



Clinical trial results:

A Phase 1/2 Study of ALKS 4230 Administered Intravenously as Monotherapy and in Combination With Pembrolizumab in Subjects With Advanced Solid Tumors –ARTISTRY-1

Summary

EudraCT number	2019-001998-90
Trial protocol	HU ES
Global end of trial date	02 August 2023

Results information

Result version number	v1 (current)
This version publication date	09 April 2025
First version publication date	09 April 2025

Trial information

Trial identification

Sponsor protocol code	ALK4230-A101
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02799095
WHO universal trial number (UTN)	-
Other trial identifiers	IND: 128,159

Notes:

Sponsors

Sponsor organisation name	Mural Oncology, Inc.
Sponsor organisation address	852 Winter Street, Waltham, United States, MA 02451
Public contact	Study Director, Mural Oncology, Inc., +1 (781) 614-0100, clinicaltrials@muraloncology.com
Scientific contact	Study Director, Mural Oncology, Inc., +1 (781) 614-0100, clinicaltrials@muraloncology.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 August 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	02 August 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives were to:

- Investigate the safety and tolerability of nemvaleukin alfa and to determine the maximum tolerated dose (MTD) and the recommended Phase 2 dose (RP2D) of nemvaleukin alfa in subjects with advanced solid tumors who were refractory or intolerant to therapies known to provide clinical benefit (Part A)
- Assess the safety profile and characterize antitumor activity by overall response rate (ORR) of nemvaleukin alfa at the RP2D in subjects with melanoma or renal cell carcinoma (RCC) (Part B)
- Characterize the safety profile and antitumor activity by ORR of nemvaleukin alfa administered intravenously (IV) in combination with pembrolizumab in subjects with advanced solid tumors (Part C)
- Describe the dose-limiting toxicity (DLT) of nemvaleukin alfa (Part A)

Protection of trial subjects:

This study was conducted in accordance with the ethical principles of Good Clinical Practice (GCP), according to the International Council on Harmonisation (ICH) Harmonised Tripartite Guideline, and in accordance with 21 CFR 312.120.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 September 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 50
Country: Number of subjects enrolled	Spain: 31
Country: Number of subjects enrolled	Belgium: 7
Country: Number of subjects enrolled	Canada: 28
Country: Number of subjects enrolled	Korea, Republic of: 5
Country: Number of subjects enrolled	United States: 159
Country: Number of subjects enrolled	Australia: 6
Worldwide total number of subjects	286
EEA total number of subjects	88

Notes:

Subjects enrolled per age group

In utero	0
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Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	154
From 65 to 84 years	131
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 47 investigative sites in the United States, Spain, Canada, South Korea, Australia, Belgium, and Poland. A total of 243 subjects were enrolled in this 3-part study (Parts A, B and C) to receive nemvaleukin alfa (ALKS 4230) either as monotherapy or in combination with pembrolizumab.

Pre-assignment

Screening details:

Selected subjects (43) enrolled in Monotherapy Parts A and B, and who did not demonstrate clinical benefit were eligible to rollover to Combination Therapy Part C and were rolled over in Part C, Cohort 4.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg

Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.1 microgram per kilogram (mcg/kg) intravenous (IV) infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Arm title	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.3 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Arm title	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 1 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Arm title	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Arm title	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Arm title	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 8 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Arm title	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 10 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Arm type	Experimental
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Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Arm title	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
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Arm description:

Subjects with melanoma received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Arm title	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg
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Arm description:

Subjects with renal cell carcinoma (RCC) received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Arm title	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg
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Arm description:

Subjects with any tumor type received nemvaleukin alfa 1 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Part C, Cohort 1 + Safety Run-in: Nemvaleukin Alfa + Pembrolizumab
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Arm description:

Subjects with programmed death receptor-1/programmed death ligand-1 (PD-1/L1) unapproved tumor types (PD-1/L1 treatment naive) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation. The Safety Run-in for nemvaleukin alfa 3 mcg/kg was combined with Cohort 1 of Part C due to same dosing level and regimen.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
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Arm description:

Subjects with PD-1/L1 approved tumor types (PD-1/L1 treatment pretreated) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab
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Arm description:

Subjects with PD-1/L1 approved tumor types (PD-1/L1 treatment naive) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa +Pembrolizumab
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Arm description:

Subjects rolled over from Parts A or B received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
Arm description:	
Subjects with melanoma received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.	
Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Nemvaleukin alfa administration via IV infusion.	
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Pembrolizumab administration via IV infusion.	
Arm title	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab

Arm description:	
Subjects with non-small-cell lung cancer (NSCLC) received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.	
Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Nemvaleukin alfa administration via IV infusion.	
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Pembrolizumab administration via IV infusion.	
Arm title	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab

Arm description:	
Subjects with squamous cell carcinoma of the head and neck (SCCHN) received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor	

and if they did not meet any other criteria for discontinuation.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nemvaleukin alfa administration via IV infusion.

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Number of subjects in period 1	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg
Started	5	4	7
Completed	0	0	0
Not completed	5	4	7
Consent withdrawn by subject	-	-	-
Physician decision	-	-	-
Adverse Event	1	-	1
Death	-	-	-
Lost to Follow-up	-	-	-
Other	-	-	-
Progressive Disease	3	3	3
Rollover from Part A or B to Part C, Cohort 4	-	-	-
Withdrawal by Subject	-	-	-
Lost to follow-up	-	1	-
Clinical Progression	1	-	2
Protocol deviation	-	-	1

Number of subjects in period 1	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg
Started	8	12	3
Completed	0	0	0
Not completed	8	12	3
Consent withdrawn by subject	-	-	1

Physician decision	-	-	-
Adverse Event	4	1	-
Death	-	-	-
Lost to Follow-up	-	-	-
Other	-	-	-
Progressive Disease	2	2	-
Rollover from Part A or B to Part C, Cohort 4	-	1	2
Withdrawal by Subject	1	3	-
Lost to follow-up	-	-	-
Clinical Progression	1	5	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg
Started	7	47	27
Completed	0	3	1
Not completed	7	44	26
Consent withdrawn by subject	1	10	7
Physician decision	-	-	-
Adverse Event	-	-	-
Death	3	7	7
Lost to Follow-up	1	-	-
Other	-	-	-
Progressive Disease	-	1	-
Rollover from Part A or B to Part C, Cohort 4	2	26	12
Withdrawal by Subject	-	-	-
Lost to follow-up	-	-	-
Clinical Progression	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
Started	3	42	26
Completed	0	1	0
Not completed	3	41	26
Consent withdrawn by subject	-	13	15
Physician decision	-	1	-
Adverse Event	-	3	1
Death	-	7	5

Lost to Follow-up	-	1	1
Other	-	-	2
Progressive Disease	2	13	2
Rollover from Part A or B to Part C, Cohort 4	-	-	-
Withdrawal by Subject	-	-	-
Lost to follow-up	-	-	-
Clinical Progression	1	3	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa +Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
Started	26	43	3
Completed	4	8	2
Not completed	22	35	1
Consent withdrawn by subject	13	21	-
Physician decision	-	-	-
Adverse Event	-	1	-
Death	6	8	1
Lost to Follow-up	1	3	-
Other	2	-	-
Progressive Disease	-	1	-
Rollover from Part A or B to Part C, Cohort 4	-	-	-
Withdrawal by Subject	-	-	-
Lost to follow-up	-	-	-
Clinical Progression	-	1	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab
Started	21	2
Completed	1	0
Not completed	20	2
Consent withdrawn by subject	12	1
Physician decision	-	-
Adverse Event	-	-
Death	8	1
Lost to Follow-up	-	-
Other	-	-
Progressive Disease	-	-
Rollover from Part A or B to Part C, Cohort 4	-	-

Withdrawal by Subject	-	-
Lost to follow-up	-	-
Clinical Progression	-	-
Protocol deviation	-	-

Baseline characteristics

Reporting groups

Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 0.1 microgram per kilogram (mcg/kg) intravenous (IV) infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 0.3 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 1 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 8 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 10 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Reporting group description: Subjects with melanoma received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg
Reporting group description: Subjects with renal cell carcinoma (RCC) received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg
Reporting group description: Subjects with any tumor type received nemvaleukin alfa 1 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for	

discontinuation.

Reporting group title	Part C, Cohort 1 + Safety Run-in: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with programmed death receptor-1/programmed death ligand-1 (PD-1/L1) unapproved tumor types (PD-1/L1 treatment naive) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation. The Safety Run-in for nemvaleukin alfa 3 mcg/kg was combined with Cohort 1 of Part C due to same dosing level and regimen.

