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Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Taminadenant (NIR178) and spartalizumab (PDR001)

Trial Indication(s)

Advanced solid tumors and non-Hodgkin lymphoma

Protocol Number

CNIR178X2201

Protocol Title

A Phase 2, multi-center, open label study of NIR178 in combination with PDR001 in patients with selected advanced solid tumors and non-Hodgkin lymphoma

Clinical Trial Phase

Phase 2

Phase of Drug Development

Phase 2 (NIR178) and phase 3 (spartalizumab)

Study Start/End Dates

Study Start Date: August 28, 2017 (Actual)
Primary Completion Date: February 13, 2023 (Actual)
Study Completion Date: February 14, 2023 (Actual)

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Reason for Termination (If applicable)

Novartis decided to halt further recruitment of patients in the CNIR178X2201 study for business reasons. Importantly, this recruitment halt was not a consequence of any safety concern. The treatment of patients enrolled or consented continued according to the protocol. Due to enrollment halt, only one tumor group (TNBC) opened in Part 3 at the NIR178 160 mg BID dose level.

Study Design/Methodology

This is an open-label multi-part, phase II study evaluating the combination of NIR178 and PDR001 in patients with advanced solid tumors and diffuse large B cell lymphoma (DLBCL).

The study has three parts:

- Part 1: Multi-arm Bayesian adaptive signal finding design in solid tumors and diffuse large B cell lymphoma (DLBCL) with continuous dosing of NIR178 in combination with PDR001.
- Part 2: Exploration of continuous and intermittent NIR178 schedules in combination with PDR001 in patients with advanced non-small cell lung cancer (NSCLC).
- Part 3: Further evaluation of optimal intermittent or continuous schedule of NIR178 in combination with PDR001 (if selected based on results of Part 2). As of protocol amendment 6, Part 3 explored the safety and pharmacokinetics of the film-coated tablet (FCT) formulation of NIR178 continuous dosing in combination with PDR001 in triple negative breast cancer (TNBC) patients.

In addition, a separate safety run-in part was conducted in Japan in order to adequately characterize the safety and pharmacokinetic profiles of NIR178 as a single-agent and in combination with PDR001.

Centers

21 centers in 15 countries/regions: Singapore(1), Taiwan(1), Netherlands(1), Italy(2), Czech Republic(1), Belgium(1), Australia(1), Austria(1), Germany(2), Spain(1), Switzerland(1), United States(5), Japan(1), France(1), Argentina(1)

Objectives:

The primary objectives of the trial were:

- Part 1: To evaluate the efficacy of NIR178 and PDR001 combination in patients with selected advanced solid tumors and diffuse large B cell lymphoma (DLBCL)
- Part 2: To assess the efficacy of continuous and several intermittent dosing schedules of NIR178 in combination with PDR001 in non-small cell lung cancer (NSCLC)
- Part 3: To evaluate efficacy of intermittent or continuous dosing schedule of NIR178 in one or two selected tumor types

The secondary objectives were:

- To assess efficacy of NIR178+PDR001 in select advanced solid tumors and lymphoma
- To assess the safety and tolerability of the NIR178 and PDR001 combination using NIR178 hard gelatin capsule and FCT formulation
- To characterize changes in the immune infiltrate in tumor
- To characterize the pharmacokinetics (PK) of NIR178, its metabolite NJI765 and PDR001 in combination using hard gelatin capsule and FCT formulation
- To assess immunogenicity of PDR001
- Japanese Safety Run-in: To assess the preliminary safety, and PK of single agent NIR178 and in combination with PDR001 in Japanese patients

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

For this study, the investigational drugs were NIR178 and PDR001, and the study treatment was defined as NIR178 in combination with PDR001.

NIR178 160 mg was administered twice daily (BID) either continuously or based on the assigned intermittent schedule (2 weeks on/2 weeks off, 1 week on/1 week off). As of Protocol Amendment 5, all newly enrolled patients in Part 1 received NIR178 240 mg BID continuously after emerging data showed a relationship between NIR178 exposure and CD8 induction. NIR178 was administered orally as a capsule or as a film-coated tablet (Part 3 only) within 60 minutes prior to PDR001 infusion.

PDR001 400 mg was administered via intravenous (i.v.) infusion over 30 minutes once every 4 weeks (Q4W). Each treatment cycle was 28 days.

Patients enrolled in the Japanese safety run-in part received NIR178 80 mg or 160 mg continuously as single agent for the first cycle (28 days). If the patients completed Cycle 1 without experiencing dose limiting toxicities (DLTs), they initiated combination therapy with PDR001 starting Cycle 2 onwards, and continued at the same dose of NIR178. An additional cohort in the Japanese safety run-in part of the study received NIR178 240 mg in combination with PDR001 starting with Cycle 1. If the patients completed Cycle 1 without experiencing DLTs, they continued to receive combination treatment.

Patients received treatment with the combination until disease progression (assessed by investigator per immune-related response criteria (iRECIST) or Cheson 2014), unacceptable toxicity, death or discontinuation from study treatment for any other reason (e.g., withdrawal of consent, start of a new anti-neoplastic therapy or at the discretion of the investigator), otherwise known as End of Treatment.

Statistical Methods

Analysis supporting primary objective(s)

Part 1: This part constituted 13 treatment indications. All doses were given in combination with PDR001 400 mg Q4W. An adaptive Bayesian design was used to assess the activity of treatment in terms of overall response rate (ORR) within each and across treatment indications.

The efficacy data from the Non-head and neck squamous cell carcinoma (HNSCC) patients, microsatellite stable colorectal cancer (MSS CRC) patients with unknown RAS status and immune-oncology (IO) naïve melanoma patients were not included in the statistical model; however, that from any new treatment indications added to the existing 13 groups before the study closure that qualified the criteria for Part 1 was used to inform the model. ORR with 90% CI for each treatment indication was reported.

Part 2: Different schedules of NIR178 160 mg BID in combination with PDR001 among patients with NSCLC were evaluated for efficacy using ORR as the primary endpoint. ORR with 90% CI was provided for each schedule.

Part 3: Part 3 explored the efficacy of FCT formulation of NIR178 160 mg continuous dosing in combination with PDR001 among the TNBC patients. ORR with 90% CI was reported.

Analysis supporting secondary objectives(s)

Efficacy: The following efficacy endpoints per iRECIST were summarized for all the treatment indication groups that contributed to the analysis of primary efficacy objective: ORR is defined as the proportion of patients with best overall response (BOR) of immuno-related complete response (iCR) or immuno-related partial response (iPR), as per local review and according to iRECIST for solid tumors. ORR as per iRECIST was provided for each treatment indication along with corresponding 90% CI.

Disease control rate (DCR) is the proportion of patients with a best overall response (BOR) of complete response (CR), partial response (PR) or stable disease. DCR was summarized by tumor type with accompanying 90% CI.

Progression-free survival (PFS), overall survival (OS) and duration of response (DOR):

PFS refers to the time from treatment start date to the date of first documented disease progression or date of death, whichever happened first. If a patient had not had the event at the date of analysis cutoff, he/she was censored at the time of the adequate tumor assessment before the cut-off.

OS refers to the time from treatment start date to the date of death due to any cause. The patient was censored at the date of his/her last contact if not known to have died. The 2 years OS rate was the proportion of patients with at least 2 years of OS.

For patients with a confirmed CR or confirmed PR, the DOR is the time from date of first documented response (CR or PR) to date of first documented progression or date of death due to underlying cancer, whichever happened first. If progression or death had not occurred at the date of analysis cut-off, then the patient was censored at the date of his/her last adequate tumor assessment before the cut-off.

Kaplan-Meier (KM) plots and estimates for time-to-event endpoints including DOR, PFS and OS were presented for treatment groups of size ≥10 patients with estimable median.

For mCRPC patients, PCWG3 criteria were evaluated and prostate-specific antigen (PSA) at each time-point was listed and its change from baseline was summarized.

Safety: The safety set was used for summaries and listings of safety data. Adverse events (AEs) were coded using the MedDRA version 26.0 and assessed according to the common terminology criteria for adverse events (CTCAE) version 4.03, respectively.

Pharmacodynamic biomarkers: The on-treatment immunohistochemistry (IHC) expression changes in the immune infiltrate in tumors from baseline were assessed for immunological markers such as CD8. The full analysis set (FAS) was used for all biomarker analyses.

Pharmacokinetics: Descriptive statistics for PK parameters were presented using the pharmacokinetic analysis set (PAS). PK parameters of NIR178, NJI765 (NIR178 metabolite) and PDR001 for Japanese safety run-in study were reported separately.

Immunogenicity: Immunogenicity of PDR001 was assessed as secondary objective using the immunogenicity (IG) datasets and was reported by treatment groups.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

- Male or female patients ≥18 years of age. For Japan only: written consent is necessary both from the patient and his/her legal representative if he/she is under the age of 20 years.
- Histologically documented advanced or metastatic solid tumors or lymphomas.
  - Part 1: histologically confirmed renal cell carcinoma (RCC), pancreatic cancer, urothelial cancer, head and neck cancer, diffuse large B-cell lymphoma (DLBCL), microsatellite stable (MSS) colon cancer, triple negative breast cancer (TNBC), melanoma, metastatic castration resistant prostate cancer (mCRPC)
  - Part 2: histologically confirmed diagnosis of advanced/metastatic NSCLC. For those with mixed histology, there must be a predominant histology
  - Part 3: histologically confirmed diagnosis of selected advanced/metastatic malignancies. Part 3 will be opened to further assess TNBC patients with a PD-L1 SP-142 IC score of 0 (<1%). A second tumor group will be considered for Part 3 after completion of Part 1.
  - Safety run-in part in Japanese patients can enroll any tumor type included in part 1, 2 and 3.
- Patient (except for those participating in Japanese safety run-in) must have a site of disease amenable to biopsy, and be a candidate for tumor biopsy according to the treating institution's guidelines. Patient must be willing to undergo a new tumor biopsy at screening, and again during therapy on this study. The collection of recent sample is permitted under the following conditions (both must be met):
  - Biopsy was collected ≤ 6 months before 1st dose of study treatment and available at the site.
  - No immunotherapy was given to the patient since collection of biopsy.

- Part 1 - 3 only: Patients (other than those with DLBCL) must previously have received at least 1 and no more than 3 prior lines of therapy for their disease (with the exception of IO-pretreated cutaneous melanoma, HNSCC and RCC), unless considered inappropriate for the patient (e.g. safety concern, label contraindication):
  - Patients with NSCLC must have received a prior platinum-based combination.
  - Patients with EGFR positive NSCLC with a T790M mutation must have progressed on osimertinib or discontinued due to toxicity.
  - Patients with head and neck cancer must have received a prior platinum-containing regimen.
  - Patients with bladder cancer must have received a prior platinum-containing regimen or be ineligible for cisplatin.
  - Patients with renal cell carcinoma must have received a prior VEGF tyrosine kinase inhibitor (TKI).
  - Patients with MSS colorectal cancer must have received (or be intolerant to) prior therapy with fluoropyrimidine-oxaliplatin- and irinotecan- based regimens.
  - Patients with triple negative breast cancer:
    - Part 1: must have received a prior taxane-containing regimen
    - Part 3: should have received no more than 2 prior lines of therapy including taxane-based chemotherapy and should have a known PD-L1 status as per local available testing as determined by VENTANA PD-L1 SP142 Assay with IC score of 0 (<1%)
  - Patients with DLBCL:
    - Should be limited to those with no available therapies of proven clinical benefit
    - Should have had prior autologous hematopoietic stem cell transplantation (auto-HSCT) or determined to be ineligible for auto-HSCT.
  - Patients with melanoma:

- BRAF V600E wild type patients: must have received anti-PD-1/PD-L1 single agent, or in combination with anti-CTLA-4 therapy
- BRAF V600E mutant patients: must have received prior anti-PD-1/PD-L1 single-agent, or in combination with anti-CTLA-4 therapy. In addition, subjects must have received prior BRAF V600E inhibitor therapy, either single-agent or in combination with a MEK inhibitor

- Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC):
  - Of the 1-3 prior lines of therapy, patients must have received and failed at least one line of treatment after emergence of castration resistant disease

– Patients must not have received prior immunotherapy (previous immune checkpoint inhibitors; single agent and/or combination therapy with anti-CTLA-4, anti-PD-1, anti-PD-L1), except for NSCLC patients enrolled in part 3 and Japanese safety run-in part.

– Patients must have measurable disease, defined as at least one lesion that can be accurately measured in at least one dimension (longest diameter to be recorded for non-nodal lesions and short axis for nodal lesions) as >20 mm with conventional techniques or as >10 mm with spiral computer tomography (CT) scan, Magnetic Resonance Imaging (MRI), or calipers by clinical exam.

Exclusion Criteria:

– Ongoing or prior treatment with A2aR inhibitors. Patients previously treated with A2aR inhibitors for non-oncologic indications (e.g. Parkinson's disease) may be considered for enrollment on a case by case basis.

– Current or prior use of immunosuppressive medication within 28 days before the first dose of PDR001, with the exception of intranasal/inhaled corticosteroids or systemic corticosteroids at physiological doses (not exceeding equivalent of 10 mg/day of prednisone).

- History of another primary malignancy except for:
  - Malignancy treated with curative intent and with no known active disease ≥2 years before the first dose of study drug and of low potential risk for recurrence.
  - Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease.
  - Adequately treated carcinoma in situ without evidence of disease.
- Active or prior documented autoimmune disease within the past 2 years. Patients with vitiligo, Grave's disease, or psoriasis not requiring systemic treatment (within the past 2 years) are not excluded.
- More than 3 prior lines of therapy except for Japanese safety run-in part.
- History of interstitial lung disease or non-infectious pneumonitis.
- 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. GnRH therapy to maintain effective testosterone suppression levels is allowed for mCRPC patients.

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Participant Flow Table

Part 1:

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: H-N pre 240 mg	Part 1: MSS CRC wt 160 mg	Part 1: MSS CRC mu 160 mg	Part 1: MSS CRC unk 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma naïve 160 mg	Part 1: Melanoma pre 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with unknown RAS status	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had not been previously treated with immuno-oncology	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)

	therapy	therapy				treated with immuno-oncology therapy	immuno-oncology therapy	immuno-oncology therapy					therapy				
Started	11	12	11	14	14	15	11	12	27	29	2	30	3	13	13	6	15
Completed	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed*	11	12	11	14	14	15	11	12	27	29	2	30	3	13	13	6	15
Adverse Event	1	0	1	0	0	2	1	1	2	2	0	0	0	0	0	0	3
Death	0	0	0	0	0	1	0	3	1	2	0	1	0	1	0	0	0
Physician Decision	3	5	0	3	2	0	0	0	4	2	0	4	0	0	2	1	1
Progressive Disease	7	7	9	10	11	10	9	8	19	23	2	24	3	11	9	5	10
Patient/guardian Decision	0	0	1	1	1	2	1	0	1	0	0	1	0	1	2	0	1

*Treatment discontinued.

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Part 2, Part 3, Japan safety run-in and Total in the study:

	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont	Total
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in	
Started	22	20	20	6	3	3	3	315
Completed	0	0	0	0	0	0	0	0
Not Completed*	22	20	20	6	3	3	3	315
Adverse Event	1	2	1	0	0	0	0	17
Death	2	0	1	0	0	0	0	12
Physician Decision	2	1	3	0	0	0	0	33
Progressive Disease	14	13	14	6	3	3	3	233
Patient/guardian Decision	3	4	1	0	0	0	0	20

*Treatment discontinued.

