Bronchial obstruction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	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 %)
Cough	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (22.22%)	1 (50.00%)	1 (16.67 %)	1 (16.67 %)	3 (50.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (50.00%)	0 (0.00 %)
Dysphonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (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 %)
Dyspnoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11%)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.67%)	1 (20.00%)	1 (16.67%)	0 (0.00 %)
Dyspnoea exertional	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Epistaxis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Haemoptysis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	1 (16.6 7%)
Hypoxia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lung opacity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Oropharyngeal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
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 %)	1 (16.6 7%)	0 (0.00 %)
Pneumonitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Productive cough	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Rhinorrhoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Wheezing	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin and subcutaneous tissue disorders													
Blister	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)
Dermatitis acneiform	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dry skin	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Erythema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperhidrosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)

Pruritus	0 (0.00 %)	1 (25.0 0%)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	1 (16.67 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)
Rash	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	2 (33.33 %)	1 (16.67 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Rash maculo-papular	1 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash pruritic	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (16.67 %)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urticaria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	1 (16.6 7%)
Vascular disorders													
Deep vein thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Embolism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Flushing	0 (0.00 %)	1 (25.0 0%)	1 (16.6 7%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hot flush	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypertension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)
Hypotension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.1 1%)	0 (0.00 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Dose escalation and expansion: NZV930+PDR001+NIR178

	NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 80 mg BID N = 7	**NZV930 200 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID N = 5**	**NZV930 400 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID N = 6**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 160 mg BID N = 6**	**NZV930 600 mg Q2W + PDR001 400 mg Q4W + NIR178 240 mg BID N = 6**	**NZV930 600mg Q2W (step-up) +PDR001 400mg Q4W +NIR178**	**All patients N = 127**

						240mg BID N = 27	
Arm/Group Description	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 80 mg BID	Dose escalation part. NZV930 200 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 400 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 160 mg BID	Dose escalation part. NZV930 600 mg Q2W in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	Dose escalation part and dose expansion part. NZV930 600 mg Q2W (step-up) in combination with spartalizumab 400 mg Q4W and NIR178 240 mg BID	All patients in the trial
Total # Affected by any Other Adverse Event	7	5	6	6	6	27	127
Total # at Risk by any Other Adverse Event	7	5	6	6	6	27	127
Blood and lymphatic system disorders							
Anaemia	1 (14.29%)	1 (20.00%)	1 (16.67%)	3 (50.00%)	0 (0.00%)	4 (14.81%)	17 (13.39%)
Iron deficiency anaemia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Leukocytosis	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (3.15%)
Lymph node pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Cardiac disorders							
Atrial fibrillation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Sinus tachycardia	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (3.15%)
Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	3 (2.36%)

Ear and labyrinth disorders							
Ear pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Hypoacusis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Tinnitus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (3.70%)	2 (1.57%)
Vertigo	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Endocrine disorders							
Hyperthyroidism	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Hypothyroidism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (3.70%)	2 (1.57%)
Eye disorders							
Diplopia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Vision blurred	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Gastrointestinal disorders							
Abdominal distension	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	8 (6.30%)
Abdominal pain	1 (14.29%)	0 (0.00%)	1 (16.67%)	3 (50.00%)	2 (33.33%)	7 (25.93%)	23 (18.11%)
Abdominal pain lower	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Abdominal pain upper	0 (0.00%)	0 (0.00%)	2 (33.33%)	1 (16.67%)	0 (0.00%)	1 (3.70%)	9 (7.09%)
Anal haemorrhage	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Anal incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Anorectal discomfort	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (5.51%)
Constipation	0 (0.00%)	1 (20.00%)	0 (0.00%)	2 (33.33%)	2 (33.33%)	8 (29.63%)	28 (22.05%)
Diarrhoea	0 (0.00%)	1 (20.00%)	2 (33.33%)	0 (0.00%)	1 (16.67%)	7 (25.93%)	20 (15.75%)
Dry mouth	1 (14.29%)	1 (20.00%)	2 (33.33%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	7 (5.51%)