Reporting group title	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with PD-1/L1 approved tumor types (PD-1/L1 treatment pretreated) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Reporting group title	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with PD-1/L1 approved tumor types (PD-1/L1 treatment naive) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Reporting group title	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects rolled over from Parts A or B received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Reporting group title	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with melanoma received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Reporting group title	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with non-small-cell lung cancer (NSCLC) received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Reporting group title	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with squamous cell carcinoma of the head and neck (SCCHN) received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the

subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Reporting group values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg
Number of subjects	5	4	7
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	3	5
From 65-84 years	0	1	2
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	1	1	0
Male	4	3	7
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	4	4	7
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	5	4	6
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg
Number of subjects	8	12	3
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	4	3
From 65-84 years	4	8	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	4	7	2
Male	4	5	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	8	12	3
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	2	1
White	8	10	2
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg
Number of subjects	7	47	27
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	20	10
From 65-84 years	3	27	17
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	4	22	3
Male	3	25	24
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	1
Not Hispanic or Latino	6	47	26

Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	5	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	6	42	25
More than one race	0	0	0
Unknown or Not Reported	1	0	0

Reporting group values	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 + Safety Run-in: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
Number of subjects	3	42	26
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	30	20
From 65-84 years	3	12	6
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	1	28	12
Male	2	14	14
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	1	1
Not Hispanic or Latino	3	40	25
Unknown or Not Reported	0	1	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	7	3
White	3	34	20
More than one race	0	0	0
Unknown or Not Reported	0	1	2

Reporting group values	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
Number of subjects	26	43	3

Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	15	18	1
From 65-84 years	11	25	2
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	13	18	1
Male	13	25	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	1	0
Not Hispanic or Latino	24	42	3
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	1	0
White	22	40	3
More than one race	0	0	0
Unknown or Not Reported	1	1	0

Reporting group values	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab	Total
Number of subjects	21	2	286
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	7	1	150
From 65-84 years	14	1	136
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	7	1	125
Male	14	1	161

Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	0	9
Not Hispanic or Latino	20	2	276
Unknown or Not Reported	0	0	1
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	9
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	20
White	18	2	250
More than one race	0	0	0
Unknown or Not Reported	1	0	7

End points

End points reporting groups

Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 0.1 microgram per kilogram (mcg/kg) intravenous (IV) infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 0.3 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 1 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 8 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg
Reporting group description: Subjects with advanced solid tumors received nemvaleukin alfa 10 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Reporting group description: Subjects with melanoma received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg
Reporting group description: Subjects with renal cell carcinoma (RCC) received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.	
Reporting group title	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg
Reporting group description: Subjects with any tumor type received nemvaleukin alfa 1 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for	

discontinuation.

Reporting group title	Part C, Cohort 1 + Safety Run-in: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with programmed death receptor-1/programmed death ligand-1 (PD-1/L1) unapproved tumor types (PD-1/L1 treatment naive) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation. The Safety Run-in for nemvaleukin alfa 3 mcg/kg was combined with Cohort 1 of Part C due to same dosing level and regimen.

Reporting group title	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with PD-1/L1 approved tumor types (PD-1/L1 treatment pretreated) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Reporting group title	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with PD-1/L1 approved tumor types (PD-1/L1 treatment naive) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Reporting group title	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects rolled over from Parts A or B received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Reporting group title	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with melanoma received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Reporting group title	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with non-small-cell lung cancer (NSCLC) received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Reporting group title	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with squamous cell carcinoma of the head and neck (SCCHN) received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the

subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Subject analysis set title	Part C, Safety Run-in: Nemvaleukin Alfa 3 mcg/kg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with PD-1/L1 unapproved tumor types (PD-1/L1 treatment naive) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subject could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Subject analysis set title	Part C, Cohort 1: Nemvaleukin Alfa + Pembrolizumab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects with PD-1/L1 unapproved tumor types (PD-1/L1 treatment naive) received nemvaleukin alfa 3 mcg/kg infusion IV administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Primary: Part A: Number of Subjects With Dose-limiting Toxicities (DLTs) Based on Common Terminology Criteria for Adverse Events (CTCAE)

End point title	Part A: Number of Subjects With Dose-limiting Toxicities (DLTs) Based on Common Terminology Criteria for Adverse Events (CTCAE) ^{[1][2]}
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End point description:

DLT defined by any of following events possibly, probably, or definitely related to ALKS 4230: Grade 4 neutrophil count decreased (neutropenia); Febrile neutropenia; CTCAE Grade 4 thrombocytopenia; Thrombocytopenia; Any Grade 3 cardiac or central nervous system toxicity; Liver transaminase elevation higher than 8*upper limit of normal (ULN) or total bilirubin higher than 6*ULN; Grade 4 hypoalbuminemia; Fever more than (>) 40 degree Celsius (°C) sustained for >24 hours; Hypotension required the use of pressors or prolonged hospitalization (>48 hours) for hypotension requiring medical intervention; Grade 3 or higher electrolyte abnormalities; Increase in amylase or lipase; Grade 3 or higher nausea, vomiting, or diarrhea; Any other Grade 4 nonhematologic toxicity or any other Grade 3 non-hematologic toxicity; Any other toxicity or adverse event (AE) not defined above that resulted in subject removal from the study or discontinuation of dosing by the Investigator. Safety population.

End point type	Primary
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End point timeframe:

Cycle 1 Day 1 through Cycle 2 Day 15 (Cycle 1 length = 14 days; Cycle 2 length= 21 days)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	7	8
Units: Subjects	0	0	0	2

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	3	7	
Units: Subjects	3	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Parts A, B, and C: Number of Subjects With Treatment-emergent Adverse Events (TEAEs)

End point title	Parts A, B, and C: Number of Subjects With Treatment-emergent Adverse Events (TEAEs) ^[3]
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End point description:

TEAEs were defined as AEs that were newly occurring or worsening from the time of the first dose of study drug. An AE was any untoward medical occurrence in a subjects or clinical investigation subject administered a pharmaceutical product. Safety population included all subjects who received at least 1 dose of nemvaleukin alfa or pembrolizumab.

End point type	Primary
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End point timeframe:

From first dose of study drug until 30 days after last dose (up to 10 months for Part A; up to 41.3 months for Part B; up to 51.5 months for Part C)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned.

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	7	8
Units: Subjects	5	4	7	8

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	3	7	47
Units: Subjects	12	3	7	46

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	3	42	26
Units: Subjects	27	3	42	26

End point values	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa +Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	43	3	21
Units: Subjects	26	39	3	21

End point values	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Subjects	2			

Statistical analyses

No statistical analyses for this end point

Primary: Parts A, B, and C: Number of Subjects With TEAEs by Severity Grading

End point title	Parts A, B, and C: Number of Subjects With TEAEs by Severity Grading ^[4]
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End point description:

TEAEs were defined as AEs that were newly occurring or worsening from the time of the first dose of study drug. Severity was graded according to the National Cancer Institute (NCI) CTCAE (version 4.03) where, Grade 1: Mild- asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. Grade 2: Moderate- minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living (ADL) Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL. Grade 4: Life-threatening consequences; urgent intervention indicated. Grade 5: Death related to AE. As planned, Grades 1 and 2 were combined for reporting. Safety population included all subjects who received at least 1 dose of nemvaleukin alfa or pembrolizumab.

End point type	Primary
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End point timeframe:

From first dose of study drug until 30 days after last dose (up to 10 months for Part A; up to 41.3 months for Part B; up to 51.5 months for Part C)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned.

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	7	8
Units: Subjects				
Grade 1 and 2 TEAEs	2	3	4	2
Grade 3 TEAEs	3	1	3	6
Grade 4 TEAEs	0	0	0	0
Grade 5 TEAEs	0	0	0	0

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	3	7	47
Units: Subjects				
Grade 1 and 2 TEAEs	3	1	1	6
Grade 3 TEAEs	8	2	3	28
Grade 4 TEAEs	0	0	2	12
Grade 5 TEAEs	1	0	1	0

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	3	42	26
Units: Subjects				
Grade 1 and 2 TEAEs	5	3	16	7
Grade 3 TEAEs	16	0	19	14
Grade 4 TEAEs	5	0	4	5
Grade 5 TEAEs	1	0	3	0

End point values	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	43	3	21
Units: Subjects				
Grade 1 and 2 TEAEs	6	13	1	4
Grade 3 TEAEs	15	21	1	16
Grade 4 TEAEs	5	4	1	1
Grade 5 TEAEs	0	1	0	0

End point values	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Subjects				
Grade 1 and 2 TEAEs	0			
Grade 3 TEAEs	1			
Grade 4 TEAEs	1			
Grade 5 TEAEs	0			

Statistical analyses

No statistical analyses for this end point

Primary: Parts B and C: Overall Response Rate (ORR) Based on Response Evaluation Criteria in Solid Tumors (RECIST) Version (v) 1.1

End point title	Parts B and C: Overall Response Rate (ORR) Based on Response Evaluation Criteria in Solid Tumors (RECIST) Version (v) 1.1 ^{[5][6]}
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End point description:

ORR rate was defined as the percentage of subjects with objective evidence of CR or PR based on RECIST v1.1. Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<) 10 millimeters (mm). Partial Response (PR): At least a 30 percent (%) decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. The antitumor evaluable population consisted of subjects who complete 2 cycles of therapy and had at least one follow-up scan.

End point type	Primary
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End point timeframe:

From first dose of study drug up to 40.3 months for Part B and up to 50.5 months for Part C

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	22	3	36
Units: Percentage of subjects				
number (confidence interval 95%)	8.7 (2.4 to 20.8)	13.6 (2.9 to 34.9)	0.0 (0.0 to 70.8)	13.9 (4.7 to 29.5)

End point values	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa +Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	21	39	3
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 15.4)	28.6 (11.3 to 52.2)	7.7 (1.6 to 20.9)	66.7 (9.4 to 99.2)

End point values	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	2		
Units: Percentage of subjects				
number (confidence interval 95%)	11.1 (1.4 to 34.7)	50.0 (1.3 to 98.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A and B: Serum Concentrations of Nemvaleukin Alfa

End point title	Parts A and B: Serum Concentrations of Nemvaleukin Alfa ^[7]
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End point description:

Cycle 1 length = 14 days for Part A and 21 days for Part B; Cycle 2 length= 21 days for Parts A and B. The PK population consisted of all subjects who received at least 1 dose of nemvareukin alfa and had at least 1 measurable serum concentration of nemvareukin alfa at any scheduled PK time point. Here, "number of subjects analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable at specified timepoints. Here, "99999" means data could not be calculated due to less subject.