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Baseline Characteristics

Part 1:

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: H-N pre 240 mg	Part 1: MSS CRC wt 160 mg	Part 1: MSS CRC mu 160 mg	Part 1: MSS CRC unk 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma naïve 160 mg	Part 1: Melanoma pre 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretre	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretre	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with unknown RAS status	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had not been previously treated with immuno-oncolo	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)

	oncology therapy	oncology therapy	therapy			previously treated with immuno-oncology therapy	ated with immuno-oncology therapy	ated with immuno-oncology therapy					gy therapy	therapy			
Number of Participants [units: participants]	11	12	11	14	14	15	11	12	27	29	2	30	3	13	13	6	15
Baseline Analysis Population Description																	
Age Continuous (units: years) Analysis Population Type: Participants Mean ± Standard Deviation																	
	65.5± 10.86	60.0± 11.96	60.6± 8.54	60.4± 8.98	66.9± 9.63	61.6± 7.13	59.4± 9.05	60.2± 7.07	56.5± 9.04	58.1± 11.21	46.0± 15.56	49.8± 10.81	50.3± 20.65	54.2± 14.87	55.0± 18.65	61.5± 13.10	68.3± 8.14
Sex: Female, Male (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)																	
Female	3	0	2	6	5	2	3	3	9	8	1	30	1	3	7	3	0
Male	8	12	9	8	9	13	8	9	18	21	1	0	2	10	6	3	15

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

White	9	3	10	13	5	14	9	12	20	23	2	21	1	13	7	0	13
Black or African American	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Asian	2	8	0	0	8	1	0	0	6	1	0	2	2	0	4	6	2
American Indian or Alaska Native	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Unknown	0	1	1	1	0	0	1	0	0	5	0	7	0	0	2	0	0

Part 2, Part 3, Japan safety run-in and Total in the study:

	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont	Total

Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in	
Number of Participants [units: participants]	22	20	20	6	3	3	3	315
Baseline Analysis Population Description								
Age Continuous (units: years) Analysis Population Type: Participants Mean ± Standard Deviation								
	65.0±9.02	61.8±9.51	64.2±8.94	58.5±16.16	61.3±10.69	57.0±9.54	44.3±8.33	59.5±11.59
Sex: Female, Male (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)								
Female	7	7	8	6	3	1	1	119
Male	15	13	12	0	0	2	2	196
Race/Ethnicity, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)								
White	10	7	7	1	0	0	0	200

Black or African American	0	0	0	0	3	3	3	10
Asian	11	13	12	0	0	0	0	78
American Indian or Alaska Native	0	0	0	0	0	0	0	1
Other	1	0	0	3	0	0	0	5
Unknown	0	0	1	2	0	0	0	21

Primary Outcome Result(s)

Part 1: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors

Description	ORR is the percentage of patients with a best overall response of complete response (CR) or partial response (PR), based on local investigator assessment per Response Evaluation Criteria for Solid Tumors (RECIST) v1.1. 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	Up to 3.9 years
Analysis Population Description	All patients from Part 1 who received at least 1 full or partial dose of assigned combination of study drugs and were included in the selected advanced solid tumors groups defined in the study protocol for efficacy assessment: RCC naïve 160 mg, RCC naïve 240 mg, RCC pre 240 mg, pancreatic 160 mg, urothelial 160 mg, H-N naïve 160 mg, H-N pre 160 mg, MSS CRC wt 160 mg, MSS CRC mu 160 mg, TNBC 160 mg, melanoma pre 160 mg and mCRPC 240 mg

	Part 1: RCC naïve 160 mg	**Part 1: RCC naïve 240 mg**	**Part 1: RCC pre 240 mg**	**Part 1: Pancreatic 160 mg**	**Part 1: Urothelial 160 mg**	**Part 1: H-N naïve 160 mg**	**Part 1: H-N pre 160 mg**	**Part 1: MSS CRC wt 160 mg**	**Part 1: MSS CRC mu 160 mg**	**Part 1: TNBC 160 mg**	**Part 1: Melanoma pre 160 mg**	**Part 1: mCRPC 240 mg**
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with	NIR178 240 mg twice daily continuous in combination with	NIR178 240 mg twice daily continuous in combination with	NIR178 160 mg twice daily continuous in combination with	NIR178 160 mg twice daily continuous in combination with	NIR178 160 mg twice daily continuous in combination with	NIR178 160 mg twice daily continuous in combination with	NIR178 160 mg twice daily continuous in combination with	NIR178 160 mg twice daily continuous in combination with	NIR178 160 mg twice daily continuous in combination with	NIR178 160 mg twice daily continuous in combination with	NIR178 240 mg twice daily continuous in combination with

	PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	PDR001 in patients with pancreatic cancer	PDR001 in patients with urothelial cancer	PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy	PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	PDR001 in patients with triple negative breast cancer (TNBC)	PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)
Number of Participants Analyzed [units: participants]	11	12	11	14	14	15	11	27	29	30	13	15
Part 1: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors (units: percentage of participants)	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**
	27.3 (7.9 to 56.4)	25.0 (7.2 to 52.7)	0 (0.0 to 23.8)	0 (0.0 to 19.3)	7.1 (0.4 to 29.7)	13.3 (2.4 to 36.3)	0 (0.0 to 23.8)	0 (0.0 to 10.5)	3.4 (0.2 to 15.3)	10.0 (2.8 to 23.9)	0 (0.0 to 20.6)	0 (0.0 to 18.1)

Part 1: Overall Response Rate (ORR) per Cheson 2014 for DLBCL

Description	ORR is the percentage of patients with a best overall response of complete response (CR) or partial response (PR), based on local investigator assessment per Cheson 2014 criteria for diffuse large B-cell lymphoma (DLBCL). For Cheson 2014 criteria, CR= Target nodes/nodal masses must regress to ≤1.5 cm in longest diameter (LDi), no extralymphatic sites of disease, absent non-measured lesions, organ enlargement regress to normal, no new lesions, and bone marrow normal by morphology (if indeterminate, immunohistochemistry negative); PR= ≥50% decrease in the sum of the product of the perpendicular diameters (SPD) of up to 6 target measurable nodes, absent or regressed non-measured lesions, spleen must have regressed by >50% in length beyond normal, and no new lesions.
Time Frame	Up to 2.5 years
Analysis Population Description	All patients from Part 1 who received at least 1 full or partial dose of assigned combination of study drugs and were included in the selected lymphoma group defined in the study protocol for efficacy assessment: DLBCL 160 mg

	Part 1: DLBCL 160 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)
Number of Participants Analyzed [units: participants]	13
Part 1: Overall Response Rate (ORR) per Cheson 2014 for DLBCL (units: percentage of participants)	**Number (90% Confidence Interval)**
	15.4 (2.8 to 41.0)

Part 2: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors

Description	ORR is the percentage of patients with a best overall response of complete response (CR) or partial response (PR), based on local investigator assessment per RECIST v1.1. 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	Up to 4.7 years

Analysis Population Description: All patients from Part 2 who were randomized to the study treatment dosing schedule.

	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)
Number of Participants Analyzed [units: participants]	22	20	20
Part 2: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors (units: percentage of participants)	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**
	9.1 (1.6 to 25.9)	0 (0.0 to 13.9)	10.0 (1.8 to 28.3)

Part 3: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors

Description: ORR is the percentage of patients with a best overall response of complete response (CR) or partial response (PR), based on local investigator assessment per RECIST v1.1. 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: Up to 0.5 years

Analysis Population Description: All patients from Part 3 who received at least 1 full or partial dose of assigned combination of study drugs.

	Part 3: TNBC 160 mg cont

Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	6
Part 3: Overall Response Rate (ORR) per RECIST v1.1 for solid tumors (units: percentage of participants)	**Number (90% Confidence Interval)**
	16.7 (0.9 to 58.2)

Secondary Outcome Result(s)

Part 1: Overall Response Rate (ORR) per iRECIST for solid tumors

Description	ORR is the percentage of patients with a best overall response of complete response (iCR) or partial response (iPR), based on local investigator assessment per immune-related RECIST (iRECIST).
Time Frame	Up to 3.9 years
Analysis Population Description	All patients from Part 1 who received at least 1 full or partial dose of assigned combination of study drugs and were included in the selected advanced solid tumors groups defined in the study protocol for efficacy assessment: RCC naïve 160 mg, RCC naïve 240 mg, RCC pre 240 mg, pancreatic 160 mg, urothelial 160 mg, H-N naïve 160 mg, H-N pre 160 mg, MSS CRC wt 160 mg, MSS CRC mu 160 mg, TNBC 160 mg, melanoma pre 160 mg and mCRPC 240 mg

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients	NIR178 240 mg twice daily continuous in combination with PDR001 in patients	NIR178 240 mg twice daily continuous in combination with PDR001 in patients	NIR178 160 mg twice daily continuous in combination with PDR001 in patients	NIR178 160 mg twice daily continuous in combination with PDR001 in patients	NIR178 160 mg twice daily continuous in combination with PDR001 in patients	NIR178 160 mg twice daily continuous in combination with PDR001 in patients	NIR178 160 mg twice daily continuous in combination with PDR001 in patients	NIR178 160 mg twice daily continuous in combination with PDR001 in patients	NIR178 160 mg twice daily continuous in combination with PDR001 in patients	NIR178 160 mg twice daily continuous in combination with PDR001 in patients	NIR178 240 mg twice daily continuous in combination with PDR001 in patients

	with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	with pancreatic cancer	with urothelial cancer	with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy	with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	with triple negative breast cancer (TNBC)	with cutaneous melanoma who had been pretreated with immuno-oncology therapy	with metastatic castration resistant prostate cancer (mCRPC)
Number of Participants Analyzed [units: participants]	11	12	11	14	14	15	11	27	29	30	13	15
Part 1: Overall Response Rate (ORR) per iRECIST for solid tumors (units: percentage of participants)	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**
	36.4 (13.5 to 65.0)	25.0 (7.2 to 52.7)	0 (0.0 to 23.8)	0 (0.0 to 19.3)	7.1 (0.4 to 29.7)	13.3 (2.4 to 36.3)	0 (0.0 to 23.8)	0 (0.0 to 10.5)	3.4 (0.2 to 15.3)	10.0 (2.8 to 23.9)	0 (0.0 to 20.6)	0 (0.0 to 18.1)

Part 2: Overall Response Rate (ORR) per iRECIST for solid tumors

Description	ORR is the percentage of patients with a best overall response of complete response (iCR) or partial response (iPR), based on local investigator assessment per immune-related RECIST (iRECIST).
Time Frame	Up to 4.7 years
Analysis Population Description	All patients from Part 2 who were randomized to the study treatment dosing schedule.

	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)
Number of Participants Analyzed [units: participants]	22	20	20
Part 2: Overall Response Rate (ORR) per iRECIST for solid tumors (units: percentage of participants)	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**
	9.1 (1.6 to 25.9)	5.0 (0.3 to 21.6)	15.0 (4.2 to 34.4)

Part 3: Overall Response Rate (ORR) per iRECIST for solid tumors

Description	ORR is the percentage of patients with a best overall response of complete response (iCR) or partial response (iPR), based on local investigator assessment per immune-related RECIST (iRECIST).
Time Frame	Up to 0.5 years
Analysis Population Description	All patients from Part 3 who received at least 1 full or partial dose of assigned combination of study drugs.

	Part 3: TNBC 160 mg cont
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	6
Part 3: Overall Response Rate (ORR) per iRECIST for solid tumors (units: percentage of participants)	**Number** **(90% Confidence Interval)**
	16.7 (0.9 to 58.2)

Part 1: Mean percentage change in PSA from baseline

Description	Prostate-specific antigen (PSA) levels were assessed in serum. Rising PSA is generally a manifestation of progression of prostate cancer.
Time Frame	Baseline, up to 0.8 years
Analysis Population Description	All patients from Part 1 who received at least 1 full or partial dose of assigned combination of study drugs and were included in the prostate cancer group defined in the study protocol for efficacy assessment: mCRPC 240 mg

	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)
Number of Participants Analyzed [units: participants]	15
Part 1: Mean percentage change in PSA from baseline (units: percentage change in PSA from baseline)	**Mean** **± Standard Deviation**
	214.46 ± 329.459

NOVARTIS

Part 1: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors

Description	DCR is the percentage of patients with a best overall response of complete response (CR), partial response (PR), stable disease (SD) or Non-CR or Non-progressive disease (NCRNPD), based on local investigator assessment per Response Evaluation Criteria for Solid Tumors (RECIST) v1.1.
Time Frame	Up to 3.9 years
Analysis Population Description	All patients from Part 1 who received at least 1 full or partial dose of assigned combination of study drugs and were included in the selected advanced solid tumors groups defined in the study protocol for efficacy assessment: RCC naïve 160 mg, RCC naïve 240 mg, RCC pre 240 mg, pancreatic 160 mg, urothelial 160 mg, H-N naïve 160 mg, H-N pre 160 mg, MSS CRC wt 160 mg, MSS CRC mu 160 mg, TNBC 160 mg, melanoma pre 160 mg and mCRPC 240 mg

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)

Number of Participants Analyzed [units: participants]	11	12	11	14	14	15	11	27	29	30	13	15
Part 1: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors (units: percentage of participants)	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**
	54.5 (27.1 to 80.0)	66.7 (39.1 to 87.7)	18.2 (3.3 to 47.0)	0 (0.0 to 19.3)	28.6 (10.4 to 54.0)	40.0 (19.1 to 64.0)	63.6 (35.0 to 86.5)	25.9 (12.9 to 43.2)	17.2 (7.0 to 32.9)	33.3 (19.3 to 49.9)	0 (0.0 to 20.6)	46.7 (24.4 to 70.0)

Part 1: Disease Control Rate (DCR) per iRECIST for solid tumors

Description	DCR is the percentage of patients with a best overall response of complete response (iCR), partial response (iPR), stable disease (iSD) or Non-iCR or Non-unconfirmed progressive disease (NON-iCR or NON-iUPD), based on local investigator assessment per immune-related RECIST (iRECIST).
Time Frame	Up to 3.9 years
Analysis Population Description	All patients from Part 1 who received at least 1 full or partial dose of assigned combination of study drugs and were included in the selected advanced solid tumors groups defined in the study protocol for efficacy assessment: RCC naïve 160 mg, RCC naïve 240 mg, RCC pre 240 mg, pancreatic 160 mg, urothelial 160 mg, H-N naïve 160 mg, H-N pre 160 mg, MSS CRC wt 160 mg, MSS CRC mu 160 mg, TNBC 160 mg, melanoma pre 160 mg and mCRPC 240 mg

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)
Number of Participants Analyzed [units: participants]	11	12	11	14	14	15	11	27	29	30	13	15
Part 1: Disease Control Rate (DCR) per iRECIST for solid	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**

tumors (units: percentage of participants)												
	63.6 (35.0 to 86.5)	66.7 (39.1 to 87.7)	18.2 (3.3 to 47.0)	0 (0.0 to 19.3)	35.7 (15.3 to 61.0)	40.0 (19.1 to 64.0)	54.5 (27.1 to 80.0)	25.9 (12.9 to 43.2)	13.8 (4.9 to 28.8)	36.7 (22.1 to 53.3)	0 (0.0 to 20.6)	46.7 (24.4 to 70.0)

Part 1: Disease Control Rate (DCR) per Cheson 2014 for DLBCL

Description	DCR is the percentage of patients with a best overall response of complete response (CR), partial response (PR) or stable disease (SD), based on local investigator assessment per Cheson 2014 criteria for diffuse large B-cell lymphoma (DLBCL).
Time Frame	Up to 2.5 years
Analysis Population Description	All patients from Part 1 who received at least 1 full or partial dose of assigned combination of study drugs and were included in the selected lymphoma group defined in the study protocol for efficacy assessment: DLBCL 160 mg

	Part 1: DLBCL 160 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)
Number of Participants Analyzed [units: participants]	13
Part 1: Disease Control Rate (DCR) per Cheson 2014 for DLBCL (units: percentage of participants)	**Number (90% Confidence Interval)**
	23.1 (6.6 to 49.5)

Part 2: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors

Description	DCR is the percentage of patients with a best overall response of complete response (CR), partial response (PR), stable disease (SD) or Non-CR or Non-progressive disease (NCRNPD), based on local investigator assessment per Response Evaluation Criteria for Solid Tumors (RECIST) v1.1.
Time Frame	Up to 4.7 years
Analysis Population Description	All patients from Part 2 who were randomized to the study treatment dosing schedule.

	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)
Number of Participants Analyzed [units: participants]	22	20	20
Part 2: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors (units: percentage of participants)	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**
	36.4 (19.6 to 56.1)	40.0 (21.7 to 60.6)	35.0 (17.7 to 55.8)

Part 2: Disease Control Rate (DCR) per iRECIST for solid tumors

Description	DCR is the percentage of patients with a best overall response of complete response (iCR), partial response (iPR), stable disease (iSD) or Non-iCR or Non-unconfirmed progressive disease (NON-iCR or NON-iUPD), based on local investigator assessment per immune-related RECIST (iRECIST).
Time Frame	Up to 4.7 years
Analysis Population Description	All patients from Part 2 who were randomized to the study treatment dosing schedule.

	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)
Number of Participants Analyzed [units: participants]	22	20	20
Part 2: Disease Control Rate (DCR) per iRECIST for solid tumors (units: percentage of participants)	**Number** **(90% Confidence Interval)**	**Number** **(90% Confidence Interval)**	**Number** **(90% Confidence Interval)**
	36.4 (19.6 to 56.1)	45.0 (25.9 to 65.3)	45.0 (25.9 to 65.3)

Part 3: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors

Description	DCR is the percentage of patients with a best overall response of complete response (CR), partial response (PR), stable disease (SD) or Non-CR or Non-progressive disease (NCRNPD), based on local investigator assessment per Response Evaluation Criteria for Solid Tumors (RECIST) v1.1.
Time Frame	Up to 0.5 years
Analysis Population Description	All patients from Part 3 who received at least 1 full or partial dose of assigned combination of study drugs.

	Part 3: TNBC 160 mg cont
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	6

Part 3: Disease Control Rate (DCR) per RECIST v1.1 for solid tumors (units: percentage of participants)	Number (90% Confidence Interval)
	16.7 (0.9 to 58.2)

Part 3: Disease Control Rate (DCR) per iRECIST for solid tumors

Description	DCR is the percentage of patients with a best overall response of complete response (iCR), partial response (iPR), stable disease (iSD) or Non-iCR or Non-unconfirmed progressive disease (NON-iCR or NON-iUPD), based on local investigator assessment per immune-related RECIST (iRECIST).
Time Frame	Up to 0.5 years
Analysis Population Description	All patients from Part 3 who received at least 1 full or partial dose of assigned combination of study drugs.