Dyspepsia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	4 (3.15%)
Epigastric discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Flatulence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Frequent bowel movements	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Gastrooesophageal reflux disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	4 (3.15%)
Haematochezia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	2 (1.57%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Hyperaesthesia teeth	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (0.79%)
Intestinal dilatation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Mouth ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Nausea	2 (28.57%)	3 (60.00%)	2 (33.33%)	3 (50.00%)	2 (33.33%)	17 (62.96%)	63 (49.61%)
Obstruction gastric	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Proctalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	2 (1.57%)
Rectal haemorrhage	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Stomatitis	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Tongue discolouration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Tongue ulceration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Vomiting	4 (57.14%)	2 (40.00%)	2 (33.33%)	1 (16.67%)	4 (66.67%)	9 (33.33%)	52 (40.94%)
General disorders and administration site conditions							
Asthenia	2 (28.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	7 (25.93%)	23 (18.11%)
Chest discomfort	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	4 (3.15%)
Chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	5 (3.94%)
Chills	0 (0.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	3 (11.11%)	12 (9.45%)

Fatigue	2 (28.57%)	2 (40.00%)	2 (33.33%)	3 (50.00%)	2 (33.33%)	7 (25.93%)	36 (28.35%)
Gait disturbance	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	2 (1.57%)
Hypothermia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Influenza like illness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Infusion site reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Localised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Malaise	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	4 (3.15%)
Mucosal inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Oedema peripheral	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	1 (3.70%)	10 (7.87%)
Pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	2 (7.41%)	5 (3.94%)
Peripheral swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Pyrexia	2 (28.57%)	2 (40.00%)	1 (16.67%)	2 (33.33%)	1 (16.67%)	13 (48.15%)	47 (37.01%)
Hepatobiliary disorders							
Hepatic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Hyperbilirubinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	3 (2.36%)
Hypertransaminasaemia	1 (14.29%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (2.36%)
Jaundice	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Immune system disorders							
Cytokine release syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Drug hypersensitivity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Infections and infestations							
Herpes virus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Histoplasmosis disseminated	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)

Nasopharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Oral herpes	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	4 (3.15%)
Otitis externa	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Perirectal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	5 (3.94%)
Tooth infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Urinary tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (16.67%)	2 (7.41%)	7 (5.51%)
Viral upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Vulvovaginal candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Injury, poisoning and procedural complications							
Infusion related reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Post procedural complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Post procedural haemorrhage	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Procedural pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Procedural pneumothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Skin injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Tooth fracture	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Investigations							

Activated partial thromboplastin time prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Alanine aminotransferase increased	0 (0.00%)	1 (20.00%)	1 (16.67%)	1 (16.67%)	2 (33.33%)	6 (22.22%)	19 (14.96%)
Amylase increased	0 (0.00%)	1 (20.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	7 (5.51%)
Aspartate aminotransferase increased	0 (0.00%)	1 (20.00%)	2 (33.33%)	1 (16.67%)	3 (50.00%)	6 (22.22%)	24 (18.90%)
Bilirubin conjugated increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Blood alkaline phosphatase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (3.70%)	8 (6.30%)
Blood bilirubin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	6 (4.72%)
Blood creatine phosphokinase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	7 (5.51%)
Blood creatinine increased	0 (0.00%)	1 (20.00%)	1 (16.67%)	2 (33.33%)	0 (0.00%)	2 (7.41%)	8 (6.30%)
Blood lactate dehydrogenase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Blood thyroid stimulating hormone decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	2 (1.57%)
Blood thyroid stimulating hormone increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Creatinine renal clearance decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)

Electrocardiogram QT prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	2 (1.57%)
Gamma-glutamyltransferase increased	0 (0.00%)	1 (20.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	1 (3.70%)	9 (7.09%)
International normalised ratio increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Lipase increased	0 (0.00%)	1 (20.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	6 (4.72%)
Lymphocyte count decreased	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
SARS-CoV-2 test negative	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Weight decreased	0 (0.00%)	1 (20.00%)	1 (16.67%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	3 (2.36%)
White blood cell count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Metabolism and nutrition disorders							
Abnormal loss of weight	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Appetite disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (3.15%)
Cachexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Decreased appetite	1 (14.29%)	1 (20.00%)	0 (0.00%)	2 (33.33%)	1 (16.67%)	6 (22.22%)	31 (24.41%)
Dehydration	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	3 (2.36%)
Hypercalcaemia	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	4 (3.15%)
Hyperglycaemia	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	3 (2.36%)
Hyperkalaemia	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	3 (2.36%)
Hyperphosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Hyperuricaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Hypervolaemia	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Hypoalbuminaemia	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (5.51%)

Hypocalcaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	3 (2.36%)
Hypokalaemia	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	9 (7.09%)
Hypomagnesaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (11.11%)	8 (6.30%)
Hyponatraemia	1 (14.29%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	3 (11.11%)	13 (10.24%)
Hypophosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	2 (7.41%)	6 (4.72%)
Lactic acidosis	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Malnutrition	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Type 1 diabetes mellitus	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Musculoskeletal and connective tissue disorders							
Arthralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	2 (7.41%)	10 (7.87%)
Back pain	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (16.67%)	1 (16.67%)	4 (14.81%)	16 (12.60%)
Flank pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	4 (3.15%)
Muscle spasms	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (11.11%)	5 (3.94%)
Muscle twitching	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Muscular weakness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Musculoskeletal chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Musculoskeletal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	3 (2.36%)
Musculoskeletal stiffness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	2 (1.57%)
Myalgia	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (22.22%)	8 (6.30%)
Myositis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Neck pain	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	4 (14.81%)	11 (8.66%)
Pain in extremity	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	6 (4.72%)
Spinal disorder	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)

Tendon pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (0.79%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Cancer pain	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Lymphangiosis carcinomatosa	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Metastases to central nervous system	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Paraneoplastic syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Tumour obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Tumour pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (2.36%)
Nervous system disorders							
Amnesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Dizziness	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (16.67%)	4 (14.81%)	10 (7.87%)
Dizziness postural	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Dysarthria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (0.79%)
Dysgeusia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Headache	3 (42.86%)	4 (80.00%)	5 (83.33%)	4 (66.67%)	5 (83.33%)	21 (77.78%)	87 (68.50%)
Hypoaesthesia	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Memory impairment	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Migraine	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	2 (1.57%)
Neuralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Neuropathy peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Paraesthesia	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)

Peripheral sensory neuropathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (3.70%)	2 (1.57%)
Presyncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Restless legs syndrome	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Subarachnoid haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (0.79%)
Tardive dyskinesia	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Taste disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Psychiatric disorders							
Anxiety	2 (28.57%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	6 (4.72%)
Delirium	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Depression	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Hallucination, auditory	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Insomnia	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (16.67%)	1 (16.67%)	3 (11.11%)	10 (7.87%)
Mental status changes	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Renal and urinary disorders							
Acute kidney injury	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Dysuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (0.79%)
Haematuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	3 (2.36%)
Hydronephrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Renal failure	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Urinary incontinence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Urinary tract obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Reproductive system and breast disorders							
Breast inflammation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)

Pelvic pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Penile pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (0.79%)
Testicular oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Testicular pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Vaginal haemorrhage	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Respiratory, thoracic and mediastinal disorders							
Aphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Bronchial obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Cough	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	5 (18.52%)	18 (14.17%)
Dysphonia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	3 (2.36%)
Dyspnoea	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (11.11%)	9 (7.09%)
Dyspnoea exertional	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (2.36%)
Epistaxis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	2 (7.41%)	3 (2.36%)
Haemoptysis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (2.36%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Lung opacity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Oropharyngeal pain	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Pleural effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Pneumonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Productive cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	4 (3.15%)
Rhinorrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	4 (3.15%)
Wheezing	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Skin and subcutaneous tissue disorders							
Blister	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)

Dermatitis acneiform	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (0.79%)
Dry skin	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	3 (2.36%)
Erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Hyperhidrosis	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	3 (2.36%)
Pruritus	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.41%)	8 (6.30%)
Rash	1 (14.29%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	5 (18.52%)	13 (10.24%)
Rash maculo-papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (3.70%)	3 (2.36%)
Rash pruritic	0 (0.00%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Urticaria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Vascular disorders							
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.79%)
Embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Flushing	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (1.57%)
Hot flush	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	2 (1.57%)
Hypertension	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	4 (3.15%)
Hypotension	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	2 (1.57%)

Conclusion:

- This study enrolled predominantly heavily pretreated patients with advanced colorectal cancer. Minimal clinical benefit was observed with no objective responses in any patient enrolled across all treatment arms.
- Overall, results from this FIH study indicate an acceptable and manageable safety profile of NZV930 when administered with step-up dosing and with premedication to manage potential AEs of headache, pyrexia, nausea and vomiting upon first infusion. The RD from this study was determined to be NZV930 600 mg Q2W in combination with PDR001 400 mg

Q4W + NIR178 240 mg BID with step-up regimen. The FIH study results are supportive of further investigation of NZV930 in future studies.

Date of Clinical Trial Report

11-Oct-2023