End point type	Secondary
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End point timeframe:

Cycle (C) 1 and 2 Day (D) 1: 0, 0.5, 1, 2, 4, 8, 16, and 24 hours (h) post-dose; Cycle 1 Day 5: 0, 0.5, 1, 2, 4, 8, 16, 24, and 72 hours post-dose; Cycle 2 Day 5: 0, 0.5, 1, 2, 4, 8, 16, 24, 72, and 240 hours post-dose

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only descriptive data was planned.

End point values	Part A, Dose Escalation: Nemvareukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvareukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvareukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvareukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	7	8
Units: nanograms per milliliter (ng/mL)				
arithmetic mean (standard deviation)				
C1D1:0 h (n=5,4,7,8,11,3,7,45,27)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
C1D1: 0.5 h (n=5,3,5,6,9,3,5,41,26)	2.24 (± 1.06)	6.13 (± 0.653)	20.1 (± 5.32)	77.9 (± 15.5)
C1D1: 1 h (n=3,4,7,8,12,3,5,43,26)	1.61 (± 0.265)	5.67 (± 1.61)	16.6 (± 3.84)	58.8 (± 25.3)
C1D1: 2 h (n=3,4,7,8,12,3,5,45,27)	0.965 (± 0.0894)	3.83 (± 1.01)	12.3 (± 2.80)	44.0 (± 18.5)
C1D1: 4 h (n=5,3,7,8,12,3,6,45,27)	0.142 (± 0.318)	1.87 (± 0.710)	6.97 (± 2.25)	25.2 (± 11.7)
C1D1: 8 h (n=5,4,6,8,11,3,6,43,26)	0.00 (± 0.00)	0.453 (± 0.314)	2.55 (± 1.27)	10.0 (± 4.85)
C1D1: 16 h (n=5,4,5,4,4,0,6,0,0)	0.00 (± 0.00)	0.00 (± 0.00)	0.522 (± 0.641)	1.50 (± 1.20)
C1D1: 24 h (n=5,4,7,8,11,2,7,44,26)	0.00 (± 0.00)	0.00 (± 0.00)	0.106 (± 0.280)	1.19 (± 0.633)
C1D5: 0 h (n=5,4,7,7,10,3,4,37,20)	0.00 (± 0.00)	0.00 (± 0.00)	0.104 (± 0.276)	0.619 (± 0.462)
C1D5: 0.5 h (n=4,3,6,5,8,3,4,32,16)	2.00 (± 0.238)	6.00 (± 1.45)	20.1 (± 8.08)	71.3 (± 14.0)
C1D5: 1 h (n=3,3,7,6,8,3,3,35,15)	1.55 (± 0.245)	5.28 (± 1.07)	13.8 (± 7.79)	48.9 (± 26.6)
C1D5: 2 h (n=3,3,7,7,9,3,4,33,14)	0.909 (± 0.164)	3.53 (± 1.10)	9.26 (± 5.76)	30.1 (± 18.1)
C1D5: 4 h (n=5,3,7,7,9,2,4,36,14)	0.00 (± 0.00)	1.17 (± 0.450)	4.17 (± 3.72)	12.9 (± 7.19)
C1D5: 8 h (n=5,4,7,7,8,2,4,28,14)	0.00 (± 0.00)	0.00 (± 0.00)	1.16 (± 1.31)	3.25 (± 1.84)
C1D5: 16 h (n=5,4,4,3,3,0,0,0,0)	0.00 (± 0.00)	0.158 (± 0.316)	0.244 (± 0.488)	0.625 (± 0.586)
C1D5: 24 h (n=5,4,4,3,3,0,0,0,0)	0.00 (± 0.00)	0.00 (± 0.00)	0.147 (± 0.294)	0.221 (± 0.382)
C1D5: 72 h (n=5,4,4,6,8,3,7,8,7)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
C2D1: 0 h (n=4,4,6,7,9,3,4,42,23)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
C2D1: 0.5 h (n=4,1,6,5,4,3,3,36,22)	1.80 (± 0.590)	5.42 (± 99999)	20.7 (± 6.83)	72.2 (± 13.0)
C2D1: 1 h (n=2,4,6,5,6,3,3,39,21)	1.36 (± 0.646)	4.84 (± 0.806)	17.3 (± 5.46)	58.3 (± 11.8)
C2D1: 2 h (n=3,4,6,6,7,3,3,2,22)	0.889 (± 0.174)	3.43 (± 0.797)	12.6 (± 4.40)	44.9 (± 14.5)
C2D1: 4 h (n=4,4,6,6,7,3,3,39,22)	0.00 (± 0.00)	1.31 (± 0.422)	7.16 (± 3.53)	27.8 (± 10.6)

C2D1: 8 h (n=4,4,5,6,7,3,3,40,21)	0.00 (± 0.00)	0.00 (± 0.00)	2.32 (± 1.45)	9.29 (± 4.62)
C2D1: 16 h (n=4,4,3,3,2,0,0,0)	0.00 (± 0.00)	0.00 (± 0.00)	0.405 (± 0.701)	2.47 (± 2.14)
C2D1: 24 h (n=4,4,6,6,7,3,3,40,22)	0.00 (± 0.00)	0.205 (± 0.410)	0.219 (± 0.342)	0.940 (± 0.561)
C2D5: 0 h (n=3,4,6,5,10,2,3,40,21)	0.00 (± 0.00)	0.00 (± 0.00)	0.0868 (± 0.213)	0.914 (± 0.614)
C2D5: 0.5 h (n=2,3,4,2,6,2,3,34,19)	1.92 (± 0.296)	6.06 (± 0.454)	17.2 (± 3.44)	69.1 (± 16.8)
C2D5: 1 h (n=2,4,6,3,7,2,3,33,19)	1.44 (± 0.260)	4.82 (± 0.794)	14.7 (± 3.80)	44.9 (± 18.3)
C2D5: 2 h (n=2,4,6,4,7,2,3,34,19)	0.988 (± 0.0219)	2.84 (± 0.751)	9.09 (± 3.13)	29.9 (± 12.3)
C2D5: 4 h (n=3,4,6,4,7,2,3,35,19)	0.00 (± 0.00)	1.13 (± 0.471)	4.18 (± 1.98)	14.9 (± 6.75)
C2D5: 8 h (n=3,4,6,5,7,2,2,29,18)	0.00 (± 0.00)	0.00 (± 0.00)	1.27 (± 0.509)	3.89 (± 1.58)
C2D5: 16 h (n=3,4,3,3,3,0,0,0)	0.00 (± 0.00)	0.00 (± 0.00)	0.218 (± 0.378)	1.15 (± 0.687)
C2D5: 24 h (n=3,4,3,3,3,0,0,0)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.631 (± 0.630)
C2D5: 72 h (n=3,3,2,3,7,3,2,6,11)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.200 (± 0.347)
C2D5: 240 h (n=3,2,3,5,6,3,3,10,12)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	3	7	45
Units: nanograms per milliliter (ng/mL)				
arithmetic mean (standard deviation)				
C1D1:0 h (n=5,4,7,8,11,3,7,45,27)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.0137 (± 0.0917)
C1D1: 0.5 h (n=5,3,5,6,9,3,5,41,26)	109 (± 29.6)	157 (± 56.8)	148 (± 18.2)	102 (± 36.1)
C1D1: 1 h (n=3,4,7,8,12,3,5,43,26)	112 (± 24.5)	132 (± 33.0)	135 (± 33.9)	101 (± 32.3)
C1D1: 2 h (n=3,4,7,8,12,3,5,45,27)	83.0 (± 19.6)	98.9 (± 21.8)	100 (± 27.1)	77.4 (± 21.5)
C1D1: 4 h (n=5,3,7,8,12,3,6,45,27)	51.4 (± 15.9)	57.4 (± 11.9)	62.1 (± 26.5)	50.1 (± 16.2)
C1D1: 8 h (n=5,4,6,8,11,3,6,43,26)	21.6 (± 7.61)	24.9 (± 9.77)	31.2 (± 16.9)	31.8 (± 28.9)
C1D1: 16 h (n=5,4,5,4,4,0,6,0,0)	7.27 (± 4.49)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D1: 24 h (n=5,4,7,8,11,2,7,44,26)	2.95 (± 1.61)	3.21 (± 0.253)	5.18 (± 4.20)	3.64 (± 1.90)
C1D5: 0 h (n=5,4,7,7,10,3,4,37,20)	2.36 (± 2.29)	1.59 (± 0.692)	1.67 (± 0.531)	1.51 (± 0.654)
C1D5: 0.5 h (n=4,3,6,5,8,3,4,32,16)	111 (± 26.0)	112 (± 14.6)	104 (± 13.0)	85.1 (± 28.1)
C1D5: 1 h (n=3,3,7,6,8,3,3,35,15)	87.6 (± 14.7)	98.4 (± 10.5)	70.3 (± 9.27)	78.0 (± 29.5)
C1D5: 2 h (n=3,3,7,7,9,3,4,33,14)	65.2 (± 22.1)	66.4 (± 6.97)	66.2 (± 15.1)	57.8 (± 20.2)
C1D5: 4 h (n=5,3,7,7,9,2,4,36,14)	32.0 (± 14.0)	29.1 (± 7.92)	28.0 (± 14.0)	39.4 (± 43.2)
C1D5: 8 h (n=5,4,7,7,8,2,4,28,14)	6.67 (± 2.74)	6.68 (± 1.85)	5.06 (± 1.68)	6.78 (± 3.25)
C1D5: 16 h (n=5,4,4,3,3,0,0,0,0)	1.65 (± 0.707)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D5: 24 h (n=5,4,4,3,3,0,0,0,0)	1.38 (± 0.631)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D5: 72 h (n=5,4,4,6,8,3,7,8,7)	0.498 (± 0.596)	0.824 (± 0.333)	0.664 (± 0.597)	0.623 (± 0.973)
C2D1: 0 h (n=4,4,6,7,9,3,4,42,23)	8.24 (± 24.7)	0.00 (± 0.00)	0.00 (± 0.00)	2.11 (± 13.7)
C2D1: 0.5 h (n=4,1,6,5,4,3,3,36,22)	105 (± 23.9)	113 (± 15.1)	121 (± 40.4)	174 (± 372)