	Part 3: TNBC 160 mg cont
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	6
Part 3: Disease Control Rate (DCR) per iRECIST for solid tumors (units: percentage of participants)	**Number** **(90% Confidence Interval)**
	16.7 (0.9 to 58.2)

Part 1: Duration Of Response (DOR) per RECIST v1.1 for solid tumors

Description	DOR only applies to patients for whom best overall response is complete response (CR) or partial response (PR) based on local investigator assessment per RECIST v1.1. DOR is defined as the time from the date of first documented response (CR or PR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment. DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Time Frame	Up to 3.9 years

Analysis Population Description: All patients from Part 1 for whom best overall response was CR or PR and were included in the selected advanced solid tumors groups defined in the study protocol for efficacy assessment: RCC naïve 160 mg, RCC naïve 240 mg, RCC pre 240 mg, pancreatic 160 mg, urothelial 160 mg, H-N naïve 160 mg, H-N pre 160 mg, MSS CRC wt 160 mg, MSS CRC mu 160 mg, TNBC 160 mg, melanoma pre 160 mg and mCRPC 240 mg

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)
Number of Participants Analyzed [units: participants]	3	3	0	0	1	2	0	0	1	3	0	0

Part 1: Duration Of Response (DOR) per RECIST v1.1 for solid tumors (units: months)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)
	NA (NA to NA)[1]	NA (NA to NA)[1]			NA (NA to NA)[1]	NA (NA to NA)[1]			NA (NA to NA)[1]	NA (NA to NA)[1]		

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

Part 1: Duration Of Response (DOR) per iRECIST for solid tumors

Description	DOR only applies to patients for whom best overall response is complete response (iCR) or partial response (iPR) based on local investigator assessment per iRECIST. DOR is defined as the time from the date of first documented response (iCR or iPR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment. DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Time Frame	Up to 3.9 years
Analysis Population Description	All patients from Part 1 for whom best overall response was iCR or iPR and were included in the selected advanced solid tumors groups defined in the study protocol for efficacy assessment: RCC naïve 160 mg, RCC naïve 240 mg, RCC pre 240 mg, pancreatic 160 mg, urothelial 160 mg, H-N naïve 160 mg, H-N pre 160 mg, MSS CRC wt 160 mg, MSS CRC mu 160 mg, TNBC 160 mg, melanoma pre 160 mg and mCRPC 240 mg

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Arm/Group	NIR178 160 mg twice daily continuous	NIR178 240 mg twice daily continuous	NIR178 240 mg twice daily continuous	NIR178 160 mg twice daily continuous	NIR178 160 mg twice daily continuous	NIR178 160 mg twice daily continuous	NIR178 160 mg twice daily continuous	NIR178 160 mg twice daily continuous	NIR178 160 mg twice daily continuous	NIR178 160 mg twice daily continuous	NIR178 160 mg twice daily continuous	NIR178 240 mg twice daily continuous

Description	in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	in combination with PDR001 in patients with pancreatic cancer	in combination with PDR001 in patients with urothelial cancer	in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy	in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	in combination with PDR001 in patients with triple negative breast cancer (TNBC)	in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)
Number of Participants Analyzed [units: participants]	4	3	0	0	1	2	0	0	1	3	0	0
Part 1: Duration Of Response (DOR) per iRECIST for solid tumors (units: months)	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**
	NA (NA to NA)[1]	NA (NA to NA)[1]			NA (NA to NA)[1]	NA (NA to NA)[1]			NA (NA to NA)[1]	NA (NA to NA)[1]		

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

Part 1: Duration Of Response (DOR) per Cheson 2014 for DLBCL

Description	DOR only applies to patients for whom best overall response is complete response (CR) or partial response (PR) based on local investigator assessment per Cheson 2014 criteria for DLBCL. DOR is defined as the time from the date of first documented response (CR or PR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment. DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Time Frame	Up to 2.5 years
Analysis Population Description	All patients from Part 1 for whom best overall response was CR or PR and were included in the selected lymphoma group defined in the study protocol for efficacy assessment: DLBCL 160 mg

	Part 1: DLBCL 160 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)
Number of Participants Analyzed [units: participants]	2
Part 1: Duration Of Response (DOR) per Cheson 2014 for DLBCL (units: months)	**Median (90% Confidence Interval)**
	NA (NA to NA)[1]

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

Part 2: Duration Of Response (DOR) per RECIST v1.1 for solid tumors

Description	DOR only applies to patients for whom best overall response is complete response (CR) or partial response (PR) based on local investigator assessment per RECIST v1.1. DOR is defined as the time from the date of first documented response (CR or PR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment. DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Time Frame	Up to 4.7 years

Analysis Population Description	All patients from Part 2 for whom best overall response was CR or PR

	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)
Number of Participants Analyzed [units: participants]	2	0	2
Part 2: Duration Of Response (DOR) per RECIST v1.1 for solid tumors (units: months)	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**
	NA (NA to NA)[1]		NA (NA to NA)[1]

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

Part 2: Duration Of Response (DOR) per iRECIST for solid tumors

Description	DOR only applies to patients for whom best overall response is complete response (iCR) or partial response (iPR) based on local investigator assessment per iRECIST. DOR is defined as the time from the date of first documented response (iCR or iPR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment. DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Time Frame	Up to 4.7 years
Analysis Population Description	All patients from Part 2 for whom best overall response was iCR or iPR

	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off

Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)
Number of Participants Analyzed [units: participants]	2	1	3
Part 2: Duration Of Response (DOR) per iRECIST for solid tumors (units: months)	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**
	NA (NA to NA)[1]	NA (NA to NA)[1]	NA (NA to NA)[1]

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

Part 3: Duration Of Response (DOR) per RECIST v1.1 for solid tumors

Description	DOR only applies to patients for whom best overall response is complete response (CR) or partial response (PR) based on local investigator assessment per RECIST v1.1. DOR is defined as the time from the date of first documented response (CR or PR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment. DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Time Frame	Up to 0.5 years
Analysis Population Description	All patients from Part 3 for whom best overall response was CR or PR

	Part 3: TNBC 160 mg cont
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	1
Part 3: Duration Of Response (DOR) per RECIST v1.1 for solid tumors (units: months)	**Median (90% Confidence Interval)**

NA
(NA to NA)[1]

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

Part 3: Duration Of Response (DOR) per iRECIST for solid tumors

Description	DOR only applies to patients for whom best overall response is complete response (iCR) or partial response (iPR) based on local investigator assessment per iRECIST. DOR is defined as the time from the date of first documented response (iCR or iPR) to the date of first documented progression or death due to underlying cancer. If a patient did not have an event, DOR was censored at the date of last adequate tumor assessment. DOR was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Time Frame	Up to 0.5 years
Analysis Population Description	All patients from Part 3 for whom best overall response was iCR or iPR

	Part 3: TNBC 160 mg cont
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	1
Part 3: Duration Of Response (DOR) per iRECIST for solid tumors (units: months)	**Median (90% Confidence Interval)**
	NA (NA to NA)[1]

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

Part 1: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors

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, whichever happened first. 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 as defined in the statistical analysis plan.
Time Frame	Up to 3.9 years

Analysis Population Description: All patients from Part 1 who received at least 1 full or partial dose of assigned combination of study drugs and were included in the selected advanced solid tumors groups defined in the study protocol for efficacy assessment: RCC naïve 160 mg, RCC naïve 240 mg, RCC pre 240 mg, pancreatic 160 mg, urothelial 160 mg, H-N naïve 160 mg, H-N pre 160 mg, MSS CRC wt 160 mg, MSS CRC mu 160 mg, TNBC 160 mg, melanoma pre 160 mg and mCRPC 240 mg

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)
Number of Participants Analyzed [units: participants]	11	12	11	14	14	15	11	27	29	30	13	15

Part 1: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors (units: months)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)	Median (90% Confidence Interval)
	3.5 (1.9 to 15.4)	7.2 (1.8 to 8.6)	1.9 (1.7 to 2.0)	1.7 (1.6 to 1.7)	1.9 (1.7 to 3.5)	2.0 (1.6 to 3.7)	3.5 (1.7 to 3.7)	1.7 (1.6 to 1.9)	1.9 (1.7 to 2.0)	1.7 (1.6 to 1.9)	1.8 (1.6 to 1.9)	3.7 (1.7 to 5.3)

Part 1: Progression-Free Survival (PFS) per iRECIST for solid tumors

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, whichever happened first. 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 iRECIST. PFS was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Time Frame	Up to 3.9 years
Analysis Population Description	All patients from Part 1 who received at least 1 full or partial dose of assigned combination of study drugs and were included in the selected advanced solid tumors groups defined in the study protocol for efficacy assessment: RCC naïve 160 mg, RCC naïve 240 mg, RCC pre 240 mg, pancreatic 160 mg, urothelial 160 mg, H-N naïve 160 mg, H-N pre 160 mg, MSS CRC wt 160 mg, MSS CRC mu 160 mg, TNBC 160 mg, melanoma pre 160 mg and mCRPC 240 mg

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 160 mg twice daily continuo	NIR178 240 mg twice daily continuo	NIR178 240 mg twice daily continuo	NIR178 160 mg twice daily continuo	NIR178 160 mg twice daily continuo	NIR178 160 mg twice daily continuo	NIR178 160 mg twice daily continuo	NIR178 160 mg twice daily continuou	NIR178 160 mg twice daily continuou	NIR178 160 mg twice daily continuo	NIR178 160 mg twice daily continuo	NIR178 240 mg twice daily continuo

	us in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	us in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	us in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	us in combination with PDR001 in patients with pancreatic cancer	us in combination with PDR001 in patients with urothelial cancer	us in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy	us in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	s in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	s in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	us in combination with PDR001 in patients with triple negative breast cancer (TNBC)	us in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	us in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)
Number of Participants Analyzed [units: participants]	11	12	11	14	14	15	11	27	29	30	13	15
Part 1: Progression-Free Survival (PFS) per iRECIST for solid tumors (units: months)	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**

8.7 (2.1 to NA)[1]	7.2 (1.8 to NA)[1]	1.9 (1.7 to 2.0)	1.7 (1.1 to 1.7)	2.1 (1.7 to 3.5)	2.0 (1.6 to 3.7)	3.5 (1.7 to 3.7)	1.8 (1.6 to 2.0)	1.9 (1.7 to 2.0)	1.8 (1.6 to 3.5)	1.8 (1.6 to 1.9)	3.7 (1.7 to 5.3)

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

Part 1: Progression-Free Survival (PFS) per Cheson 2014 for DLBCL

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, whichever happened first. 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 Cheson 2014 for DLBCL. PFS was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Time Frame	Up to 2.5 years
Analysis Population Description	All patients from Part 1 who received at least 1 full or partial dose of assigned combination of study drugs and were included in the selected lymphoma group defined in the study protocol for efficacy assessment: DLBCL 160 mg

	Part 1: DLBCL 160 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)
Number of Participants Analyzed [units: participants]	13
Part 1: Progression-Free Survival (PFS) per Cheson 2014 for DLBCL (units: months)	**Median (90% Confidence Interval)**
	1.7 (1.4 to 2.2)

Part 2: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors

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, whichever happened first. 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 as defined in the statistical analysis plan.

Time Frame	Up to 4.7 years
Analysis Population Description	All patients from Part 2 who were randomized to the study treatment dosing schedule.

	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)
Number of Participants Analyzed [units: participants]	22	20	20
Part 2: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors (units: months)	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**
	2.0 (1.8 to 3.8)	2.1 (1.7 to 3.7)	1.9 (1.7 to 3.7)

Part 2: Progression-Free Survival (PFS) per iRECIST for solid tumors

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, whichever happened first. 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 iRECIST. PFS was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Time Frame	Up to 4.7 years
Analysis Population Description	All patients from Part 2 who were randomized to the study treatment dosing schedule.

	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)
Number of Participants Analyzed [units: participants]	22	20	20
Part 2: Progression-Free Survival (PFS) per iRECIST for solid tumors (units: months)	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**	**Median (90% Confidence Interval)**
	2.1 (1.8 to 3.8)	2.2 (1.8 to 3.7)	2.8 (1.7 to 9.0)

Part 3: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors

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, whichever happened first. 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 as defined in the statistical analysis plan.
Time Frame	Up to 0.5 years
Analysis Population Description	All patients from Part 3 who received at least 1 full or partial dose of assigned combination of study drugs.

	Part 3: TNBC 160 mg cont
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	6

Part 3: Progression-Free Survival (PFS) per RECIST v1.1 for solid tumors (units: months)	Median (90% Confidence Interval)
	1.6 (0.9 to 1.8)

Part 3: Progression-Free Survival (PFS) per iRECIST for solid tumors

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, whichever happened first. 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 iRECIST. PFS was analyzed using Kaplan-Meier estimates as defined in the statistical analysis plan.
Time Frame	Up to 0.5 years
Analysis Population Description	All patients from Part 3 who received at least 1 full or partial dose of assigned combination of study drugs.

	Part 3: TNBC 160 mg cont
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	6
Part 3: Progression-Free Survival (PFS) per iRECIST for solid tumors (units: months)	**Median (90% Confidence Interval)**
	1.6 (0.9 to 1.8)

Part 1: 2-year Overall Survival (OS)

Description	OS represents the percentage of participants who are alive after the start of study treatment. OS at 2 years was estimated using the Kaplan-Meier method as defined in the statistical analysis plan (SAP).
Time Frame	2 years

Analysis Population Description: All patients from Part 1 who received at least 1 full or partial dose of assigned combination of study drugs and were included in the selected cancer groups defined in the protocol for efficacy assessment: RCC naïve 160 mg, RCC naïve 240 mg, RCC pre 240 mg, pancreatic 160 mg, urothelial 160 mg, H-N naïve 160 mg, H-N pre 160 mg, MSS CRC wt 160 mg, MSS CRC mu 160 mg, TNBC 160 mg, melanoma pre 160 mg, DLBCL 160 mg and mCRPC 240 mg

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: DLBCL 160 mg	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncolog	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)

						y therapy							
Number of Participants Analyzed [units: participants]	11	12	11	14	14	15	11	27	29	30	13	13	15
Part 1: 2-year Overall Survival (OS) (units: percentage of participants)	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**
	63.6 (35.5 to 82.1)	42.1 (14.6 to 67.8)	27.3 (8.9 to 49.8)	NA (NA to NA)[1]	36.1 (15.0 to 57.9)	33.3 (15.0 to 52.9)	15.3 (1.9 to 41.2)	22.1 (9.4 to 38.2)	14.3 (4.3 to 29.9)	30.8 (16.0 to 46.9)	NA (NA to NA)[1]	23.1 (7.5 to 43.6)	31.4 (10.8 to 54.7)

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

Part 2: 2-year Overall Survival (OS)

Description	OS represents the percentage of participants who are alive after the start of study treatment. OS at 2 years was estimated using the Kaplan-Meier method as defined in the statistical analysis plan.
Time Frame	2 years
Analysis Population Description	All patients from Part 2 who were randomized to the study treatment dosing schedule.

	Part 2: NSCLC 160 mg cont	**Part 2: NSCLC 160 mg 2wk-on/2wk-off**	**Part 2: NSCLC 160 mg 1wk-on/1wk-off**

Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)
Number of Participants Analyzed [units: participants]	22	20	20
Part 2: 2-year Overall Survival (OS) (units: percentage of participants)	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**	**Number (90% Confidence Interval)**
	33.6 (15.5 to 52.9)	22.7 (7.5 to 42.7)	39.7 (20.3 to 58.6)

Part 3: 2-year Overall Survival (OS)

Description	OS represents the percentage of participants who are alive after the start of study treatment. OS at 2 years was estimated using the Kaplan-Meier method as defined in the statistical analysis plan.
Time Frame	2 years
Analysis Population Description	All patients from Part 3 who received at least 1 full or partial dose of assigned combination of study drugs.