C2D1: 1 h (n=2,4,6,5,6,3,3,39,21)	94.6 (± 14.3)	105 (± 27.7)	102 (± 33.2)	93.3 (± 34.9)
C2D1: 2 h (n=3,4,6,6,7,3,3,2,22)	74.5 (± 18.2)	76.9 (± 23.3)	85.9 (± 26.8)	76.7 (± 26.5)
C2D1: 4 h (n=4,4,6,6,7,3,3,39,22)	45.1 (± 14.0)	50.5 (± 16.2)	52.5 (± 15.8)	46.8 (± 16.5)
C2D1: 8 h (n=4,4,5,6,7,3,3,40,21)	16.5 (± 7.44)	18.7 (± 9.48)	24.9 (± 13.1)	26.8 (± 35.4)
C2D1: 16 h (n=4,4,3,3,2,0,0,0,0)	4.24 (± 3.60)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D1: 24 h (n=4,4,6,6,7,3,3,40,22)	2.11 (± 1.45)	1.81 (± 1.30)	2.51 (± 1.19)	2.03 (± 1.69)
C2D5: 0 h (n=3,4,6,5,10,2,3,40,21)	1.36 (± 0.589)	2.24 (± 1.46)	2.36 (± 1.11)	1.58 (± 0.653)
C2D5: 0.5 h (n=2,3,4,2,6,2,3,34,19)	93.9 (± 22.2)	98.8 (± 34.7)	91.2 (± 40.2)	153 (± 300)
C2D5: 1 h (n=2,4,6,3,7,2,3,33,19)	84.8 (± 23.7)	90.5 (± 16.3)	78.4 (± 39.9)	94.8 (± 104)
C2D5: 2 h (n=2,4,6,4,7,2,3,34,19)	58.4 (± 19.3)	59.0 (± 6.87)	49.9 (± 15.2)	55.3 (± 20.9)
C2D5: 4 h (n=3,4,6,4,7,2,3,35,19)	27.1 (± 10.4)	24.2 (± 2.26)	24.3 (± 11.6)	27.6 (± 8.71)
C2D5: 8 h (n=3,4,6,5,7,2,2,29,18)	6.93 (± 3.91)	5.74 (± 0.0933)	7.51 (± 3.23)	7.94 (± 6.53)
C2D5: 16 h (n=3,4,3,3,3,0,0,0,0)	1.64 (± 0.597)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D5: 24 h (n=3,4,3,3,3,0,0,0,0)	1.38 (± 0.697)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D5: 72 h (n=3,3,2,3,7,3,2,6,11)	0.488 (± 0.376)	0.611 (± 0.625)	1.57 (± 0.584)	0.578 (± 0.475)
C2D5: 240 h (n=3,2,3,5,6,3,3,10,12)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: nanograms per milliliter (ng/mL)				
arithmetic mean (standard deviation)				
C1D1:0 h (n=5,4,7,8,11,3,7,45,27)	0.0329 (± 0.171)			
C1D1: 0.5 h (n=5,3,5,6,9,3,5,41,26)	131 (± 51.3)			
C1D1: 1 h (n=3,4,7,8,12,3,5,43,26)	117 (± 19.9)			
C1D1: 2 h (n=3,4,7,8,12,3,5,45,27)	97.6 (± 21.7)			
C1D1: 4 h (n=5,3,7,8,12,3,6,45,27)	66.4 (± 15.9)			
C1D1: 8 h (n=5,4,6,8,11,3,6,43,26)	32.5 (± 7.83)			
C1D1: 16 h (n=5,4,5,4,4,0,6,0,0)	99999 (± 99999)			
C1D1: 24 h (n=5,4,7,8,11,2,7,44,26)	3.53 (± 1.25)			
C1D5: 0 h (n=5,4,7,7,10,3,4,37,20)	1.96 (± 0.987)			
C1D5: 0.5 h (n=4,3,6,5,8,3,4,32,16)	101 (± 29.2)			
C1D5: 1 h (n=3,3,7,6,8,3,3,35,15)	83.8 (± 14.8)			
C1D5: 2 h (n=3,3,7,7,9,3,4,33,14)	61.0 (± 14.3)			
C1D5: 4 h (n=5,3,7,7,9,2,4,36,14)	30.3 (± 6.20)			
C1D5: 8 h (n=5,4,7,7,8,2,4,28,14)	6.33 (± 2.04)			
C1D5: 16 h (n=5,4,4,3,3,0,0,0,0)	99999 (± 99999)			
C1D5: 24 h (n=5,4,4,3,3,0,0,0,0)	99999 (± 99999)			
C1D5: 72 h (n=5,4,4,6,8,3,7,8,7)	0.538 (± 0.383)			

C2D1: 0 h (n=4,4,6,7,9,3,4,42,23)	0.120 (± 0.410)			
C2D1: 0.5 h (n=4,1,6,5,4,3,3,36,22)	123 (± 31.7)			
C2D1: 1 h (n=2,4,6,5,6,3,3,39,21)	106 (± 30.3)			
C2D1: 2 h (n=3,4,6,6,7,3,3,2,22)	87.9 (± 23.5)			
C2D1: 4 h (n=4,4,6,6,7,3,3,39,22)	57.1 (± 14.9)			
C2D1: 8 h (n=4,4,5,6,7,3,3,40,21)	24.1 (± 8.09)			
C2D1: 16 h (n=4,4,3,3,2,0,0,0,0)	99999 (± 99999)			
C2D1: 24 h (n=4,4,6,6,7,3,3,40,22)	1.95 (± 0.854)			
C2D5: 0 h (n=3,4,6,5,10,2,3,40,21)	1.72 (± 0.599)			
C2D5: 0.5 h (n=2,3,4,2,6,2,3,34,19)	101 (± 18.6)			
C2D5: 1 h (n=2,4,6,3,7,2,3,33,19)	83.4 (± 19.4)			
C2D5: 2 h (n=2,4,6,4,7,2,3,34,19)	62.0 (± 17.8)			
C2D5: 4 h (n=3,4,6,4,7,2,3,35,19)	29.1 (± 10.4)			
C2D5: 8 h (n=3,4,6,5,7,2,2,29,18)	6.49 (± 2.96)			
C2D5: 16 h (n=3,4,3,3,3,0,0,0,0)	99999 (± 99999)			
C2D5: 24 h (n=3,4,3,3,3,0,0,0,0)	99999 (± 99999)			
C2D5: 72 h (n=3,3,2,3,7,3,2,6,11)	0.396 (± 0.450)			
C2D5: 240 h (n=3,2,3,5,6,3,3,10,12)	0.00 (± 0.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C: Serum Concentrations of Nemvaleukin Alfa

End point title	Parts C: Serum Concentrations of Nemvaleukin Alfa ^[8]
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End point description:

The PK population consisted of all subjects who received at least 1 dose of nemvaleukin alfa and had at least 1 measurable serum concentration of nemvaleukin alfa at any scheduled PK time point. Here, "number of subjects analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable at specified timepoints. Here, "99999" means data could not be calculated due to less subject.

End point type	Secondary
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End point timeframe:

Cycle (C) 1 and 2 Day (D) 1: 0, 0.5, 1, 2, 4, 8, 16, and 24 hours (h) post-dose; Cycle 1 Day 5: 0, 0.5, 1, 2, 4, 8, 16, 24, and 72 hours post-dose; Cycle 2 Day 5: 0, 0.5, 1, 2, 4, 8, 16, 24, 72, and 240 hours post-dose (Cycle length = 21 days)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only descriptive data was planned.