	Part 3: TNBC 160 mg cont
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	6
Part 3: 2-year Overall Survival (OS) (units: percentage of participants)	**Number (90% Confidence Interval)**
	NA (NA to NA)[1]

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

NOVARTIS

Part 1: Change from baseline in CD8 percent marker area in tumor tissue

Description	The tumor expression of CD8 was measured by immunohistochemical (IHC) methods. Newly obtained pre- and on-treatment paired tumor samples were required and collected at screening and after approximately two cycles of therapy.
Time Frame	Screening and on-treatment (Cycle 2 Day 1 or Day 15). The duration of one cycle was 28 days.
Analysis Population Description	All patients from Part 1 who received any study drug, had paired tumor samples, had a valid assessment for the outcome measure and were included in the selected cancer groups defined in the protocol for efficacy assessment: RCC naïve 160 mg, RCC naïve 240 mg, RCC pre 240 mg, pancreatic 160 mg, urothelial 160 mg, H-N naïve 160 mg, H-N pre 160 mg, MSS CRC wt 160 mg, MSS CRC mu 160 mg, TNBC 160 mg, melanoma pre 160 mg, DLBCL 160 mg and mCRPC 240 mg

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve 240 mg	Part 1: RCC pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve 160 mg	Part 1: H-N pre 160 mg	Part 1: MSS CRC wt 160 mg	Part 1: MSS CRC mu 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma pre 160 mg	Part 1: DLBCL 160 mg	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had not been previously treated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS wildtype	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) with RAS mutant	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)

Number of Participants Analyzed [units: participants]	2	5	3	2	6	5	4	7	9	10	4	1	4
Part 1: Change from baseline in CD8 percent marker area in tumor tissue (units: CD8 percent marker area)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
	10.93 ± 14.227	10.53 ± 12.456	0.70 ± 2.645	-0.81 ± 0.537	0.96 ± 1.345	1.63 ± 2.372	-0.42 ± 1.477	0.70 ± 1.141	-0.01 ± 1.164	4.86 ± 3.751	0.16 ± 0.540	7.84	2.67 ± 4.156

Part 2: Change from baseline in CD8 percent marker area in tumor tissue

Description	The tumor expression of CD8 was measured by immunohistochemical (IHC) methods. Newly obtained pre- and on-treatment paired tumor samples were required and collected at screening and after approximately two cycles of therapy.
Time Frame	Screening and on-treatment (Cycle 2 Day 1 or Day 15). The duration of one cycle was 28 days.
Analysis Population Description	All patients from Part 2 who received any study drug, had paired tumor samples and had a valid assessment for the outcome measure

	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)
Number of Participants Analyzed [units: participants]	6	4	4
Part 2: Change from baseline in CD8 percent marker area in tumor tissue (units: CD8 percent marker area)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
	3.81 ± 4.551	-2.35 ± 5.586	1.23 ± 2.955

Part 3: Change from baseline in CD8 percent marker area in tumor tissue

Description	The tumor expression of CD8 was measured by immunohistochemical (IHC) methods. Newly obtained pre- and on-treatment paired tumor samples were required and collected at screening and after approximately two cycles of therapy.
Time Frame	Screening and on-treatment (Cycle 2 Day 1 or Day 15). The duration of one cycle was 28 days.
Analysis Population Description	All patients from Part 3 who received any study drug, had paired tumor samples and had a valid assessment for the outcome measure

	Part 3: TNBC 160 mg cont
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	1
Part 3: Change from baseline in CD8 percent marker area in tumor tissue (units: CD8 percent marker area)	**Mean ± Standard Deviation**
	0.26

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Part 1, 2 and 3: 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	Up to 4 years (Part 1), 4.8 years (Part 2) and 0.6 years (Part 3)
Analysis Population Description	All patients from Part 1, 2 and 3 who received at least 1 dose of NIR178 or PDR001. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status.

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve + pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve + pre 160 mg	Part 1: H-N pre 240 mg	Part 1: MSS CRC 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma naïve + pre 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont
Arm/ Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC), naïve and	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma, naïve and pretrea	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostat	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)

	been previously treated with immuno-oncology therapy	pretreated with immuno-oncology therapy			(HNSCC), naïve and pretreated with immuno-oncology therapy	(HNSCC) who had been pretreated with immuno-oncology therapy	CRC) and RAS wildtype, RAS mutant and RAS unknown status		ted with immuno-oncology therapy	(DLBCL)	(DLBCL)	e cancer (mCRPC)	(NSCLC)	(NSCLC)	(NSCLC)	
Number of Participants Analyzed [units: participants]	11	23	14	14	26	12	58	30	16	13	6	15	22	20	20	6
Part 1, 2 and 3: Number of participants with Adverse Events (AEs) and Serious Adverse Events	**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)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**

(SAEs) during the on-treatment period (units: participants)																
AEs	10 (90.91 %)	22 (95.65 %)	14 (100%)	14 (100%)	26 (100%)	12 (100%)	57 (98.28 %)	29 (96.67 %)	15 (93.75 %)	13 (100%)	5 (83.33 %)	14 (93.33 %)	22 (100%)	18 (90%)	18 (90%)	6 (100%)
Treatment-related AEs	7 (63.64 %)	16 (69.57 %)	9 (64.29 %)	9 (64.29 %)	16 (61.54 %)	9 (75%)	34 (58.62 %)	23 (76.67 %)	6 (37.5%)	11 (84.62 %)	2 (33.33 %)	12 (80%)	15 (68.18 %)	14 (70%)	9 (45%)	4 (66.67 %)
SAEs	3 (27.27 %)	7 (30.43 %)	9 (64.29 %)	7 (50%)	15 (57.69 %)	5 (41.67 %)	28 (48.28 %)	11 (36.67 %)	3 (18.75 %)	6 (46.15 %)	0 (%)	4 (26.67 %)	11 (50%)	7 (35%)	7 (35%)	3 (50%)
Treatment-related SAEs	0 (%)	2 (8.7%)	2 (14.29 %)	1 (7.14%)	3 (11.54 %)	2 (16.67 %)	7 (12.07 %)	2 (6.67%)	0 (%)	2 (15.38 %)	0 (%)	2 (13.33 %)	6 (27.27 %)	3 (15%)	0 (%)	0 (%)
Fatal SAEs	1 (9.09%)	0 (%)	1 (7.14%)	0 (%)	2 (7.69%)	1 (8.33%)	3 (5.17%)	1 (3.33%)	0 (%)	1 (7.69%)	0 (%)	0 (%)	1 (4.55%)	2 (10%)	0 (%)	0 (%)
Treatment-related fatal SAEs	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

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Part 1, 2 and 3: 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. Dose or schedule adjustments were permitted for patients who did not tolerate the protocol-specified dosing schedule.
Time Frame	Up to 3.9 years (Part 1), 4.7 years (Part 2) and 0.5 years (Part 3)
Analysis Population Description	All patients from Part 1, 2 and 3 who received at least 1 dose of NIR178 or PDR001. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status.

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve + pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve + pre 160 mg	Part 1: H-N pre 240 mg	Part 1: MSS CRC 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma naïve + pre 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg	Part 2: NSCLC 160 mg cont	Part 2: NSCLC 160 mg 2wk-on/2wk-off	Part 2: NSCLC 160 mg 1wk-on/1wk-off	Part 3: TNBC 160 mg cont
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC), naïve and pretreated with immun	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC), naïve and	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) and RAS wildtyp	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma, naïve and pretreated with immuno-	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)

	with immuno-oncology therapy	o-oncology therapy			pretreated with immuno-oncology therapy	pretreated with immuno-oncology therapy	e, RAS mutant and RAS unknown status		oncology therapy							
Number of Participants Analyzed [units: participants]	11	23	14	14	26	12	58	30	16	13	6	15	22	20	20	6
Part 1, 2 and 3: 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)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
At least one	2 (18.18%)	1 (4.35%)	0 (%)	2 (14.29%)	8 (30.77%)	1 (8.33%)	7 (12.07%)	3 (10%)	1 (6.25%)	1 (7.69%)	0 (%)	2 (13.33%)	2 (9.09%)	1 (5%)	1 (5%)	0 (%)

dose reduction																
At least one dose interruption	6 (54.55 %)	9 (39.13 %)	2 (14.29 %)	8 (57.14 %)	12 (46.15 %)	3 (25%)	20 (34.48 %)	9 (30%)	3 (18.75 %)	3 (23.08 %)	1 (16.67 %)	5 (33.33 %)	8 (36.36 %)	5 (25%)	4 (20%)	0 (%)

Part 1, 2 and 3: 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 or schedule adjustments were permitted for patients who did not tolerate the protocol-specified dosing schedule. Dose reductions were not permitted for PDR001.
Time Frame	Up to 3.9 years (Part 1), 4.7 years (Part 2) and 0.5 years (Part 3)
Analysis Population Description	All patients from Part 1, 2 and 3 who received at least 1 dose of NIR178 or PDR001. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status.

	Part 1: RCC naïve 160 mg	**Part 1: RCC naïve + pre 240 mg**	**Part 1: Pancreatic 160 mg**	**Part 1: Urothelial 160 mg**	**Part 1: H-N naïve + pre 160 mg**	**Part 1: H-N pre 240 mg**	**Part 1: MSS CRC 160 mg**	**Part 1: TNBC 160 mg**	**Part 1: Melanoma naïve + pre 160 mg**	**Part 1: DLBCL 160 mg**	**Part 1: DLBCL 240 mg**	**Part 1: mCRPC 240 mg**	**Part 2: NSCLC 160 mg cont**	**Part 2: NSCLC 160 mg 2wk-on/2wk-off**	**Part 2: NSCLC 160 mg 1wk-on/1wk-off**	**Part 3: TNBC 160 mg cont**
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR00	NIR178 240 mg twice daily continuous in combination with PDR00	NIR178 160 mg twice daily continuous in combination with PDR00	NIR178 160 mg twice daily continuous in combination with PDR00	NIR178 160 mg twice daily continuous in combination with PDR00	NIR178 240 mg twice daily continuous in combination with PDR00	NIR178 160 mg twice daily continuous in combination with PDR00	NIR178 160 mg twice daily continuous in combination with PDR00	NIR178 160 mg twice daily continuous in combination with PDR00	NIR178 160 mg twice daily continuous in combination with PDR00	NIR178 240 mg twice daily continuous in combination with PDR00	NIR178 240 mg twice daily continuous in combination with PDR00	NIR178 160 mg twice daily continuous in combination with PDR00	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination	NIR178 160 mg twice daily 1 week on/1 week off in combination	NIR178 160 mg twice daily continuous in combination with PDR00

	1 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	1 in patients with renal cell carcinoma (RCC), naïve and pretreated with immuno-oncology therapy	1 in patients with pancreatic cancer	1 in patients with urothelial cancer	1 in patients with squamous cell carcinoma of head and neck (HNSCC), naïve and pretreated with immuno-oncology therapy	1 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	1 in patients with microsatellite stable colorectal cancer (MSS CRC) and RAS wildtype, RAS mutant and RAS unknown status	1 in patients with triple negative breast cancer (TNBC)	1 in patients with cutaneous melanoma, naïve and pretreated with immuno-oncology therapy	1 in patients with diffuse large B-cell lymphoma (DLBCL)	1 in patients with diffuse large B-cell lymphoma (DLBCL)	1 in patients with metastatic castration resistant prostate cancer (mCRPC)	1 in patients with non-small cell lung cancer (NSCLC)	with PDR001 in patients with non-small cell lung cancer (NSCLC)	with PDR001 in patients with non-small cell lung cancer (NSCLC)	1 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	11	23	14	14	26	12	58	30	16	13	6	15	22	20	20	6
Part 1, 2 and 3: Number of participants with dose reductions and	**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)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**

dose interruptions of PDR001 (units: participants)																
At least one dose reduction	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
At least one dose interruption	6 (54.55 %)	7 (30.43 %)	1 (7.14%)	6 (42.86 %)	9 (34.62 %)	1 (8.33%)	13 (22.41 %)	8 (26.67 %)	2 (12.5%)	0 (%)	0 (%)	2 (13.33 %)	6 (27.27 %)	4 (20%)	2 (10%)	0 (%)

Part 1, 2 and 3: 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	Up to 3.9 years (Part 1), 4.7 years (Part 2) and 0.5 years (Part 3)
Analysis Population Description	All patients from Part 1, 2 and 3 who received at least 1 dose of NIR178 or PDR001. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status.

Part 1: RCC naïve 160 mg	**Part 1: RCC naïve + pre**	**Part 1: Pancreatic 160 mg**	**Part 1: Urothelial 160 mg**	**Part 1: H-N naïve + pre 160 mg**	**Part 1: H-N pre 240 mg**	**Part 1: MSS CRC 160 mg**	**Part 1: TNBC 160 mg**	**Part 1: Melanoma naïve + pre**	**Part 1: DLBCL 160 mg**	**Part 1: DLBCL 240 mg**	**Part 1: mCRPC 240 mg**	**Part 2: NSCLC 160 mg cont**	**Part 2: NSCLC 160 mg 2wk-**	**Part 2: NSCLC 160 mg 1wk-**	**Part 3: TNBC 160 mg cont**

		240 mg							160 mg						on/2wk-off	on/1wk-off	
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC), naïve and pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC), naïve and pretreated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) and RAS wildtype, RAS mutant and RAS unknown status	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma, naïve and pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units:	11	23	14	14	26	12	58	30	16	13	6	15	22	20	20	6

participants]																
Part 1, 2 and 3: Dose intensity of NIR178 (units: mg/day)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
	316.7 (187 to 320)	477.3 (321 to 480)	320.0 (241 to 320)	295.7 (140 to 320)	309.8 (141 to 320)	480.0 (272 to 480)	320.0 (134 to 320)	320.0 (179 to 320)	320.0 (208 to 320)	320.0 (233 to 320)	480.0 (363 to 480)	480.0 (382 to 496)	320.0 (137 to 320)	160.0 (96 to 173)	160.0 (71 to 189)	320.0 (319 to 320)

Part 1, 2 and 3: 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	Up to 3.9 years (Part 1), 4.7 years (Part 2) and 0.5 years (Part 3)
Analysis Population Description	All patients from Part 1, 2 and 3 who received at least 1 dose of NIR178 or PDR001. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status.

	Part 1: RCC naïve 160 mg	**Part 1: RCC naïve + pre 240 mg**	**Part 1: Pancreatic 160 mg**	**Part 1: Urothelial 160 mg**	**Part 1: H-N naïve + pre 160 mg**	**Part 1: H-N pre 240 mg**	**Part 1: MSS CRC 160 mg**	**Part 1: TNBC 160 mg**	**Part 1: Melanoma naïve + pre 160 mg**	**Part 1: DLBCL 160 mg**	**Part 1: DLBCL 240 mg**	**Part 1: mCRPC 240 mg**	**Part 2: NSCLC 160 mg cont**	**Part 2: NSCLC 160 mg 2wk-on/2wk-off**	**Part 2: NSCLC 160 mg 1wk-on/1wk-off**	**Part 3: TNBC 160 mg cont**
Arm/Group Description	NIR178 160 mg twice daily	NIR178 240 mg twice daily	NIR178 160 mg twice daily continu	NIR178 160 mg twice daily	NIR178 160 mg twice daily	NIR178 240 mg twice daily	NIR178 160 mg twice daily continu	NIR178 160 mg twice daily	NIR178 160 mg twice daily continu	NIR178 160 mg twice daily	NIR178 240 mg twice daily	NIR178 240 mg twice daily	NIR178 160 mg twice daily	NIR178 160 mg twice daily 2	NIR178 160 mg twice daily 1	NIR178 160 mg twice daily

	continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	continuous in combination with PDR001 in patients with renal cell carcinoma (RCC), naïve and pretreated with immuno-oncology therapy	ous in combination with PDR001 in patients with pancreatic cancer	continuous in combination with PDR001 in patients with urothelial cancer	continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC), naïve and pretreated with immuno-oncology therapy	continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	ous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) and RAS wildtype, RAS mutant and RAS unknown status	continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	ous in combination with PDR001 in patients with cutaneous melanoma, naïve and pretreated with immuno-oncology therapy	continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)	continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	weekson/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	11	23	14	14	26	12	58	30	16	13	6	15	22	20	20	6
Part 1, 2 and 3: Dose intensity of	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**

PDR001 (units: mg/28 days)	394.2 (300 to 400)	396.2 (267 to 431)	400.0 (395 to 400)	393.1 (350 to 400)	398.2 (319 to 402)	400.0 (365 to 407)	400.0 (236 to 405)	400.0 (305 to 404)	400.0 (389 to 406)	400.0 (386 to 400)	400.0 (400 to 400)	400.0 (378 to 404)	400.0 (224 to 406)	400.0 (300 to 401)	400.0 (387 to 410)	400.0 (400 to 400)

Part 1, 2 and 3: Number of participants with anti-PDR001 antibodies

Description	PDR001 immunogenicity was evaluated in serum samples. Patient anti-drug antibodies (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: ADA-negative sample at baseline and at least 1 post-baseline sample, all of which are ADA-negative samples • Treatment-reduced ADA-positive: ADA-positive sample at baseline and at least 1 post-baseline sample, all of which are ADA-negative samples • 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 • ADA-inconclusive: patient who does not qualify for any of the above definitions or a patient for which the baseline sample is missing
Time Frame	Up to approximately 5 years
Analysis Population Description	All patients from Part 1, 2 and 3 who received at least 1 dose of NIR178 or PDR001 and had a determinant baseline immunogenicity (IG) sample and at least 1 determinant post-baseline IG sample for assessing anti-PDR001 antibodies. For the safety endpoints, patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status.

	Part 1: RCC naïve 160 mg	**Part 1: RCC naïve + pre 240 mg**	**Part 1: Pancreatic 160 mg**	**Part 1: Urothelial 160 mg**	**Part 1: H-N naïve + pre 160 mg**	**Part 1: H-N pre 240 mg**	**Part 1: MSS CRC 160 mg**	**Part 1: TNBC 160 mg**	**Part 1: Melanoma naïve + pre 160 mg**	**Part 1: DLBCL 160 mg**	**Part 1: DLBCL 240 mg**	**Part 1: mCRPC 240 mg**	**Part 2: NSCLC 160 mg cont**	**Part 2: NSCLC 160 mg 2wk-on/2wk-off**	**Part 2: NSCLC 160 mg 1wk-on/1wk-off**	**Part 3: TNBC 160 mg cont**
Arm/ Group	NIR178 160 mg twice daily	NIR178 240 mg twice daily	NIR178 160 mg twice daily	NIR178 160 mg twice daily	NIR178 160 mg twice daily	NIR178 240 mg twice daily	NIR178 160 mg twice daily	NIR178 160 mg twice daily	NIR178 160 mg twice daily	NIR178 160 mg twice daily	NIR178 240 mg twice daily	NIR178 240 mg twice daily	NIR178 160 mg twice daily	NIR178 160 mg twice daily 2	NIR178 160 mg twice daily 1	NIR178 160 mg twice daily

Description	continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	continuous in combination with PDR001 in patients with renal cell carcinoma (RCC), naïve and pretreated with immuno-oncology therapy	continuous in combination with PDR001 in patients with pancreatic cancer	continuous in combination with PDR001 in patients with urothelial cancer	continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC), naïve and pretreated with immuno-oncology therapy	continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) and RAS wildtype, RAS mutant and RAS unknown status	continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	continuous in combination with PDR001 in patients with cutaneous melanoma, naïve and pretreated with immuno-oncology therapy	continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)	continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)
Number of Participants Analyzed [units: participants]	11	23	12	13	24	11	52	27	13	10	6	13	21	19	17	6
Part 1, 2 and 3: Number of partici	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**	**Count of Participants (Perc**

pants with anti-PDR001 antibodies (units: participants)	entage)	entage)	entage)	entage)	entage)	entage)	entage)	entage)	entage)	entage)	entage)	entage)	entage)	entage)	entage)	entage)
ADA-negative at baseline	11 (100%)	23 (100%)	12 (100%)	13 (100%)	24 (100%)	11 (100%)	49 (94.23%)	27 (100%)	13 (100%)	10 (100%)	6 (100%)	13 (100%)	21 (100%)	19 (100%)	17 (100%)	6 (100%)
ADA-positive at baseline	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	3 (5.77%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
ADA-negative post-baseline	10 (90.91%)	23 (100%)	11 (91.67%)	12 (92.31%)	22 (91.67%)	11 (100%)	48 (92.31%)	25 (92.59%)	13 (100%)	10 (100%)	6 (100%)	11 (84.62%)	21 (100%)	14 (73.68%)	14 (82.35%)	5 (83.33%)
Treatment-reduced ADA-positive	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (1.92%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Treatment-induced ADA-	1 (9.09%)	0 (%)	1 (8.33%)	1 (7.69%)	2 (8.33%)	0 (%)	1 (1.92%)	2 (7.41%)	0 (%)	0 (%)	0 (%)	2 (15.38%)	0 (%)	5 (26.32%)	3 (17.65%)	1 (16.67%)

positive																
Treatment-boosted ADA-positive	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
ADA-inconclusive	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (3.85%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Japan Safety Run-in: Number of participants with Dose-Limiting Toxicities (DLTs)

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, which occurs within the first 28 days of treatment with NIR178 as single agent or in combination with PDR001 during the Japan safety run-in part of the study. Other clinically significant toxicities may be considered to be DLTs, even if not CTCAE grade 3 or higher.
Time Frame	28 days
Analysis Population Description	All patients in the Japan safety run-in who either met the minimum exposure criterion defined in the protocol and had sufficient safety evaluations, or had experienced a DLT during Cycle 1.

	JSR: 80 mg cont	**JSR: 160 mg cont**	**JSR: 240 mg cont**
Arm/Group Description	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in
Number of Participants Analyzed [units: participants]	3	3	3
Japan Safety Run-in: Number of participants with Dose-Limiting Toxicities (DLTs) (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**

	0 (%)	0 (%)	0 (%)

Japan Safety Run-in: 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	Up to 0.7 years
Analysis Population Description	All patients from the Japan safety run-in who received at least 1 dose of NIR178 or PDR001.

	JSR: 80 mg cont	**JSR: 160 mg cont**	**JSR: 240 mg cont**
Arm/Group Description	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in
Number of Participants Analyzed [units: participants]	3	3	3
Japan Safety Run-in: Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) during the on-treatment period (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
AEs	3 (100%)	3 (100%)	3 (100%)
Treatment-related AEs	0 (%)	2 (66.67%)	1 (33.33%)
SAEs	2 (66.67%)	1 (33.33%)	1 (33.33%)

Treatment-related SAEs	0 (%)	1 (33.33%)	0 (%)
Fatal SAEs	0 (%)	0 (%)	0 (%)
Treatment-related fatal SAEs	0 (%)	0 (%)	0 (%)

All study parts: 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	Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received NIR178 and had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments, provided at least one PK parameter and did not vomit within 4 hours after dosing with NIR178. Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)	**NIR178 240 mg capsule in Non-Japanese (Part 1)**	**NIR178 160 mg tablet in Non-Japanese (Part 3)**	**JSR: 80 mg cont**	**JSR: 160 mg cont**	**JSR: 240 mg cont**
Arm/Group Description	Patients in Part 1 and 2 who received NIR178 160 mg as a capsule in combination with PDR001 400 mg every 4 weeks	Patients in Part 1 who received NIR178 240 mg as a capsule in combination with PDR001 400 mg every 4 weeks	Patients in Part 3 who received NIR178 160 mg as a film-coated tablet in combination with PDR001 400 mg every 4 weeks	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in
Number of Participants Analyzed [units: participants]	206	54	6	3	3	3
All study parts: Maximum observed plasma concentration (Cmax) of	**Geometric Mean (Geometric**	**Geometric Mean (Geometric**	**Geometric Mean (Geometric**	**Geometric Mean (Geometric**	**Geometric Mean (Geometric**	**Geometric Mean (Geometric**

NIR178 (units: ng/mL)	Coefficient of Variation)	Coefficient of Variation)	Coefficient of Variation)	Coefficient of Variation)	Coefficient of Variation)	Coefficient of Variation)
Cycle 1 Day 1 (all regimens) (n=206,54,6,3,3,3)	129 (335.0%)	160 (247.8%)	75.1 (382.3%)	81.8 (99.9%)	30.1 (32.9%)	234 (70.9%)
Cycle 1 Day 7 (1 wk-on/1 wk-off) (n=17,0,0,0,0,0)	576 (83.1%)					
Cycle 1 Day 14 (2 wk-on/2 wk-off) (n=11,0,0,0,0,0)	392 (212.7%)					
Cycle 1 Day 28 (continuous) (n=100,41,4,3,3,3)	297 (291.4%)	622 (154.3%)	723 (295.5%)	311 (91.5%)	167 (40.9%)	3760 (39.6%)

All study parts: Time to reach maximum plasma concentration (Tmax) of NIR178

Description	Pharmacokinetic (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	Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received NIR178 and had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments, provided at least one PK parameter and did not vomit within 4 hours after dosing with NIR178. Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)	NIR178 240 mg capsule in Non-Japanese (Part 1)	NIR178 160 mg tablet in Non-Japanese (Part 3)	JSR: 80 mg cont	JSR: 160 mg cont	JSR: 240 mg cont
Arm/Group Description	Patients in Part 1 and 2 who received NIR178 160 mg as a capsule in combination with	Patients in Part 1 who received NIR178 240 mg as a capsule in combination with PDR001 400 mg every 4 weeks	Patients in Part 3 who received NIR178 160 mg as a film-coated tablet in combination with	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in

	PDR001 400 mg every 4 weeks		PDR001 400 mg every 4 weeks	the Japan safety run-in	the Japan safety run-in	the Japan safety run-in
Number of Participants Analyzed [units: participants]	206	54	6	3	3	3
All study parts: Time to reach maximum plasma concentration (Tmax) of NIR178 (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 Day 1 (all regimens) (n=206,54,6,3,3,3)	2.00 (0.250 to 8.00)	2.13 (0.50 to 8.00)	1.50 (0.450 to 4.05)	1.50 (1.47 to 1.50)	1.50 (0.583 to 3.95)	3.00 (2.03 to 3.03)
Cycle 1 Day 7 (1 wk-on/1 wk-off) (n=17,0,0,0,0,0)	1.45 (0.50 to 4.00)					
Cycle 1 Day 14 (2 wk-on/2 wk-off) (n=11,0,0,0,0,0)	1.97 (0.550 to 7.67)					
Cycle 1 Day 28 (continuous) (n=100,41,4,3,3,3)	2.00 (0.267 to 8.00)	2.02 (0.250 to 7.60)	1.52 (0.50 to 3.00)	1.43 (0.50 to 1.48)	1.45 (0.50 to 1.50)	2.87 (1.92 to 4.00)

All study parts: Area under the plasma concentration-time curve from time zero to 12 hours post dose (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	Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received NIR178 and had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments, provided at least one PK parameter and did not vomit within 4 hours after dosing with NIR178. Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

	NIR178 160 mg capsule in Non-	**NIR178 240 mg capsule in Non-**	**NIR178 160 mg tablet in Non-**	**JSR: 80 mg cont**	**JSR: 160 mg cont**	**JSR: 240 mg cont**

	Japanese (Part 1 and 2)	Japanese (Part 1)	Japanese (Part 3)			
Arm/Group Description	Patients in Part 1 and 2 who received NIR178 160 mg as a capsule in combination with PDR001 400 mg every 4 weeks	Patients in Part 1 who received NIR178 240 mg as a capsule in combination with PDR001 400 mg every 4 weeks	Patients in Part 3 who received NIR178 160 mg as a film-coated tablet in combination with PDR001 400 mg every 4 weeks	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in
Number of Participants Analyzed [units: participants]	95	24	4	3	2	1
All study parts: Area under the plasma concentration-time curve from time zero to 12 hours post dose (AUC0-12hr) of NIR178 (units: hr*ng/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)**
Cycle 1 Day 1 (all regimens) (n=95,24,4,3,2,1)	295 (198.3%)	487 (126.3%)	232 (437.4%)	170 (124.9%)	63.3 (88.0%)	550
Cycle 1 Day 7 (1 wk-on/1 wk-off) (n=12,0,0,0,0,0)	1260 (63.2%)					
Cycle 1 Day 14 (2 wk-on/2 wk-off) (n=7,0,0,0,0,0)	1680 (94.4%)					
Cycle 1 Day 28 (continuous) (n=63,24,3,3,2,1)	918 (187.5%)	1620 (147.9%)	938 (412.2%)	697 (131.8%)	242 (13.5%)	12800

All study parts: Maximum observed plasma concentration (Cmax) of NJI765 (NIR178 metabolite)

Description: NJI765 is a NIR178 metabolite. PK parameters were calculated based on NJI765 plasma concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed plasma concentration following a dose.

Time Frame: Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days

Analysis Population Description: Patients in the pharmacokinetic analysis set (PAS) who received NIR178 and had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments, provided at least one PK parameter and did not vomit within 4 hours after dosing with NIR178. Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)	**NIR178 240 mg capsule in Non-Japanese (Part 1)**	**NIR178 160 mg tablet in Non-Japanese (Part 3)**	**JSR: 80 mg cont**	**JSR: 160 mg cont**	**JSR: 240 mg cont**
Arm/Group Description	Patients in Part 1 and 2 who received NIR178 160 mg as a capsule in combination with PDR001 400 mg every 4 weeks	Patients in Part 1 who received NIR178 240 mg as a capsule in combination with PDR001 400 mg every 4 weeks	Patients in Part 3 who received NIR178 160 mg as a film-coated tablet in combination with PDR001 400 mg every 4 weeks	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in
Number of Participants Analyzed [units: participants]	201	54	6	2	3	3
All study parts: Maximum observed plasma concentration (Cmax) of NJI765 (NIR178 metabolite) (units: ng/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)**
Cycle 1 Day 1 (all regimens) (n=201,54,6,0,3,3)	25.5 (85.2%)	33.7 (64.2%)	20.1 (99.2%)		25.9 (77.0%)	28.5 (99.9%)
Cycle 1 Day 7 (1 wk-on/1 wk-off) (n=17,0,0,0,0,0)	62.9 (39.4%)					
Cycle 1 Day 14 (2 wk-on/2 wk-off) (n=8,0,0,0,0,0)	71.3 (43.3%)					
Cycle 1 Day 28 (continuous) (n=96,40,4,2,3,3)	42.6 (82.2%)	77.3 (49.9%)	54.1 (102.4%)	45.6 (74.0%)	53.9 (64.2%)	111 (36.6%)

NOVARTIS

All study parts: Time to reach maximum plasma concentration (Tmax) of NJI765 (NIR178 metabolite)

Description	NJI765 is a NIR178 metabolite. Pharmacokinetic (PK) parameters were calculated based on NJI765 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	Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received NIR178 and had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments, provided at least one PK parameter and did not vomit within 4 hours after dosing with NIR178. Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)	**NIR178 240 mg capsule in Non-Japanese (Part 1)**	**NIR178 160 mg tablet in Non-Japanese (Part 3)**	**JSR: 80 mg cont**	**JSR: 160 mg cont**	**JSR: 240 mg cont**
Arm/Group Description	Patients in Part 1 and 2 who received NIR178 160 mg as a capsule in combination with PDR001 400 mg every 4 weeks	Patients in Part 1 who received NIR178 240 mg as a capsule in combination with PDR001 400 mg every 4 weeks	Patients in Part 3 who received NIR178 160 mg as a film-coated tablet in combination with PDR001 400 mg every 4 weeks	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in
Number of Participants Analyzed [units: participants]	201	54	6	2	3	3
All study parts: Time to reach maximum plasma concentration (Tmax) of NJI765 (NIR178 metabolite) (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 Day 1 (all regimens) (n=201,54,6,0,3,3)	2.00 (0.250 to 8.05)	2.08 (0.50 to 8.00)	2.10 (0.450 to 4.05)		1.95 (0.583 to 2.00)	3.00 (2.03 to 3.03)
Cycle 1 Day 7 (1 wk-on/1 wk-off) (n=17,0,0,0,0,0)	1.50 (0.50 to 4.00)					

Cycle 1 Day 14 (2 wk-on/2 wk-off) (n=8,0,0,0,0,0)	1.98 (0.550 to 3.00)					
Cycle 1 Day 28 (continuous) (n=96,40,4,2,3,3)	2.00 (0.483 to 8.03)	2.10 (0.250 to 7.88)	0.750 (0.50 to 2.03)	2.23 (1.43 to 3.02)	1.45 (0.50 to 1.50)	2.87 (1.92 to 4.00)

All study parts: Area under the plasma concentration-time curve from time zero to 12 hours post dose (AUC0-12hr) of NJI765 (NIR178 metabolite)

Description	NJI765 is a NIR178 metabolite. PK parameters were calculated based on NJI765 plasma concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUC0-12hr calculation.
Time Frame	Cycle 1 Day 1 (all), Cycle 1 Day 7 (1wk-on/1wk-off), Cycle 1 Day 14 (2wk-on/2wk-off) and Cycle 1 Day 28 (continuous dosing): pre-dose, 15 and 30 minutes, 1, 1.5, 2, 3, 4 and 8 hours after morning dose and 12 hours after evening dose. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received NIR178 and had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments, provided at least one PK parameter and did not vomit within 4 hours after dosing with NIR178. Patients from the same ethnicity (Non-Japanese, Japanese) treated with the same formulation (capsule, tablet) at the same NIR178 dose level are pooled together.

	NIR178 160 mg capsule in Non-Japanese (Part 1 and 2)	**NIR178 240 mg capsule in Non-Japanese (Part 1)**	**NIR178 160 mg tablet in Non-Japanese (Part 3)**	**JSR: 80 mg cont**	**JSR: 160 mg cont**	**JSR: 240 mg cont**
Arm/Group Description	Patients in Part 1 and 2 who received NIR178 160 mg as a capsule in combination with PDR001 400 mg every 4 weeks	Patients in Part 1 who received NIR178 240 mg as a capsule in combination with PDR001 400 mg every 4 weeks	Patients in Part 3 who received NIR178 160 mg as a film-coated tablet in combination with PDR001 400 mg every 4 weeks	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in
Number of Participants Analyzed [units: participants]	62	20	2	0	3	1
All study parts: Area under the plasma concentration-time curve from time zero to 12 hours post dose (AUC0-12hr)	**Geometric Mean (Geometric**	**Geometric Mean (Geometric**	**Geometric Mean (Geometric**	**Geometric Mean (Geometric**	**Geometric Mean (Geometric**	**Geometric Mean (Geometric**

of NJI765 (NIR178 metabolite) (units: hr*ng/mL)	**Coefficient of Variation)**	**Coefficient of Variation)**	**Coefficient of Variation)**	**Coefficient of Variation)**	**Coefficient of Variation)**	**Coefficient of Variation)**
Cycle 1 Day 1 (all regimens) (n=62,20,2,0,3,1)	98.2 (87.1%)	122 (75.6%)	77.1 (35.9%)		117 (68.2%)	119
Cycle 1 Day 7 (1 wk-on/1 wk-off) (n=8,0,0,0,0,0)	243 (57.5%)					
Cycle 1 Day 14 (2 wk-on/2 wk-off) (n=5,0,0,0,0,0)	288 (23.7%)					
Cycle 1 Day 28 (continuous) (n=41,16,2,0,2,1)	214 (76.6%)	382 (43.7%)	226 (147.0%)		277 (69.0%)	362

All study parts: Maximum observed serum concentration (Cmax) of PDR001

Description	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	First dose (Cycle 1 Day 1 or Cycle 2 Day 1 for Japanese patients treated with NIR178 80 or 160 mg) and Cycle 3 Day 1: pre-infusion, 1, 168, 336, 504 and 672 hours after end of infusion. Average duration of infusion=30 minutes. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received PDR001 and had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments, provided at least one PK parameter and did not vomit within 4 hours after dosing with NIR178. Patients from the same ethnicity (Non-Japanese, Japanese) treated at the same PDR001 dose level are pooled together.