End point values	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	25	26	43

Units: ng/mL				
arithmetic mean (standard deviation)				
C1D1: 0 h (n=3,25,26,43,3,19,2,6,35)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.0151 (± 0.0988)
C1D1: 0.5h (n=3,23,25,33,2,15,2,6,29)	18.6 (± 3.94)	71.5 (± 51.7)	62.5 (± 20.2)	48.9 (± 19.8)
C1D1: 1 h (n=2,23,24,36,3,20,1,6,33)	17.4 (± 5.33)	61.6 (± 25.5)	57.5 (± 17.9)	49.9 (± 37.0)
C1D1: 2 h (n=3,24,24,35,3,20,2,6,34)	14.0 (± 2.74)	43.6 (± 11.5)	42.6 (± 13.8)	34.0 (± 18.8)
C1D1: 4 h (n=3,24,26,37,3,20,2,6,35)	8.74 (± 1.50)	27.6 (± 7.91)	26.4 (± 8.67)	22.5 (± 13.6)
C1D1: 8 h (n=2,25,25,32,3,20,2,6,32)	4.49 (± 1.26)	10.8 (± 4.41)	10.8 (± 4.29)	11.8 (± 11.9)
C1D1: 16 h (n=0,0,1,0,0,0,0,1,0)	99999 (± 99999)	99999 (± 99999)	4.95 (± 99999)	99999 (± 99999)
C1D1: 24 h (n=2,25,25,37,3,20,2,5,31)	0.498 (± 0.704)	1.64 (± 1.42)	1.29 (± 0.749)	2.94 (± 6.88)
C1D5: 0 h (n=3,20,22,37,3,17,2,6,33)	0.209 (± 0.361)	2.16 (± 3.95)	0.933 (± 0.529)	3.90 (± 9.89)
C1D5: 0.5 h (n=3,17,20,31,2,16,2,5,30)	19.5 (± 3.90)	63.6 (± 41.8)	61.1 (± 30.1)	51.8 (± 29.6)
C1D5: 1 h (n=2,19,21,31,2,16,2,5,31)	18.9 (± 2.50)	47.3 (± 12.2)	41.9 (± 11.7)	45.0 (± 28.2)
C1D5: 2 h (n=2,19,22,32,2,16,2,5,31)	13.1 (± 0.626)	31.8 (± 9.39)	27.4 (± 9.80)	39.6 (± 38.3)
C1D5: 4 h (n=3,19,22,32,2,16,2,5,33)	6.18 (± 0.687)	17.2 (± 18.5)	13.0 (± 7.01)	17.7 (± 16.2)
C1D5: 8 h (n=3,17,19,26,2,17,2,5,32)	1.86 (± 0.257)	4.85 (± 3.63)	3.26 (± 1.32)	7.80 (± 12.3)
C1D5: 16 h (n=0,0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D5: 24 h (n=0,0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D5: 72 h (n=0,4,26,5,0,2,1,0,0)	99999 (± 99999)	0.210 (± 0.419)	0.103 (± 0.273)	0.00 (± 0.00)
C2D1: 0 h (n=3,23,20,38,3,17,2,5,31)	0.00 (± 0.00)	0.00 (± 0.00)	2.10 (± 9.24)	0.00 (± 0.00)
C2D1: 0.5 h (n=2,22,19,34,3,16,0,5,26)	15.8 (± 2.82)	79.6 (± 93.1)	55.7 (± 22.7)	51.1 (± 28.0)
C2D1: 1 h (n=1,22,20,34,3,17,2,6,29)	13.7 (± 99999)	54.2 (± 14.2)	47.8 (± 13.0)	43.0 (± 27.4)
C2D1: 2 h (n=2,23,20,34,3,17,2,6,30)	11.3 (± 1.39)	38.3 (± 11.1)	37.1 (± 10.5)	35.6 (± 30.6)
C2D1: 4 h (n=2,23,20,34,3,17,2,6,30)	7.00 (± 0.412)	24.0 (± 7.15)	21.4 (± 8.75)	24.1 (± 19.1)
C2D1: 8 h (n=1,20,16,32,3,17,2,5,30)	2.51 (± 99999)	8.85 (± 3.92)	7.40 (± 3.67)	12.8 (± 18.3)
C2D1: 16 h (n=0,0,1,1,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	1.97 (± 99999)	1.69 (± 99999)
C2D1: 24 h (n=2,20,19,35,3,15,2,6,28)	0.00 (± 0.00)	1.16 (± 0.777)	1.15 (± 1.40)	4.96 (± 11.7)
C2D5: 0 h (n=3,22,18,37,2,16,2,6,27)	0.180 (± 0.312)	0.922 (± 0.670)	1.01 (± 1.71)	4.17 (± 8.72)
C2D5: 0.5 h (n=2,20,19,33,2,15,1,5,23)	13.4 (± 3.07)	58.8 (± 38.5)	52.7 (± 14.4)	56.7 (± 31.1)
C2D5: 1 h (n=2,20,19,31,2,14,2,6,22)	16.8 (± 5.53)	42.7 (± 12.9)	42.3 (± 15.5)	48.1 (± 28.2)
C2D5: 2 h (n=2,20,19,29,2,14,2,6,22)	10.3 (± 4.44)	29.9 (± 9.94)	28.5 (± 9.68)	36.7 (± 27.9)
C2D5: 4 h (n=3,21,19,34,2,15,2,6,25)	6.40 (± 2.13)	14.8 (± 6.00)	13.3 (± 5.22)	25.2 (± 32.6)
C2D5: 8 h (n=3,17,16,27,2,15,2,6,25)	1.47 (± 0.445)	3.99 (± 1.69)	3.94 (± 1.97)	12.2 (± 19.7)
C2D5: 16 h (n=0,0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D5: 24 h (n=0,0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D5: 72 h (n=0,1,6,4,0,2,1,0,0)	99999 (± 99999)	0.00 (± 99999)	0.00 (± 0.00)	0.00 (± 0.00)
C2D5: 240 h (n=0,2,10,6,1,7,0,0,2)	99999 (± 99999)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)

End point values	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab	Part C, Safety Run-in: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	3	20	2	6
Units: ng/mL				
arithmetic mean (standard deviation)				
C1D1: 0 h (n=3,25,26,43,3,19,2,6,35)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
C1D1: 0.5h (n=3,23,25,33,2,15,2,6,29)	120 (± 6.24)	131 (± 52.7)	89.3 (± 2.71)	67.1 (± 14.9)
C1D1: 1 h (n=2,23,24,36,3,20,1,6,33)	120 (± 22.0)	121 (± 32.2)	86.3 (± 99999)	50.0 (± 22.3)
C1D1: 2 h (n=3,24,24,35,3,20,2,6,34)	94.9 (± 19.7)	93.5 (± 30.7)	70.7 (± 5.51)	38.7 (± 17.4)
C1D1: 4 h (n=3,24,26,37,3,20,2,6,35)	63.8 (± 12.3)	59.7 (± 15.5)	48.9 (± 12.6)	21.9 (± 7.94)
C1D1: 8 h (n=2,25,25,32,3,20,2,6,32)	27.7 (± 6.94)	30.2 (± 8.92)	18.7 (± 99999)	9.63 (± 4.37)
C1D1: 16 h (n=0,0,1,0,0,0,1,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	0.00 (± 99999)
C1D1: 24 h (n=2,25,25,37,3,20,2,5,31)	4.49 (± 2.06)	13.8 (± 43.0)	3.45 (± 1.59)	1.46 (± 0.803)
C1D5: 0 h (n=3,20,22,37,3,17,2,6,33)	2.03 (± 0.979)	2.67 (± 2.06)	1.92 (± 0.336)	0.416 (± 0.538)
C1D5: 0.5 h (n=3,17,20,31,2,16,2,5,30)	118 (± 2.15)	111 (± 42.4)	104 (± 1.86)	49.5 (± 19.7)
C1D5: 1 h (n=2,19,21,31,2,16,2,5,31)	105 (± 14.3)	102 (± 29.5)	89.8 (± 99999)	45.6 (± 22.3)
C1D5: 2 h (n= 2,19,22,32,2,16,2,5,31)	65.1 (± 0.651)	71.1 (± 23.8)	66.5 (± 4.01)	31.8 (± 17.0)
C1D5: 4 h (n=3,19,22,32,2,16,2,5,33)	28.4 (± 1.42)	32.4 (± 13.5)	33.4 (± 7.99)	13.1 (± 11.7)
C1D5: 8 h (n=3,17,19,26,2,17,2,5,32)	20.2 (± 18.7)	8.60 (± 5.71)	7.22 (± 0.698)	3.39 (± 3.39)
C1D5: 16 h (n=0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D5: 24 h (n=0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C1D5: 72 h (n=0,4,26,5,0,2,1,0,0)	99999 (± 99999)	0.610 (± 0.00778)	0.989 (± 99999)	99999 (± 99999)
C2D1: 0 h (n=3,23,20,38,3,17,2,5,31)	0.00 (± 0.00)	0.372 (± 1.36)	0.00 (± 0.00)	0.00 (± 0.00)
C2D1: 0.5 h (n=2,22,19,34,3,16,0,5,26)	113 (± 16.8)	137 (± 47.3)	99999 (± 99999)	56.3 (± 9.99)
C2D1: 1 h (n=1,22,20,34,3,17,2,6,29)	117 (± 17.2)	114 (± 29.2)	120 (± 5.86)	48.2 (± 13.7)
C2D1: 2 h (n=2,23,20,34,3,17,2,6,30)	92.6 (± 16.1)	84.4 (± 24.6)	89.7 (± 5.33)	35.6 (± 8.32)
C2D1: 4 h (n=2,23,20,34,3,17,2,6,30)	54.9 (± 6.38)	54.7 (± 16.7)	58.0 (± 8.50)	19.5 (± 4.90)
C2D1: 8 h (n=1,20,16,32,3,17,2,5,30)	24.3 (± 3.79)	24.0 (± 11.5)	26.4 (± 6.55)	8.66 (± 4.83)
C2D1: 16 h (n=0,0,1,1,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D1: 24 h (n=2,20,19,35,3,15,2,6,28)	3.16 (± 1.58)	2.98 (± 1.51)	3.19 (± 1.10)	0.737 (± 0.518)
C2D5: 0 h (n=3,22,18,37,2,16,2,6,27)	1.45 (± 0.417)	2.17 (± 1.46)	1.86 (± 0.354)	0.756 (± 0.786)
C2D5: 0.5 h (n=2,20,19,33,2,15,1,5,23)	100 (± 20.0)	100 (± 28.8)	103 (± 99999)	44.3 (± 9.53)
C2D5: 1 h (n=2,20,19,31,2,14,2,6,22)	86.3 (± 15.0)	90.9 (± 24.6)	89.7 (± 4.66)	33.8 (± 7.91)
C2D5: 2 h (n=2,20,19,29,2,14,2,6,22)	57.6 (± 10.5)	59.9 (± 19.7)	67.3 (± 4.50)	21.3 (± 4.81)
C2D5: 4 h (n=3,21,19,34,2,15,2,6,25)	29.8 (± 2.81)	30.8 (± 12.5)	34.7 (± 8.12)	8.11 (± 2.77)
C2D5: 8 h (n=3,17,16,27,2,15,2,6,25)	4.98 (± 1.92)	9.78 (± 5.22)	8.47 (± 3.87)	28.2 (± 64.5)
C2D5: 16 h (n=0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D5: 24 h (n=0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D5: 72 h (n=0,1,6,4,0,2,1,0,0)	99999 (± 99999)	1.17 (± 0.409)	0.741 (± 99999)	99999 (± 99999)