	Non-Japanese patients	**Japanese patients**
Arm/Group Description	Patients in Parts 1, 2 and 3 who received NIR178 (any dose level) in combination with PDR001 400 mg every 4 weeks	Patients in the Japanese safety run-in part who received NIR178 (any dose level) in combination with PDR001 400 mg every 4 weeks
Number of Participants Analyzed [units: participants]	257	3
All study parts: Maximum observed serum concentration (Cmax) of PDR001 (units: µg/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
First dose (Cycle 1 Day 1 or Cycle 2 Day 1) (n=257,3)	93.2 (30.8%)	85.0 (12.8%)

Cycle 3 Day 1 (n=132,1)	126 (37.4%)	119

All study parts: 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	First dose (Cycle 1 Day 1 or Cycle 2 Day 1 for Japanese patients treated with NIR178 80 or 160 mg) and Cycle 3 Day 1: pre-infusion, 1, 168, 336, 504 and 672 hours after end of infusion. Average duration of infusion=30 minutes. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received PDR001 and had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments, provided at least one PK parameter and did not vomit within 4 hours after dosing with NIR178. Patients from the same ethnicity (Non-Japanese, Japanese) treated at the same PDR001 dose level are pooled together.

	Non-Japanese patients	**Japanese patients**
Arm/Group Description	Patients in Parts 1, 2 and 3 who received NIR178 (any dose level) in combination with PDR001 400 mg every 4 weeks	Patients in the Japanese safety run-in part who received NIR178 (any dose level) in combination with PDR001 400 mg every 4 weeks
Number of Participants Analyzed [units: participants]	257	3
All study parts: Time to reach maximum serum concentration (Tmax) of PDR001 (units: hours)	**Median (Full Range)**	**Median (Full Range)**
First dose (Cycle 1 Day 1 or Cycle 2 Day 1) (n=257,3)	1.50 (0.333 to 718)	1.50 (1.48 to 1.52)
Cycle 3 Day 1 (n=132,1)	1.50 (0.550 to 358)	1.65 (1.65 to 1.65)

All study parts: Area under the serum concentration-time curve from time zero to 28 days post dose (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	First dose (Cycle 1 Day 1 or Cycle 2 Day 1 for Japanese patients treated with NIR178 80 or 160 mg) and Cycle 3 Day 1: pre-infusion, 1, 168, 336, 504 and 672 hours after end of infusion. Average duration of infusion=30 minutes. 1 cycle=28 days
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received PDR001 and had an available value for the outcome measure at each timepoint. PAS consists of all patients who received one of the planned treatments, provided at least one PK parameter and did not vomit within 4 hours after dosing with NIR178. Patients from the same ethnicity (Non-Japanese, Japanese) treated at the same PDR001 dose level are pooled together.

	Non-Japanese patients	**Japanese patients**
Arm/Group Description	Patients in Parts 1, 2 and 3 who received NIR178 (any dose level) in combination with PDR001 400 mg every 4 weeks	Patients in the Japanese safety run-in part who received NIR178 (any dose level) in combination with PDR001 400 mg every 4 weeks
Number of Participants Analyzed [units: participants]	236	3
All study parts: Area under the serum concentration-time curve from time zero to 28 days post dose (AUC0-28day) of PDR001 (units: day*µg/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
First dose (Cycle 1 Day 1 or Cycle 2 Day 1) (n=236,3)	1140 (31.2%)	1110 (13.9%)
Cycle 3 Day 1 (n=36,0)	2030 (41.3%)	

Post-Hoc Outcome Result(s)

All-Collected Deaths

Description	On-treatment and post-treatment safety follow-up deaths were collected from first dose of study medication to 150 days after last dose of NIR178+PDR001. Survival follow-up deaths were collected from 151 days after last dose of NIR178+PDR001 until end of study. All deaths refer to the sum of on-treatment and post-treatment safety follow-up deaths plus survival follow-up deaths.
Time Frame	On-treatment and safety follow-up (FU) deaths: up to 4.3 years (Part 1), 5.1 years (Part 2), 0.9 years (Part 3) and 0.9 years (JSR). Survival FU deaths: up to 4.3 years (Part 1), 5.1 years (Part 2) and 0.9 years (Part 3) and 0.9 years (JSR)

Analysis Population Description	All patients who received at least one dose of study treatment. Patients at each study part with the same type of cancer who are treated at the same dose level and dosing schedule are pooled together, independently of the immune-oncology (IO) pretreatment status and RAS mutation status.

Part 1:

	Part 1: RCC naïve 160 mg	Part 1: RCC naïve + pre 240 mg	Part 1: Pancreatic 160 mg	Part 1: Urothelial 160 mg	Part 1: H-N naïve + pre 160 mg	Part 1: H-N pre 240 mg	Part 1: MSS CRC 160 mg	Part 1: TNBC 160 mg	Part 1: Melanoma naïve + pre 160 mg	Part 1: DLBCL 160 mg	Part 1: DLBCL 240 mg	Part 1: mCRPC 240 mg
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC), naïve and pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC), naïve and pretreated with immuno-oncology therapy	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) and RAS wildtype, RAS mutant and RAS unknown status	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma, naïve and pretreated with immuno-oncology therapy	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL)	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC)

Number of Participants Analyzed [units: participants]	11	23	14	14	26	12	58	30	16	13	6	15
All-Collected Deaths (units: participants)												
On-treatment and post-treatment safety follow-up deaths (n=11,23,14,14,26,12,58,30, 16,13,6,15)	4	6	10	6	8	4	22	9	7	9	2	2
Survival follow-up deaths (n=7,17,4,8,18,8,36,21,9,4,4, 13)	3	7	3	4	12	4	22	12	8	2	3	7
All deaths (n=11,23,14,14,26,12,58,30, 16,13,6,15)	7	13	13	10	20	8	44	21	15	11	5	9

Part 2, Part 3 and Japan safety run-in:

	Part 2: NSCLC 160 mg cont	**Part 2: NSCLC 160 mg 2wk-on/2wk-off**	**Part 2: NSCLC 160 mg 1wk-on/1wk-off**	**Part 3: TNBC 160 mg cont**	**JSR: 80 mg cont**	**JSR: 160 mg cont**	**JSR: 240 mg cont**
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan

				cancer (TNBC)	safety run-in	safety run-in	safety run-in
Number of Participants Analyzed [units: participants]	22	20	20	6	3	3	3
All-Collected Deaths (units: participants)							
On-treatment and post-treatment safety follow-up deaths (n=22,20,20,6,3,3,3)	6	4	6	4	2	0	1
Survival follow-up deaths (n=16,16,14,2,0,0,1)	8	9	7	1			1
All deaths (n=22,20,20,6,3,3,3)	14	13	13	5	2	0	2

Safety Results

Time Frame	On-treatment and post-treatment safety follow-up: from first dose of study treatment to 150 days after last dose of NIR178+PDR001, up to 4.3 years (Part 1), 5.1 years (Part 2), 0.9 years (Part 3) and 0.9 years (Japan safety run-in; JSR). Deaths in survival period: from 151 days after last dose of NIR178+PDR001 until end of study, up to 4.3 years (Part 1), 5.1 years (Part 2), 0.9 years (Part 3) and 0.9 years (JSR).
Additional Description	Deaths in the survival period are not considered Adverse Events (AEs). No AEs were collected in the survival period.
Source Vocabulary for Table Default	MedDRA (26.0)

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Collection Approach for Table Default Systematic Assessment

All-Cause Mortality

Part 1 – On-treatment and safety follow-up:

	Part 1: RCC naïve 160 mg N = 11	Part 1: RCC naïve + pre 240 mg N = 23	Part 1: Pancreatic 160 mg N = 14	Part 1: Urothelial 160 mg N = 14	Part 1: H-N naïve + pre 160 mg N = 26	Part 1: H-N pre 240 mg N = 12	Part 1: MSS CRC 160 mg N = 58	Part 1: TNBC 160 mg N = 30	Part 1: Melanoma naïve + pre 160 mg N = 16	Part 1: DLBCL 160 mg N = 13	Part 1: DLBCL 240 mg N = 6	Part 1: mCRPC 240 mg N = 15
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy. Safety data up to 150 days after last dose of	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC), naïve and pretreated with immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer. Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer. Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC), naïve and pretreated with immuno-oncology therapy. Safety data up to 150 days after last	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy. Safety data up to 150 days	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) and RAS wildtype, RAS mutant and RAS unknown status. Safety data up to 150 days	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma, naïve and pretreated with immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC). Safety data up to 150 days after last dose of NIR178+PDR001

	NIR178+PDR001				dose of NIR178+PDR001	after last dose of NIR178+PDR001	after last dose of NIR178+PDR001					
Total Number Affected	4	6	10	6	8	4	22	9	7	9	2	2
Total Number At Risk	11	23	14	14	26	12	58	30	16	13	6	15

Part 2, Part 3 and Japan safety run-in – On-treatment and safety follow-up:

	Part 2: NSCLC 160 mg cont N = 22	**Part 2: NSCLC 160 mg 2wk-on/2wk-off N = 20**	**Part 2: NSCLC 160 mg 1wk-on/1wk-off N = 20**	**Part 3: TNBC 160 mg cont N = 6**	**JSR: 80 mg cont N = 3**	**JSR: 160 mg cont N = 3**	**JSR: 240 mg cont N = 3**
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in. Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in. Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in. Safety data up to 150 days after last dose of NIR178+PDR001
Total Number Affected	6	4	6	4	2	0	1

Total Number At Risk	22	20	20	6	3	3	3

Part 1 – Survival period:

	Part 1: RCC naïve 160 mg_Survival period N = 7	**Part 1: RCC naïve + pre 240 mg_Survival period N = 17**	**Part 1: Pancreatic 160 mg_Survival period N = 4**	**Part 1: Urothelial 160 mg_Survival period N = 8**	**Part 1: H-N naïve + pre 160 mg_Survival period N = 18**	**Part 1: H-N pre 240 mg_Survival period N = 8**	**Part 1: MSS CRC 160 mg_Survival period N = 36**	**Part 1: TNBC 160 mg_Survival period N = 21**	**Part 1: Melanoma naïve + pre 160 mg_Survival period N = 9**	**Part 1: DLBCL 160 mg_Survival period N = 4**	**Part 1: DLBCL 240 mg_Survival period N = 4**	**Part 1: mCRPC 240 mg_Survival period N = 13**
Arm/ Group Description	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+ PDR001). No AEs were collected during this period.
Total Number Affected	3	7	3	4	12	4	22	12	8	2	3	7

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Total Number At Risk	7	17	4	8	18	8	36	21	9	4	4	13

Part 2, Part 3 and Japan safety run-in – Survival period:

	Part 2: NSCLC 160 mg cont_Survival period N = 16	**Part 2: NSCLC 160 mg 2wk-on/2wk-off_Survival period N = 16**	**Part 2: NSCLC 160 mg 1wk-on/1wk-off_Survival period N = 14**	**Part 3: TNBC 160 mg cont_Survival period N = 2**	**JSR: 80 mg cont_Survival period N = 0**	**JSR: 160 mg cont_Survival period N = 0**	**JSR: 240 mg cont_Survival period N = 1**
Arm/Group Description	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+PDR001). No AEs were collected during this period.	Deaths collected in the survival follow-up period (starting from Day 151 after last dose of NIR178+PDR001). No AEs were collected during this period.
Total Number Affected	8	9	7	1	0	0	1
Total Number At Risk	16	16	14	2	0	0	1

Serious Adverse Events

Time Frame	On-treatment and post-treatment safety follow-up: from first dose of study treatment to 150 days after last dose of NIR178+PDR001, up to 4.3 years (Part 1), 5.1 years (Part 2), 0.9 years (Part 3) and 0.9 years (Japan safety run-in; JSR). Deaths in survival period: from 151 days after last dose of NIR178+PDR001 until end of study, up to 4.3 years (Part 1), 5.1 years (Part 2), 0.9 years (Part 3) and 0.9 years (JSR).
Additional Description	Deaths in the survival period are not considered Adverse Events (AEs). No AEs were collected in the survival period.
Source Vocabulary for Table Default	MedDRA (26.0)
Collection Approach for Table Default	Systematic Assessment

Part 1:

	Part 1: RCC naïve 160 mg N = 11	**Part 1: RCC naïve + pre 240 mg N = 23**	**Part 1: Pancreatic 160 mg N = 14**	**Part 1: Urothelial 160 mg N = 14**	**Part 1: H-N naïve + pre 160 mg N = 26**	**Part 1: H-N pre 240 mg N = 12**	**Part 1: MSS CRC 160 mg N = 58**	**Part 1: TNBC 160 mg N = 30**	**Part 1: Melanoma naïve + pre 160 mg N = 16**	**Part 1: DLBCL 160 mg N = 13**	**Part 1: DLBCL 240 mg N = 6**	**Part 1: mCRPC 240 mg N = 15**
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC), naïve and pretreated with	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer. Safety data up to 150 days after last	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer. Safety data up to 150 days after last	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC),	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC)	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) and	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC). Safety data up to	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma, naïve and pretreated with	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL). Safety	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL). Safety	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC).

	treated with immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+PDR001	immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+PDR001	dose of NIR178+PDR001	dose of NIR178+PDR001	naïve and pretreated with immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+PDR001	who had been pretreated with immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+PDR001	RAS wildtype, RAS mutant and RAS unknown status. Safety data up to 150 days after last dose of NIR178+PDR001	150 days after last dose of NIR178+PDR001	immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+PDR001	data up to 150 days after last dose of NIR178+PDR001	data up to 150 days after last dose of NIR178+PDR001	Safety data up to 150 days after last dose of NIR178+PDR001
Total # Affected by any Serious Adverse Event	3	7	9	7	16	5	28	14	4	7	0	5
Total # at Risk by any Serious Adverse Event	11	23	14	14	26	12	58	30	16	13	6	15
Blood and lymphatic system disorders												
Anaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (6.67%)
Febrile neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	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%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Cardiac disorders												

Atrial tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Autoimmune myocarditis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Cardiac 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%)
Myocardial infarction	1 (9.09%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericardial effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Supraventricular tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endocrine disorders												
Adrenal insufficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperthyroidism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders												
Blindness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gaze palsy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders												

Abdominal pain	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colonic fistula	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Duodenal ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphagia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Ileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Large intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pancreatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Small intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper gastrointes	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

tinal haemorrhage												
Vomiting	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	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%)
Disease progression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Face oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
General physical health deterioration	1 (9.09%)	0 (0.00%)	2 (14.29%)	0 (0.00%)	2 (7.69%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (6.25%)	2 (15.38%)	0 (0.00%)	0 (0.00%)
Generalised oedema	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (6.90%)	1 (3.33%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Hepatobiliary disorders												

Autoimmune hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cholangitis	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	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	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic failure	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Hyperbilirubinaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (5.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune-mediated hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Liver 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%)	1 (6.67%)
Infections and infestations												
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cellulitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Encephalitis	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Enterocolitis infectious	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Herpes zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Large intestine infection	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peritonitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural 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%)
Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	3 (11.54%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia aspiration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Scrotal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Sepsis	0 (0.00%)	1 (4.35%)	1 (7.14%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urogenital infection bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Vascular device infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and												

procedural complications												
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Multiple injuries	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Overdose	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations												
Alanine aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Amylase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspartate aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood bilirubin increased	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (5.17%)	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%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Blood creatinine increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Electrocardiogram	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

QT prolonged												
General physical condition abnormal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Hepatic enzyme increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Troponin I increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Metabolism and nutrition disorders												
Decreased appetite	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperglycaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)
Hypokalaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	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 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Autoimmune myositis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Back pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flank pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in extremity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sacral pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	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%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metastases to central nervous system	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metastases to meninges	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Neoplasm 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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Pulmonary tumour thrombotic microangiopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Squamous cell carcinoma of the tongue	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour pain	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (1.72%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders												
Cerebral haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cerebral infarction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cerebrospinal fluid leakage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cerebrovascular accident	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (1.72%)	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 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seizure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal cord compression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	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%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nephrolithiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
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%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Reproductive system and breast disorders												
Female genital tract fistula	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peyronie's disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and												

mediastinal disorders												
Chronic obstructive pulmonary disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	1 (9.09%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (5.17%)	2 (6.67%)	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%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hydrothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Interstitial lung disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mediastinal disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders												

Erythema multiforme	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stevens-Johnson 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%)
Vascular disorders												
Aortic aneurysm	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Part 2, Part 3 and Japan safety run-in:

	Part 2: NSCLC 160 mg cont N = 22	**Part 2: NSCLC 160 mg 2wk-on/2wk-off N = 20**	**Part 2: NSCLC 160 mg 1wk-on/1wk-off N = 20**	**Part 3: TNBC 160 mg cont N = 6**	**JSR: 80 mg cont N = 3**	**JSR: 160 mg cont N = 3**	**JSR: 240 mg cont N = 3**
Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in. Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in. Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in. Safety data up to 150 days after last dose of NIR178+PDR001
Total # Affected by any Serious Adverse Event	11	9	7	3	2	1	1

Total # at Risk by any Serious Adverse Event	22	20	20	6	3	3	3
Blood and lymphatic system disorders							
Anaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Febrile neutropenia	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%)
Cardiac disorders							
Atrial tachycardia	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Autoimmune myocarditis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac failure	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myocardial infarction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericardial effusion	0 (0.00%)	1 (5.00%)	2 (10.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Supraventricular tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endocrine disorders							
Adrenal insufficiency	2 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperthyroidism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders							
Blindness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gaze palsy	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%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ascites	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Colonic fistula	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)
Diarrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Duodenal ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphagia	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%)
Intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Large intestinal obstruction	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%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Pancreatitis	0 (0.00%)	1 (5.00%)	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%)
Small intestinal obstruction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vomiting	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
General disorders and administration site conditions							
Chest pain	0 (0.00%)	0 (0.00%)	1 (5.00%)	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%)

Face oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General physical health deterioration	0 (0.00%)	1 (5.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Generalised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatobiliary disorders							
Autoimmune hepatitis	2 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cholangitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cholecystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatitis	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%)
Immune-mediated hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Liver disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations							
Bronchitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cellulitis	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Encephalitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Enterocolitis infectious	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes zoster	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Large intestine infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peritonitis	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural infection	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	2 (9.09%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia aspiration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Scrotal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sepsis	0 (0.00%)	0 (0.00%)	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%)
Urogenital infection bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular device infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications							
Fall	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Multiple injuries	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Overdose	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations							

Alanine aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Amylase increased	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspartate aminotransferase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood bilirubin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatine phosphokinase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatinine increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Electrocardiogram QT prolonged	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General physical condition abnormal	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic enzyme increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Troponin I increased	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							
Decreased appetite	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)
Hyperglycaemia	1 (4.55%)	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%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hypokalaemia	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	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%)	0 (0.00%)
Autoimmune myositis	0 (0.00%)	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone pain	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flank pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in extremity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sacral pain	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%)
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%)
Metastases to meninges	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasm progression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary tumour thrombotic microangiopathy	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Squamous cell carcinoma of the tongue	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Tumour haemorrhage	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%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders							
Cerebral haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cerebral infarction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cerebrospinal fluid leakage	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cerebrovascular accident	1 (4.55%)	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%)	0 (0.00%)
Paraesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seizure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal cord compression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders							
Acute kidney injury	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematuria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nephrolithiasis	0 (0.00%)	0 (0.00%)	1 (5.00%)	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%)
Reproductive system and breast disorders							
Female genital tract fistula	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peyronie's disease	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							
Chronic obstructive pulmonary disease	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Dyspnoea	2 (9.09%)	0 (0.00%)	1 (5.00%)	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%)
Hydrothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Interstitial lung disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mediastinal disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	1 (4.55%)	0 (0.00%)	3 (15.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumothorax	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary embolism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pulmonary haemorrhage	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Respiratory failure	0 (0.00%)	0 (0.00%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders							
Erythema multiforme	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stevens-Johnson syndrome	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders							

Aortic aneurysm	0 (0.00%)	0 (0.00%)	1 (5.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Other (Not Including Serious) Adverse Events

Time Frame	On-treatment and post-treatment safety follow-up: from first dose of study treatment to 150 days after last dose of NIR178+PDR001, up to 4.3 years (Part 1), 5.1 years (Part 2), 0.9 years (Part 3) and 0.9 years (Japan safety run-in; JSR). Deaths in survival period: from 151 days after last dose of NIR178+PDR001 until end of study, up to 4.3 years (Part 1), 5.1 years (Part 2), 0.9 years (Part 3) and 0.9 years (JSR).
Additional Description	Deaths in the survival period are not considered Adverse Events (AEs). No AEs were collected in the survival period.
Source Vocabulary for Table Default	MedDRA (26.0)
Collection Approach for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

Part 1:

	Part 1: RCC naïve 160 mg N = 11	**Part 1: RCC naïve + pre 240 mg N = 23**	**Part 1: Pancreatic 160 mg N = 14**	**Part 1: Urothelial 160 mg N = 14**	**Part 1: H-N naïve + pre 160 mg N = 26**	**Part 1: H-N pre 240 mg N = 12**	**Part 1: MSS CRC 160 mg N = 58**	**Part 1: TNBC 160 mg N = 30**	**Part 1: Melanoma naïve + pre 160 mg N = 16**	**Part 1: DLBCL 160 mg N = 13**	**Part 1: DLBCL 240 mg N = 6**	**Part 1: mCRPC 240 mg N = 15**

Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC) who had not been previously treated with immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+ PDR001	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with renal cell carcinoma (RCC), naïve and pretreated with immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+ PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with pancreatic cancer. Safety data up to 150 days after last dose of NIR178+ PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with urothelial cancer. Safety data up to 150 days after last dose of NIR178+ PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC), naïve and pretreated with immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+ PDR001	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with squamous cell carcinoma of head and neck (HNSCC) who had been pretreated with immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+ PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with microsatellite stable colorectal cancer (MSS CRC) and RAS wildtype, RAS mutant and RAS unknown status. Safety data up to 150 days after last dose of NIR178+ PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC). Safety data up to 150 days after last dose of NIR178+ PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with cutaneous melanoma, naïve and pretreated with immuno-oncology therapy. Safety data up to 150 days after last dose of NIR178+ PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL). Safety data up to 150 days after last dose of NIR178+ PDR001	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with diffuse large B-cell lymphoma (DLBCL). Safety data up to 150 days after last dose of NIR178+ PDR001	NIR178 240 mg twice daily continuous in combination with PDR001 in patients with metastatic castration resistant prostate cancer (mCRPC). Safety data up to 150 days after last dose of NIR178+ PDR001
Total # Affected by any Other Adverse Event	10	22	14	14	25	12	52	29	14	13	5	14
Total # at Risk by any Other Adverse Event	11	23	14	14	26	12	58	30	16	13	6	15
Blood and lymphatic system disorders												

Anaemia	0 (0.00%)	2 (8.70%)	3 (21.43%)	5 (35.71%)	5 (19.23%)	0 (0.00%)	5 (8.62%)	4 (13.33%)	3 (18.75%)	3 (23.08%)	1 (16.67%)	2 (13.33%)
Leukocytosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Lymphadenitis	0 (0.00%)	0 (0.00%)	0 (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%)
Neutropenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	3 (23.08%)	1 (16.67%)	0 (0.00%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	2 (15.38%)	0 (0.00%)	1 (6.67%)
Cardiac disorders												
Atrial fibrillation	1 (9.09%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Cardiac failure congestive	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Coronary artery disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Extrasystoles	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Palpitations	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericardial effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	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 bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	2 (15.38%)	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%)	1 (1.72%)	1 (3.33%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Ear and labyrinth disorders												
Vertigo	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	1 (8.33%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Endocrine disorders												
Adrenal insufficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperthyroidism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	2 (3.45%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Hypothyroidism	1 (9.09%)	0 (0.00%)	1 (7.14%)	1 (7.14%)	1 (3.85%)	0 (0.00%)	5 (8.62%)	3 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphocytic hypophysitis	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	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												
Cataract	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Photopsia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vision blurred	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders												
Abdominal discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Abdominal distension	0 (0.00%)	3 (13.04%)	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	3 (5.17%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Abdominal pain	1 (9.09%)	2 (8.70%)	4 (28.57%)	1 (7.14%)	3 (11.54%)	0 (0.00%)	9 (15.52%)	2 (6.67%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	2 (13.33%)
Abdominal pain upper	0 (0.00%)	1 (4.35%)	2 (14.29%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	6 (10.34%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Ascites	0 (0.00%)	2 (8.70%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (6.90%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	1 (9.09%)	7 (30.43%)	1 (7.14%)	2 (14.29%)	4 (15.38%)	1 (8.33%)	9 (15.52%)	2 (6.67%)	1 (6.25%)	3 (23.08%)	1 (16.67%)	2 (13.33%)
Dental caries	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Diarrhoea	1 (9.09%)	8 (34.78%)	0 (0.00%)	4 (28.57%)	4 (15.38%)	1 (8.33%)	12 (20.69%)	3 (10.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	3 (20.00%)
Dry mouth	1 (9.09%)	1 (4.35%)	1 (7.14%)	1 (7.14%)	1 (3.85%)	1 (8.33%)	2 (3.45%)	2 (6.67%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspepsia	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	4 (6.90%)	2 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Dysphagia	1 (9.09%)	0 (0.00%)	1 (7.14%)	1 (7.14%)	4 (15.38%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Faeces soft	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flatulence	1 (9.09%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	5 (19.23%)	1 (8.33%)	5 (8.62%)	1 (3.33%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (6.67%)
Gastrointestinal 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%)
Gastrooesophageal reflux disease	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	1 (6.25%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Haematochezia	0 (0.00%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)

Ileus	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	1 (9.09%)	5 (21.74%)	4 (28.57%)	5 (35.71%)	6 (23.08%)	2 (16.67%)	13 (22.41%)	9 (30.00%)	4 (25.00%)	2 (15.38%)	0 (0.00%)	5 (33.33%)
Retching	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Stomatitis	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (7.14%)	3 (11.54%)	0 (0.00%)	3 (5.17%)	1 (3.33%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Toothache	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	1 (16.67%)	0 (0.00%)
Vomiting	0 (0.00%)	2 (8.70%)	3 (21.43%)	3 (21.43%)	4 (15.38%)	0 (0.00%)	12 (20.69%)	5 (16.67%)	0 (0.00%)	2 (15.38%)	0 (0.00%)	0 (0.00%)
General disorders and administration site conditions												
Administration site bruise	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Asthenia	2 (18.18%)	5 (21.74%)	1 (7.14%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	3 (5.17%)	5 (16.67%)	4 (25.00%)	2 (15.38%)	0 (0.00%)	1 (6.67%)
Axillary pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	4 (13.33%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Chills	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	3 (11.54%)	0 (0.00%)	4 (6.90%)	2 (6.67%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
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%)	1 (7.69%)	0 (0.00%)	0 (0.00%)

Face oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (11.54%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	4 (36.36%)	5 (21.74%)	5 (35.71%)	2 (14.29%)	11 (42.31%)	3 (25.00%)	20 (34.48%)	10 (33.33%)	3 (18.75%)	1 (7.69%)	0 (0.00%)	4 (26.67%)
Feeling of body temperature change	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gait disturbance	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General physical health deterioration	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	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%)	2 (7.69%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malaise	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (5.17%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Non-cardiac chest pain	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	2 (18.18%)	2 (8.70%)	2 (14.29%)	3 (21.43%)	2 (7.69%)	0 (0.00%)	5 (8.62%)	2 (6.67%)	0 (0.00%)	2 (15.38%)	1 (16.67%)	1 (6.67%)
Pain	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	1 (9.09%)	2 (8.70%)	1 (7.14%)	4 (28.57%)	4 (15.38%)	0 (0.00%)	9 (15.52%)	9 (30.00%)	0 (0.00%)	4 (30.77%)	1 (16.67%)	2 (13.33%)
Swelling face	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatobiliary disorders												

Cholestasis	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Hepatic failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic steatosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
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%)	1 (6.67%)
Hypertransaminasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Immune-mediated hepatitis	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Infections and infestations												
Abdominal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Body tinea	0 (0.00%)	0 (0.00%)	0 (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%)
COVID-19	0 (0.00%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Device related 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%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Diarrhoea infectious	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Eye infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)

Gastroenteritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	2 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes zoster	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (6.25%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Nasopharyngitis	1 (9.09%)	0 (0.00%)	1 (7.14%)	1 (7.14%)	1 (3.85%)	0 (0.00%)	1 (1.72%)	1 (3.33%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oesophageal 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%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Oral candidiasis	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (7.14%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Pharyngitis	0 (0.00%)	0 (0.00%)	0 (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%)
Pneumonia	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	2 (7.69%)	0 (0.00%)	1 (1.72%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash pustular	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tinea versicolour	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Tonsillitis	0 (0.00%)	0 (0.00%)	0 (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%)
Tracheitis	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	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%)	2 (14.29%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	3 (10.00%)	0 (0.00%)	2 (15.38%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	2 (18.18%)	1 (4.35%)	2 (14.29%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	5 (8.62%)	2 (6.67%)	0 (0.00%)	1 (7.69%)	1 (16.67%)	2 (13.33%)

Urinary tract infection enterococcal	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urogenital infection bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Vaginal infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Viral infection	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications												
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Procedural pain	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound necrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Investigations												
Alanine aminotransferase increased	2 (18.18%)	2 (8.70%)	0 (0.00%)	2 (14.29%)	3 (11.54%)	1 (8.33%)	11 (18.97%)	9 (30.00%)	1 (6.25%)	0 (0.00%)	1 (16.67%)	3 (20.00%)
Amylase increased	1 (9.09%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (8.33%)	1 (1.72%)	2 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (26.67%)
Aspartate aminotransferase increased	2 (18.18%)	2 (8.70%)	1 (7.14%)	2 (14.29%)	3 (11.54%)	1 (8.33%)	14 (24.14%)	9 (30.00%)	1 (6.25%)	1 (7.69%)	0 (0.00%)	3 (20.00%)

Bilirubin conjugated increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood alkaline phosphatase increased	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	3 (5.17%)	3 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood bilirubin increased	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	4 (6.90%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Blood creatine phosphokinase increased	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (7.14%)	1 (3.85%)	1 (8.33%)	4 (6.90%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatinine increased	0 (0.00%)	1 (4.35%)	0 (0.00%)	3 (21.43%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	2 (12.50%)	2 (15.38%)	1 (16.67%)	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%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Blood phosphorus increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Blood thyroid stimulating hormone increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	2 (15.38%)	0 (0.00%)	0 (0.00%)
C-reactive protein increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (3.85%)	1 (8.33%)	2 (3.45%)	1 (3.33%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	2 (13.33%)
Electrocardiogram QT prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Eosinophil count increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (15.38%)	1 (16.67%)	1 (6.67%)
Gamma-glutamyltransf	1 (9.09%)	1 (4.35%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (8.33%)	6 (10.34%)	3 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

erase increased												
Haemoglobin decreased	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Human chorionic gonadotropin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
International normalised ratio increased	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	4 (6.90%)	1 (3.33%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	4 (26.67%)
Lymphocyte count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oxygen saturation decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Platelet count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
SARS-CoV-2 test negative	0 (0.00%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
SARS-CoV-2 test positive	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transaminases increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight decreased	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	2 (7.69%)	0 (0.00%)	2 (3.45%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders												
Cachexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)