C2D5: 240 h (n=0,2,10,6,1,7,0,0,2)	0.00 (± 99999)	0.00 (± 0.00)	99999 (± 99999)	99999 (± 99999)
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End point values	Part C, Cohort 1: Nemvaleukin Alfa + Pembrolizumab			
Subject group type	Subject analysis set			
Number of subjects analysed	35			
Units: ng/mL				
arithmetic mean (standard deviation)				
C1D1: 0 h (n=3,25,26,43,3,19,2,6,35)	0.00 (± 0.00)			
C1D1: 0.5h (n=3,23,25,33,2,15,2,6,29)	61.7 (± 13.4)			
C1D1: 1 h (n=2,23,24,36,3,20,1,6,33)	56.3 (± 11.2)			
C1D1: 2 h (n=3,24,24,35,3,20,2,6,34)	42.5 (± 9.20)			
C1D1: 4 h (n=3,24,26,37,3,20,2,6,35)	25.6 (± 5.22)			
C1D1: 8 h (n=2,25,25,32,3,20,2,6,32)	10.2 (± 2.88)			
C1D1: 16 h (n=0,0,1,0,0,0,0,1,0)	99999 (± 99999)			
C1D1: 24 h (n=2,25,25,37,3,20,2,5,31)	1.64 (± 1.44)			
C1D5: 0 h (n=3,20,22,37,3,17,2,6,33)	1.10 (± 0.965)			
C1D5: 0.5 h (n=3,17,20,31,2,16,2,5,30)	58.3 (± 25.3)			
C1D5: 1 h (n=2,19,21,31,2,16,2,5,31)	47.2 (± 12.7)			
C1D5: 2 h (n= 2,19,22,32,2,16,2,5,31)	30.6 (± 9.57)			
C1D5: 4 h (n=3,19,22,32,2,16,2,5,33)	13.2 (± 5.51)			
C1D5: 8 h (n=3,17,19,26,2,17,2,5,32)	3.41 (± 1.66)			
C1D5: 16 h (n=0,0,0,0,0,0,0,0,0)	99999 (± 99999)			
C1D5: 24 h (n=0,0,0,0,0,0,0,0,0)	99999 (± 99999)			
C1D5: 72 h (n=0,4,26,5,0,2,1,0,0)	99999 (± 99999)			
C2D1: 0 h (n=3,23,20,38,3,17,2,5,31)	0.0170 (± 0.0945)			
C2D1: 0.5 h (n=2,22,19,34,3,16,0,5,26)	57.8 (± 15.4)			
C2D1: 1 h (n=1,22,20,34,3,17,2,6,29)	51.5 (± 10.0)			
C2D1: 2 h (n=2,23,20,34,3,17,2,6,30)	38.8 (± 9.33)			
C2D1: 4 h (n=2,23,20,34,3,17,2,6,30)	25.1 (± 12.7)			
C2D1: 8 h (n=1,20,16,32,3,17,2,5,30)	7.91 (± 3.47)			
C2D1: 16 h (n=0,0,1,1,0,0,0,0,0)	99999 (± 99999)			
C2D1: 24 h (n=2,20,19,35,3,15,2,6,28)	1.06 (± 0.802)			
C2D5: 0 h (n=3,22,18,37,2,16,2,6,27)	2.14 (± 6.54)			
C2D5: 0.5 h (n=2,20,19,33,2,15,1,5,23)	64.2 (± 60.1)			
C2D5: 1 h (n=2,20,19,31,2,14,2,6,22)	69.8 (± 124)			
C2D5: 2 h (n=2,20,19,29,2,14,2,6,22)	28.6 (± 9.10)			
C2D5: 4 h (n=3,21,19,34,2,15,2,6,25)	12.0 (± 4.47)			
C2D5: 8 h (n=3,17,16,27,2,15,2,6,25)	3.33 (± 1.87)			
C2D5: 16 h (n=0,0,0,0,0,0,0,0,0)	99999 (± 99999)			

C2D5: 24 h (n=0,0,0,0,0,0,0,0)	99999 (± 99999)			
C2D5: 72 h (n=0,1,6,4,0,2,1,0,0)	99999 (± 99999)			
C2D5: 240 h (n=0,2,10,6,1,7,0,0,2)	0.00 (± 0.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B and C: Area Under Concentration From Time Zero to the Last Quantifiable Concentration (AUClast) of Nemvaleukin Alfa

End point title	Parts A, B and C: Area Under Concentration From Time Zero to the Last Quantifiable Concentration (AUClast) of Nemvaleukin Alfa ^[9]
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End point description:

The PK population consisted of all subjects who received at least 1 dose of nemvaleukin alfa and had at least 1 measurable serum concentration of nemvaleukin alfa at any scheduled PK time point. Here, "number of subjects analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable at specified timepoints. Here, "99999" means data could not be calculated due to less subject. Cycle 1 length = 14 days for Part A and 21 days for Part B and C; Cycle 2 length= 21 days for all parts. C1D1 (n=5,4,6,8,12,3,6,44,27,3, 34,24,26,36,3,20,2,6,34); C1D5 (n=5,4,6,7,9,3,4,35,15,3,33,19, 22,33,2,16,2,5,33); C2D1 (n=4,3,6,6,7,3,3,41,22,2, 23,20,35,3,17,1,6,29); C2D5 (n=3,4,5,5,7,2,3,35,19, 3,21,17,32,2,15,2,6,25)

End point type	Secondary
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End point timeframe:

Cycle (C) 1 and 2 Day (D) 1: 0, 0.5, 1, 2, 4, 8, 16, and 24 hours (h) post-dose; Cycle 1 Day 5: 0, 0.5, 1, 2, 4, 8, 16, 24, and 72 hours post-dose; Cycle 2 Day 5: 0, 0.5, 1, 2, 4, 8, 16, 24, 72, and 240 hours post-dose

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	6	8
Units: hour*nanogram per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1	2.96 (± 53.1)	17.0 (± 35.6)	66.5 (± 36.5)	195 (± 252.1)
C1D5	2.52 (± 17.3)	14.4 (± 23.6)	48.2 (± 55.9)	106 (± 205.5)
C2D1	2.47 (± 32.4)	15.3 (± 45.4)	69.2 (± 50.3)	274 (± 39.0)
C2D5	2.61 (± 16.6)	11.5 (± 18.4)	40.8 (± 21.2)	167 (± 51.5)

End point values	Part A, Dose Escalation: Nemvaleukin	Part A, Dose Escalation: Nemvaleukin	Part A, Dose Escalation: Nemvaleukin	Part B, Dose Expansion, Melanoma:
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	Alfa 6 mcg/kg	Alfa 8 mcg/kg	Alfa 10 mcg/kg	Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	3	6	44
Units: hour*nanogram per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1	557 (± 28.7)	616 (± 42.3)	719 (± 39.7)	608 (± 30.1)
C1D5	379 (± 46.0)	323 (± 84.1)	346 (± 47.8)	292 (± 61.4)
C2D1	478 (± 30.7)	512 (± 35.6)	573 (± 36.8)	517 (± 44.5)
C2D5	361 (± 50.4)	439 (± 3.5)	312 (± 131.0)	287 (± 60.9)

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	3	24	26
Units: hour*nanogram per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1	723 (± 23.2)	84.1 (± 39.5)	296 (± 35.0)	276 (± 31.4)
C1D5	312 (± 40.6)	56.7 (± 18.8)	158 (± 41.6)	130 (± 40.5)
C2D1	594 (± 25.9)	56.1 (± 12.9)	243 (± 41.5)	212 (± 39.6)
C2D5	329 (± 45.3)	52.0 (± 18.5)	134 (± 35.4)	128 (± 36.6)

End point values	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	3	20	2
Units: hour*nanogram per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1	222 (± 77.2)	698 (± 21.7)	715 (± 37.6)	543 (± 25.0)
C1D5	139 (± 53.4)	343 (± 6.8)	368 (± 56.7)	393 (± 45.8)
C2D1	224 (± 85.0)	625 (± 12.5)	562 (± 33.5)	590 (± 99999)
C2D5	153 (± 73.4)	275 (± 15.0)	346 (± 43.9)	413 (± 57.6)

End point values	Part C, Safety Run-in: Nemvaleukin Alfa 3 mcg/kg	Part C, Cohort 1: Nemvaleukin Alfa +		
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		Pembrolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	34		
Units: hour*nanogram per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1	248 (± 23.4)	286 (± 22.1)		
C1D5	121 (± 68.5)	143 (± 26.2)		
C2D1	195 (± 50.1)	235 (± 30.8)		
C2D5	120 (± 72.3)	135 (± 54.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B and C: Maximum Observed Serum Concentration (Cmax) of Nemvaleukin Alfa

End point title	Parts A, B and C: Maximum Observed Serum Concentration (Cmax) of Nemvaleukin Alfa ^[10]
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End point description:

The PK population consisted of all subjects who received at least 1 dose of nemvaleukin alfa and had at least 1 measurable serum concentration of nemvaleukin alfa at any scheduled PK time point. Here, "number of subjects analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable at specified timepoints. Here, "99999" means data could not be calculated due to less subject. Cycle 1 length = 14 days for Part A and 21 days for Part B and C; Cycle 2 length= 21 days for all parts. Cycle 1 length = 14 days for Part A and 21 days for Part B and C; Cycle 2 length= 21 days for all parts. C1D1 (n=5,4,6,8,11,3,6,44,27,3,23,25,36,3,18,2,6,34); C1D5 (n=5,4,6,8,9,3,4,36,15,3,19,22,33,2,16,2,5,33); C2D1 (n=4,2,6,8,6,3,3,40,22,2,23,20,35,3,17,1,6,27); C2D5 (n=3,4,6,5,7,2,3,35,19,3,21,19,32,2,15,2,6,24).

End point type	Secondary
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End point timeframe:

Cycle (C) 1 and 2 Day (D) 1: 0, 0.5, 1, 2, 4, 8, 16, and 24 hours (h) post-dose; Cycle 1 Day 5: 0, 0.5, 1, 2, 4, 8, 16, 24, and 72 hours post-dose; Cycle 2 Day 5: 0, 0.5, 1, 2, 4, 8, 16, 24, 72, and 240 hours post-dose

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	6	8
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	2.09 (± 41.4)	6.72 (± 21.3)	20.5 (± 26.8)	47.6 (± 177.8)
C1D5	1.99 (± 10.3)	6.36 (± 24.5)	37.4 (± 19.2)	41.8 (± 178.7)

C2D1	1.72 (± 35.1)	5.34 (± 2.2)	19.8 (± 32.3)	65.3 (± 27.5)
C2D5	1.90 (± 11.0)	6.39 (± 12.7)	16.7 (± 18.5)	52.9 (± 48.1)

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	3	6	44
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	113 (± 33.7)	151 (± 36.7)	157 (± 19.4)	99.4 (± 40.8)
C1D5	108 (± 22.5)	112 (± 13.5)	104 (± 12.5)	82.1 (± 32.3)
C2D1	113 (± 24.7)	112 (± 13.0)	116 (± 33.1)	108 (± 86.7)
C2D5	97.4 (± 29.0)	95.7 (± 37.0)	83.8 (± 57.4)	103 (± 69.5)

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	3	23	25
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	124 (± 34.2)	18.1 (± 15.4)	57.5 (± 86.5)	59.5 (± 32.6)
C1D5	95.1 (± 33.8)	19.2 (± 21.7)	53.1 (± 57.9)	54.4 (± 51.8)
C2D1	119 (± 27.6)	15.6 (± 18.1)	58.1 (± 81.2)	55.6 (± 31.4)
C2D5	99.6 (± 18.3)	14.6 (± 24.0)	51.7 (± 52.0)	51.0 (± 25.9)

End point values	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	3	18	2
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	45.8 (± 48.8)	131 (± 15.8)	133 (± 31.7)	89.3 (± 3.0)
C1D5	47.0 (± 40.1)	118 (± 1.8)	101 (± 51.5)	104 (± 1.8)
C2D1	47.2 (± 47.7)	112 (± 15.3)	128 (± 30.6)	124 (± 99999)
C2D5	49.8 (± 52.6)	99.2 (± 20.3)	96.6 (± 29.7)	94.4 (± 12.5)

End point values	Part C, Safety Run-in: Nemvaleukin Alfa 3 mcg/kg	Part C, Cohort 1: Nemvaleukin Alfa + Pembrolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	34		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	65.6 (± 24.4)	61.4 (± 22.8)		
C1D5	46.5 (± 41.6)	55.8 (± 37.5)		
C2D1	52.9 (± 21.9)	55.8 (± 26.9)		
C2D5	40.8 (± 26.9)	50.3 (± 67.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B and C: Time to Reach Cmax (Tmax) of Nemvaleukin Alfa

End point title	Parts A, B and C: Time to Reach Cmax (Tmax) of Nemvaleukin Alfa ^[11]
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End point description:

The PK population consisted of all subjects who received at least 1 dose of nemvaleukin alfa and had at least 1 measurable serum concentration of nemvaleukin alfa at any scheduled PK time point. Here, "number of subjects analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable at specified timepoints. Here, "99999" means data could not be calculated due to less subject. Cycle 1 length = 14 days for Part A and 21 days for Part B and C; Cycle 2 length= 21 days for all parts. Cycle 1 length = 14 days for Part A and 21 days for Part B and C; Cycle 2 length= 21 days for all parts. C1D1 (n=5,4,6,8,11,3,6,44,27,3,23,25,36,3,18,2,6,34); C1D5 (n=5,4,6,7,9,3,4,36,15,3,19,22,33,2,16,2,5,33); C2D1 (n=4,2,6,6,6,3,3,44,22,2,23,20,35,3,17,1,6,27); C2D5

End point type	Secondary
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End point timeframe:

Cycle (C) 1 and 2 Day (D) 1: 0, 0.5, 1, 2, 4, 8, 16, and 24 hours (h) post-dose; Cycle 1 Day 5: 0, 0.5, 1, 2, 4, 8, 16, 24, and 72 hours post-dose; Cycle 2 Day 5: 0, 0.5, 1, 2, 4, 8, 16, 24, 72, and 240 hours post-dose

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	6	8
Units: hours				
median (full range (min-max))				

C1D1	0.60 (0.57 to 0.83)	0.63 (0.52 to 0.73)	0.55 (0.50 to 0.78)	0.57 (0.50 to 0.75)
C1D5	0.70 (0.50 to 0.80)	0.60 (0.48 to 0.82)	0.54 (0.50 to 0.80)	0.55 (0.50 to 0.67)
C2D1	0.67 (0.58 to 0.80)	0.73 (0.72 to 0.75)	0.53 (0.50 to 0.58)	0.55 (0.50 to 0.87)
C2D5	0.63 (0.55 to 0.80)	0.57 (0.50 to 0.68)	0.55 (0.50 to 0.75)	0.68 (0.52 to 1.58)

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	3	6	44
Units: hours				
median (full range (min-max))				
C1D1	0.57 (0.50 to 0.70)	0.57 (0.53 to 0.57)	0.51 (0.50 to 0.62)	0.52 (0.50 to 0.75)
C1D5	0.58 (0.53 to 0.73)	0.53 (0.53 to 0.58)	0.53 (0.50 to 0.68)	0.51 (0.50 to 0.80)
C2D1	0.58 (0.55 to 0.73)	0.53 (0.52 to 0.58)	0.52 (0.50 to 0.63)	0.50 (0.50 to 0.77)
C2D5	0.60 (0.50 to 0.75)	0.58 (0.58 to 0.58)	0.52 (0.50 to 0.52)	0.50 (0.50 to 0.77)

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	3	23	25
Units: hours				
median (full range (min-max))				
C1D1	0.50 (0.50 to 0.67)	0.75 (0.57 to 0.98)	0.55 (0.50 to 0.73)	0.52 (0.40 to 0.63)
C1D5	0.50 (0.43 to 0.58)	0.58 (0.55 to 0.72)	0.53 (0.30 to 0.85)	0.55 (0.48 to 0.68)
C2D1	0.50 (0.50 to 0.60)	0.71 (0.60 to 0.82)	0.53 (0.47 to 1.00)	0.53 (0.50 to 0.58)
C2D5	0.50 (0.50 to 0.67)	0.72 (0.55 to 0.73)	0.55 (0.50 to 1.08)	0.50 (0.48 to 0.62)

End point values	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	3	18	2
Units: hours				
median (full range (min-max))				
C1D1	0.50 (0.50 to 0.82)	0.50 (0.50 to 0.67)	0.53 (0.45 to 1.00)	0.78 (0.50 to 1.07)
C1D5	0.50 (0.50 to 0.75)	0.58 (0.58 to 0.58)	0.52 (0.45 to 0.63)	0.83 (0.57 to 1.08)
C2D1	0.50 (0.50 to 0.77)	0.55 (0.50 to 0.58)	0.52 (0.48 to 0.68)	1.00 (1.00 to 1.00)
C2D5	0.50 (0.50 to 0.62)	0.56 (0.50 to 0.62)	0.52 (0.50 to 0.58)	0.77 (0.53 to 1.00)

End point values	Part C, Safety Run-in: Nemvaleukin Alfa 3 mcg/kg	Part C, Cohort 1: Nemvaleukin Alfa + Pembrolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	34		
Units: hours				
median (full range (min-max))				
C1D1	0.73 (0.58 to 0.75)	0.55 (0.48 to 1.00)		
C1D5	0.73 (0.55 to 0.77)	0.57 (0.50 to 1.00)		
C2D1	0.68 (0.57 to 0.80)	0.55 (0.50 to 1.00)		
C2D5	0.68 (0.58 to 0.78)	0.55 (0.52 to 1.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B, and C: Proportion of Positive Anti-Nemvaleukin Alfa Antibodies (ADA)

End point title	Parts A, B, and C: Proportion of Positive Anti-Nemvaleukin Alfa Antibodies (ADA) ^[12]
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End point description:

Overall proportion was calculated as: Number of subjects (overall positive)/total number of subjects in the cohort. Overall positive: Subjects with at least 1 treatment-emergent ADA positive sample at any time during the treatment period. Immunogenicity analysis set included all subjects who received at least one dose of active study drug and had at least one post baseline blood sample collected to assess immunogenicity.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 9 months (for Part A); up to 40.3 months (for Part B); up to 50.5 months (for Part C)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	7	8
Units: proportion of positive ADA				
number (not applicable)	0.00	0.00	0.143	0.125

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	3	5	45
Units: proportion of positive ADA				
number (not applicable)	0.417	0.333	0.600	0.467

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	3	24	24
Units: proportion of positive ADA				
number (not applicable)	0.500	0.00	0.250	0.208

End point values	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	3	20	2
Units: proportion of positive ADA				
number (not applicable)	0.581	0.667	0.200	0.00

End point values	Part C, Safety Run-in: Nemvaleukin Alfa 3 mcg/kg	Part C, Cohort 1: Nemvaleukin Alfa + Pembrolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	34		
Units: proportion of positive ADA				
number (not applicable)	0.667	0.294		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B, and C: Immune ORR (iORR) Based on Immune RECIST (iRECIST)

End point title	Parts A, B, and C: Immune ORR (iORR) Based on Immune RECIST (iRECIST)
End point description: iORR was defined as the percentage of subjects with objective evidence of immune CR (iCR) or immune PR (iPR) based on iRECIST guidelines. Data collection or analysis based on immune-related response criteria (irRC) and iRECIST was not performed as iRECIST was implemented during the middle of the study conduct to replace irRC. Hence, no data was reported in this endpoint.	
End point type	Secondary
End point timeframe: From first dose of study drug up to 9 months for Part A; up to 40.3 months for Part B; up to 50.5 months for Part C	

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[13]	0 ^[14]	0 ^[15]	0 ^[16]
Units: Percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[13] - Data collection or analysis based on irRC and iRECIST was not performed.