Decreased appetite	1 (9.09%)	3 (13.04%)	7 (50.00%)	5 (35.71%)	6 (23.08%)	0 (0.00%)	17 (29.31%)	4 (13.33%)	2 (12.50%)	3 (23.08%)	0 (0.00%)	2 (13.33%)
Dehydration	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (5.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glucose tolerance impaired	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Hypercalcaemia	1 (9.09%)	3 (13.04%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperglycaemia	1 (9.09%)	0 (0.00%)	2 (14.29%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperkalaemia	0 (0.00%)	2 (8.70%)	0 (0.00%)	3 (21.43%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (6.67%)
Hyperlipasaemia	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperuricaemia	1 (9.09%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Hypoalbuminaemia	1 (9.09%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	1 (1.72%)	2 (6.67%)	1 (6.25%)	2 (15.38%)	0 (0.00%)	0 (0.00%)
Hypocalcaemia	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Hypokalaemia	0 (0.00%)	0 (0.00%)	3 (21.43%)	2 (14.29%)	1 (3.85%)	0 (0.00%)	4 (6.90%)	3 (10.00%)	0 (0.00%)	3 (23.08%)	0 (0.00%)	1 (6.67%)
Hypomagnesaemia	0 (0.00%)	1 (4.35%)	2 (14.29%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	1 (1.72%)	3 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	0 (0.00%)	1 (4.35%)	1 (7.14%)	2 (14.29%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (15.38%)	0 (0.00%)	0 (0.00%)
Hypophosphataemia	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	2 (7.69%)	0 (0.00%)	3 (5.17%)	1 (3.33%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (6.67%)
Iron deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Malnutrition	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Obesity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Tumour lysis 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%)	2 (15.38%)	0 (0.00%)	0 (0.00%)
Vitamin B12 deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Vitamin D deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders												
Amyotrophy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Arthralgia	3 (27.27%)	2 (8.70%)	3 (21.43%)	0 (0.00%)	4 (15.38%)	0 (0.00%)	9 (15.52%)	8 (26.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (13.33%)
Back pain	3 (27.27%)	5 (21.74%)	1 (7.14%)	3 (21.43%)	2 (7.69%)	0 (0.00%)	5 (8.62%)	4 (13.33%)	1 (6.25%)	0 (0.00%)	1 (16.67%)	3 (20.00%)
Bone pain	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Flank pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Fracture pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Groin pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (6.67%)
Joint 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%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Mobility decreased	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Muscle atrophy	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle spasms	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	1 (3.33%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (6.67%)
Muscular weakness	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	5 (8.62%)	1 (3.33%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal chest pain	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	3 (10.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Musculoskeletal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myalgia	1 (9.09%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	2 (16.67%)	4 (6.90%)	4 (13.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (20.00%)
Neck pain	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	3 (11.54%)	1 (8.33%)	1 (1.72%)	2 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteoarthritis	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in extremity	0 (0.00%)	0 (0.00%)	1 (7.14%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	3 (18.75%)	2 (15.38%)	0 (0.00%)	1 (6.67%)
Pain in jaw	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.69%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Trismus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.69%)	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)												
Hypergammaglobulinaemia benign monoclonal	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Neoplasm 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%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Seborrhoeic keratosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (3.85%)	1 (8.33%)	3 (5.17%)	2 (6.67%)	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%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anosmia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aphasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Autonomic nervous system imbalance	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Dizziness	0 (0.00%)	2 (8.70%)	5 (35.71%)	2 (14.29%)	1 (3.85%)	1 (8.33%)	1 (1.72%)	4 (13.33%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (6.67%)
Dysaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysgeusia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (3.85%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	1 (9.09%)	0 (0.00%)	2 (14.29%)	1 (7.14%)	1 (3.85%)	2 (16.67%)	3 (5.17%)	4 (13.33%)	1 (6.25%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Hypoaesthesia	1 (9.09%)	2 (8.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Neuropathy peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)

Paraesthesia	1 (9.09%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	3 (10.00%)	1 (6.25%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Peripheral sensory neuropathy	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Presyncope	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sciatica	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	1 (3.33%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seizure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Somnolence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Taste disorder	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tremor	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders												
Anxiety	0 (0.00%)	2 (8.70%)	1 (7.14%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	1 (1.72%)	3 (10.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Confusional state	0 (0.00%)	1 (4.35%)	1 (7.14%)	0 (0.00%)	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%)	1 (4.35%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (6.90%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Hallucination	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Insomnia	0 (0.00%)	3 (13.04%)	2 (14.29%)	2 (14.29%)	1 (3.85%)	0 (0.00%)	4 (6.90%)	1 (3.33%)	0 (0.00%)	2 (15.38%)	0 (0.00%)	2 (13.33%)
Mood altered	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Panic 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%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Restlessness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sleep disorder	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (6.67%)
Stress	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Azotaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bladder pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Chronic kidney disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Dysuria	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (6.67%)
Haematuria	1 (9.09%)	2 (8.70%)	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Leukocyturia	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nocturia	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Urethral 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 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary retention	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)

Reproductive system and breast disorders												
Balanoposthitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Benign prostatic hyperplasia	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Breast oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Breast pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intermenstrual bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pelvic pain	1 (9.09%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peyronie's disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vaginal discharge	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	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												
Cough	0 (0.00%)	2 (8.70%)	2 (14.29%)	4 (28.57%)	4 (15.38%)	0 (0.00%)	11 (18.97%)	10 (33.33%)	1 (6.25%)	2 (15.38%)	0 (0.00%)	2 (13.33%)
Dysphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	1 (9.09%)	1 (4.35%)	2 (14.29%)	4 (28.57%)	2 (7.69%)	1 (8.33%)	8 (13.79%)	6 (20.00%)	1 (6.25%)	2 (15.38%)	0 (0.00%)	1 (6.67%)
Dyspnoea exertional	1 (9.09%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (3.45%)	2 (6.67%)	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%)	2 (7.69%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Haemoptysis	0 (0.00%)	1 (4.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (6.25%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Nasal congestion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (3.85%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oropharyngeal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.69%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Pleural effusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (14.29%)	1 (3.85%)	0 (0.00%)	1 (1.72%)	1 (3.33%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Productive cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Rhinorrhoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	1 (16.67%)	0 (0.00%)
Sputum retention	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tonsillar erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)
Skin and subcutaneous tissue disorders												
Acne	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Alopecia	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Decubitus ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)

Dry skin	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.69%)	0 (0.00%)	3 (5.17%)	1 (3.33%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (6.67%)
Eczema	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Hyperhidrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	1 (6.25%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Hyperkeratosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intertrigo	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Night sweats	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palmar-plantar erythrodysaesthesia 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%)
Pemphigoid	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pruritus	3 (27.27%)	2 (8.70%)	0 (0.00%)	1 (7.14%)	2 (7.69%)	1 (8.33%)	8 (13.79%)	3 (10.00%)	2 (12.50%)	1 (7.69%)	0 (0.00%)	1 (6.67%)
Rash	2 (18.18%)	5 (21.74%)	0 (0.00%)	2 (14.29%)	3 (11.54%)	1 (8.33%)	3 (5.17%)	1 (3.33%)	1 (6.25%)	2 (15.38%)	0 (0.00%)	4 (26.67%)
Rash maculo-papular	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (14.29%)	1 (3.85%)	0 (0.00%)	2 (3.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Rash pruritic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Scar pain	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seborrhoeic dermatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Skin exfoliation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)

Skin lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitiligo	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders												
Angiopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Flushing	0 (0.00%)	1 (4.35%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Hot flush	1 (9.09%)	0 (0.00%)	1 (7.14%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)
Hypertension	0 (0.00%)	1 (4.35%)	0 (0.00%)	2 (14.29%)	1 (3.85%)	0 (0.00%)	2 (3.45%)	2 (6.67%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	2 (13.33%)
Hypotension	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (7.14%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Lymphoedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Raynaud's phenomenon	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Superficial vein thrombosis	0 (0.00%)	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Part 2, Part 3 and Japan safety run-in:

	Part 2: NSCLC 160 mg cont N = 22	Part 2: NSCLC 160 mg 2wk-on/2wk-off N = 20	Part 2: NSCLC 160 mg 1wk-on/1wk-off N = 20	Part 3: TNBC 160 mg cont N = 6	JSR: 80 mg cont N = 3	JSR: 160 mg cont N = 3	JSR: 240 mg cont N = 3

Arm/Group Description	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with non-small cell lung cancer (NSCLC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily 2 weeks on/2 weeks off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily 1 week on/1 week off in combination with PDR001 in patients with non-small cell lung cancer (NSCLC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 in patients with triple negative breast cancer (TNBC). Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 80 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in. Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 160 mg twice daily continuous in combination with PDR001 (starting Cycle 2 Day 1) in the Japan safety run-in. Safety data up to 150 days after last dose of NIR178+PDR001	NIR178 140 mg twice daily continuous in combination with PDR001 (starting Cycle 1 Day 1) in the Japan safety run-in. Safety data up to 150 days after last dose of NIR178+PDR001
Total # Affected by any Other Adverse Event	22	16	17	6	3	2	3
Total # at Risk by any Other Adverse Event	22	20	20	6	3	3	3
Blood and lymphatic system disorders							
Anaemia	1 (4.55%)	3 (15.00%)	3 (15.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukocytosis	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukopenia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphadenitis	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%)	1 (5.00%)	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%)
Cardiac disorders							
Atrial fibrillation	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bradycardia	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac failure congestive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Coronary artery disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Extrasystoles	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palpitations	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pericardial effusion	0 (0.00%)	1 (5.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus bradycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tachycardia	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	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Endocrine disorders							
Adrenal insufficiency	2 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperthyroidism	0 (0.00%)	1 (5.00%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypothyroidism	1 (4.55%)	0 (0.00%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphocytic hypophysitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders							
Cataract	2 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Photopsia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	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%)
Gastrointestinal disorders							
Abdominal discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal distension	2 (9.09%)	3 (15.00%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain	0 (0.00%)	1 (5.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain upper	2 (9.09%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Ascites	0 (0.00%)	1 (5.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	8 (36.36%)	3 (15.00%)	8 (40.00%)	2 (33.33%)	0 (0.00%)	1 (33.33%)	1 (33.33%)
Dental caries	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	4 (18.18%)	1 (5.00%)	2 (10.00%)	3 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry mouth	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspepsia	2 (9.09%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysphagia	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Faeces soft	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flatulence	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Gastrooesophageal reflux disease	0 (0.00%)	0 (0.00%)	2 (10.00%)	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%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	1 (5.00%)	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%)
Nausea	5 (22.73%)	3 (15.00%)	3 (15.00%)	4 (66.67%)	1 (33.33%)	0 (0.00%)	1 (33.33%)
Retching	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stomatitis	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Toothache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vomiting	5 (22.73%)	3 (15.00%)	4 (20.00%)	1 (16.67%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
General disorders and administration site conditions							
Administration site bruise	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Asthenia	2 (9.09%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Axillary pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Catheter site oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Chest discomfort	1 (4.55%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest pain	0 (0.00%)	1 (5.00%)	3 (15.00%)	1 (16.67%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Chills	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Face oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	11 (50.00%)	6 (30.00%)	5 (25.00%)	3 (50.00%)	1 (33.33%)	0 (0.00%)	1 (33.33%)
Feeling of body temperature change	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gait disturbance	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General physical health deterioration	0 (0.00%)	1 (5.00%)	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%)
Malaise	1 (4.55%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Non-cardiac chest pain	1 (4.55%)	1 (5.00%)	1 (5.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	1 (4.55%)	0 (0.00%)	4 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain	0 (0.00%)	4 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral swelling	0 (0.00%)	0 (0.00%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	2 (9.09%)	4 (20.00%)	1 (5.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Swelling face	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatobiliary disorders							
Cholestasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic steatosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatitis	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertransaminasaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Immune-mediated hepatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	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%)
Infections and infestations							
Abdominal abscess	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Body tinea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
COVID-19	1 (4.55%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Device related infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea infectious	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia sepsis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastroenteritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes zoster	1 (4.55%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infection	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Influenza	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasopharyngitis	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oesophageal candidiasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral candidiasis	0 (0.00%)	0 (0.00%)	1 (5.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	3 (13.64%)	0 (0.00%)	4 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash pustular	2 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tinea versicolour	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tonsillitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tracheitis	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	1 (4.55%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Urinary tract infection	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection enterococcal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urogenital infection bacterial	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vaginal infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications							
Fall	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Procedural pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Wound necrosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations							
Alanine aminotransferase increased	2 (9.09%)	4 (20.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Amylase increased	1 (4.55%)	1 (5.00%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aspartate aminotransferase increased	2 (9.09%)	4 (20.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	1 (33.33%)
Bilirubin conjugated increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood alkaline phosphatase increased	0 (0.00%)	3 (15.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Blood bilirubin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood creatine phosphokinase increased	0 (0.00%)	0 (0.00%)	1 (5.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Blood creatinine increased	1 (4.55%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood lactate dehydrogenase increased	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Blood phosphorus increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood thyroid stimulating hormone increased	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
C-reactive protein increased	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Electrocardiogram QT prolonged	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eosinophil count increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gamma-glutamyltransferase increased	0 (0.00%)	4 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemoglobin decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Human chorionic gonadotropin increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
International normalised ratio increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	0 (0.00%)	2 (10.00%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphocyte count decreased	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (66.67%)	0 (0.00%)	0 (0.00%)
Oxygen saturation decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Platelet count decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
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%)

SARS-CoV-2 test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Transaminases increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight decreased	2 (9.09%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders							
Cachexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Decreased appetite	6 (27.27%)	5 (25.00%)	3 (15.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (66.67%)
Dehydration	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Glucose tolerance impaired	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypercalcaemia	3 (13.64%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperglycaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperkalaemia	1 (4.55%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperlipasaemia	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%)
Hypoalbuminaemia	0 (0.00%)	0 (0.00%)	2 (10.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypocalcaemia	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypokalaemia	1 (4.55%)	3 (15.00%)	1 (5.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypomagnesaemia	1 (4.55%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	1 (4.55%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Hypophosphataemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Iron deficiency	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%)
Obesity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour lysis syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Vitamin B12 deficiency	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitamin D deficiency	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders							
Amyotrophy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Arthralgia	3 (13.64%)	3 (15.00%)	1 (5.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Back pain	3 (13.64%)	3 (15.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone pain	0 (0.00%)	1 (5.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flank pain	1 (4.55%)	1 (5.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fracture pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Groin pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Joint stiffness	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mobility decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle atrophy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle spasms	2 (9.09%)	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 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal chest pain	2 (9.09%)	1 (5.00%)	2 (10.00%)	0 (0.00%)	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%)	0 (0.00%)
Myalgia	1 (4.55%)	1 (5.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Neck pain	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Osteoarthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in extremity	2 (9.09%)	1 (5.00%)	2 (10.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain in jaw	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Trismus	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)							
Hypergammaglobulinaemia benign monoclonal	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasm progression	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seborrhoeic keratosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Tumour pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	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%)
Anosmia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Aphasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Autonomic nervous system imbalance	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dizziness	2 (9.09%)	1 (5.00%)	1 (5.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysaesthesia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dysgeusia	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	4 (18.18%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoaesthesia	1 (4.55%)	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%)	0 (0.00%)
Neuropathy peripheral	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%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral sensory neuropathy	1 (4.55%)	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sciatica	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Seizure	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Somnolence	0 (0.00%)	0 (0.00%)	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%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tremor	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%)	1 (5.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Confusional state	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Depression	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hallucination	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Insomnia	3 (13.64%)	3 (15.00%)	3 (15.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Mood altered	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Panic disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Restlessness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sleep disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Stress	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%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Azotaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bladder pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chronic kidney disease	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%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematuria	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukocyturia	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nocturia	2 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urethral pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Urinary retention	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Reproductive system and breast disorders							
Balanoposthitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Benign prostatic hyperplasia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Breast oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Breast pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intermenstrual bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Pelvic pain	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peyronie's disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vaginal discharge	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							
Cough	6 (27.27%)	2 (10.00%)	3 (15.00%)	0 (0.00%)	1 (33.33%)	1 (33.33%)	0 (0.00%)
Dysphonia	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	5 (22.73%)	1 (5.00%)	5 (25.00%)	1 (16.67%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Dyspnoea exertional	0 (0.00%)	2 (10.00%)	1 (5.00%)	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%)
Haemoptysis	1 (4.55%)	4 (20.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasal congestion	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oropharyngeal pain	1 (4.55%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pleural effusion	0 (0.00%)	0 (0.00%)	2 (10.00%)	1 (16.67%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Productive cough	2 (9.09%)	0 (0.00%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory failure	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinalgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinorrhoea	3 (13.64%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Sputum retention	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tonsillar erythema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders							
Acne	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Alopecia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Decubitus ulcer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry skin	2 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Eczema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperhidrosis	2 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperkeratosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Intertrigo	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Night sweats	1 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Palmar-plantar erythrodysaesthesia syndrome	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Pemphigoid	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pruritus	5 (22.73%)	2 (10.00%)	3 (15.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash	3 (13.64%)	2 (10.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rash maculo-papular	1 (4.55%)	0 (0.00%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)
Rash pruritic	0 (0.00%)	2 (10.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Scar pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Seborrhoeic dermatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin exfoliation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin lesion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitiligo	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Vascular disorders							
Angiopathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flushing	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haematoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hot flush	0 (0.00%)	1 (5.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypertension	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Hypotension	1 (4.55%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymphoedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Raynaud's phenomenon	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Superficial vein thrombosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Conclusion:

- The study successfully characterized the efficacy and safety of NIR178 160/240 mg BID (continuous or intermittent) in combination with PDR001 400 mg Q4W.
- None of the treated cancer types responded to treatment with clinically meaningful efficacy.
- NIR178 in combination with PDR001 was considered to have a tolerable and manageable safety profile. Available data confirmed the known safety profile of NIR178 and PDR001. No new safety concerns were identified.
- No evidence of additive toxic effects of the combinations was observed.
- AE data from patients enrolled in the Japanese safety run-in was consistent with the known safety profile of NIR178 in combination with PDR001 in non-Japanese patients.

- NIR178 showed time and dose-dependent pharmacokinetics with accumulation and a high degree of variability. Metabolite NJI765 level was 25%-33% of parent drug.

Date of Clinical Trial Report

31-Jan-2024