[14] - Data collection or analysis based on irRC and iRECIST was not performed.

[15] - Data collection or analysis based on irRC and iRECIST was not performed.

[16] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[17]	0 ^[18]	0 ^[19]	0 ^[20]
Units: Percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[17] - Data collection or analysis based on irRC and iRECIST was not performed.

[18] - Data collection or analysis based on irRC and iRECIST was not performed.

[19] - Data collection or analysis based on irRC and iRECIST was not performed.

[20] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[21]	0 ^[22]	0 ^[23]	0 ^[24]
Units: Percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[21] - Data collection or analysis based on irRC and iRECIST was not performed.

[22] - Data collection or analysis based on irRC and iRECIST was not performed.

[23] - Data collection or analysis based on irRC and iRECIST was not performed.

[24] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa +Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[25]	0 ^[26]	0 ^[27]	0 ^[28]
Units: Percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[25] - Data collection or analysis based on irRC and iRECIST was not performed.

[26] - Data collection or analysis based on irRC and iRECIST was not performed.

[27] - Data collection or analysis based on irRC and iRECIST was not performed.

[28] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[29]			
Units: Percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[29] - Data collection or analysis based on irRC and iRECIST was not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B, and C: Disease Control Rate (DCR) Based on RECIST v.1.1

End point title	Parts A, B, and C: Disease Control Rate (DCR) Based on RECIST v.1.1
End point description:	
Disease control rate was defined as the percentage of subjects with objective evidence of CR, PR, or SD based on RECIST v.1.1. CR: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm. PR: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. SD: Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum diameters while on study. The antitumor evaluable population consisted of subjects who complete 2 cycles of therapy and had at least one follow-up scan.	
End point type	Secondary
End point timeframe:	
From first dose of study drug up to 9 months for Part A; up to 40.3 months for Part B; up to 50.5 months for Part C	

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 60.2)	25.0 (0.6 to 80.6)	20.0 (0.5 to 71.6)	60.0 (14.7 to 94.7)

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	3	4	46
Units: percentage of subjects				
number (confidence interval 95%)	33.3 (7.5 to 70.1)	33.3 (0.8 to 90.6)	25.0 (0.6 to 80.6)	47.8 (32.9 to 63.1)

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	3	36	22
Units: percentage of subjects				
number (confidence interval 95%)	50.0 (28.2 to 71.8)	0.0 (0.0 to 70.8)	30.6 (16.3 to 48.1)	22.7 (7.8 to 45.4)

End point values	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	39	3	18
Units: percentage of subjects				
number (confidence interval 95%)	47.6 (25.7 to 70.2)	46.2 (30.1 to 62.8)	66.7 (9.4 to 99.2)	50.0 (26.0 to 74.0)

End point values	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: percentage of subjects				
number (confidence interval 95%)	100 (15.8 to 100.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B, and C: Immune DCR (iDCR) Based on iRECIST v1.1

End point title	Parts A, B, and C: Immune DCR (iDCR) Based on iRECIST v1.1
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End point description:

iDCR was defined as the percentage of subjects with objective evidence of iCR, iPR (where iCR or iPR required confirmation), or immune stable disease (iSD) (where the iSD requires to occur at Cycle 4 or later). Data collection or analysis based on irRC and iRECIST was not performed as iRECIST was implemented during the middle of the study conduct to replace irRC. Hence, no data was reported in this outcome measure.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 9 months for Part A; up to 40.3 months for Part B; up to 50.5 months for Part C

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[30]	0 ^[31]	0 ^[32]	0 ^[33]
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[30] - Data collection or analysis based on irRC and iRECIST was not performed

[31] - Data collection or analysis based on irRC and iRECIST was not performed.

[32] - Data collection or analysis based on irRC and iRECIST was not performed.

[33] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[34]	0 ^[35]	0 ^[36]	0 ^[37]
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[34] - Data collection or analysis based on irRC and iRECIST was not performed.

[35] - Data collection or analysis based on irRC and iRECIST was not performed.

[36] - Data collection or analysis based on irRC and iRECIST was not performed.

[37] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[38]	0 ^[39]	0 ^[40]	0 ^[41]
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[38] - Data collection or analysis based on irRC and iRECIST was not performed.

[39] - Data collection or analysis based on irRC and iRECIST was not performed.

[40] - Data collection or analysis based on irRC and iRECIST was not performed.

[41] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa +Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[42]	0 ^[43]	0 ^[44]	0 ^[45]
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[42] - Data collection or analysis based on irRC and iRECIST was not performed.

[43] - Data collection or analysis based on irRC and iRECIST was not performed.

[44] - Data collection or analysis based on irRC and iRECIST was not performed.

[45] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[46]			
Units: percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[46] - Data collection or analysis based on irRC and iRECIST was not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Parts B, and C: Duration of Response (DOR) Based on RECIST v1.1

End point title	Parts B, and C: Duration of Response (DOR) Based on RECIST v1.1 ^[47]
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End point description:

DOR: time from the first documentation of response (CR or PR) to first documentation of objective tumor progression or death due to any cause. CR: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm. PR: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. PD: At least a 20% increase in sum of diameters of target lesions, taking as reference smallest sum on study. In addition to the relative increase of 20%, sum must also demonstrate an absolute increase of at least 5 mm. Antitumor evaluable population. "Number of subjects analysed" signifies subjects who had CR or PR. "99999" means data could not be estimated due to insufficient events.

End point type	Secondary
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End point timeframe:

From the first documentation of response (CR or PR) to the first documentation of objective tumor progression or death due to any cause (up to 40.3 months for Part B and up to 50.5 months for Part C)

Notes:

[47] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 + Safety Run-in: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	4	0 ^[48]	6
Units: weeks				
median (confidence interval 95%)	18.43 (6.14 to 99999)	28.86 (12.43 to 99999)	(to)	35.14 (8.29 to 160.14)

Notes:

[48] - No subjects had CR or PR.

End point values	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	7	5	2
Units: weeks				
median (confidence interval 95%)	99999 (99999 to 99999)	63.14 (6.86 to 99999)	99999 (7.14 to 99999)	99999 (99999 to 99999)

End point values	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: weeks				
median (confidence interval 95%)	39.07 (13.14 to 65.00)	27.86 (-99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts B, and C: Immune DOR (iDOR) Based on iRECIST

End point title	Parts B, and C: Immune DOR (iDOR) Based on iRECIST ^[49]
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End point description:

iDOR was defined as the time from the first documentation of response (iCR or iPR) to the first documentation of objective tumor progression (immune confirmed progressive disease [iCPD]) or death due to any cause based on iRECIST. Data collection or analysis based on irRC and iRECIST was not performed as iRECIST was implemented during the middle of the study conduct to replace irRC. Hence, no data was reported in this endpoint.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 40.3 months for Part B; up to 50.5 months for Part C

Notes:

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[50]	0 ^[51]	0 ^[52]	0 ^[53]
Units: weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[50] - Data collection or analysis based on irRC and iRECIST was not performed.

[51] - Data collection or analysis based on irRC and iRECIST was not performed.

[52] - Data collection or analysis based on irRC and iRECIST was not performed.

[53] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[54]	0 ^[55]	0 ^[56]	0 ^[57]
Units: weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[54] - Data collection or analysis based on irRC and iRECIST was not performed.

[55] - Data collection or analysis based on irRC and iRECIST was not performed.

[56] - Data collection or analysis based on irRC and iRECIST was not performed.

[57] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[58]	0 ^[59]		
Units: weeks				
median (confidence interval 95%)	(to)	(to)		

Notes:

[58] - Data collection or analysis based on irRC and iRECIST was not performed.

[59] - Data collection or analysis based on irRC and iRECIST was not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B and Part C Cohorts C5, C6, C7: Durable Response Rate (DRR) Based on RECIST v.1.1

End point title	Part B and Part C Cohorts C5, C6, C7: Durable Response Rate (DRR) Based on RECIST v.1.1 ^[60]
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End point description:

DRR was defined as the percentage of subjects with an objective response (complete or partial response per RECIST 1.1) lasting continuously for 6 months and starting any time within 12 months of initiating the study drug. As pre-specified in statistical analysis plan (SAP), this endpoint of DRR was not

summarized and hence, no data was reported in this endpoint.

End point type	Secondary
End point timeframe:	
From first dose of study drug up to 40.3 months for Part B; up to 50.5 months for Part C	

Notes:

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[61]	0 ^[62]	0 ^[63]	0 ^[64]
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[61] - As pre-specified in SAP, this endpoint was not summarized and hence, no data was reported.

[62] - As pre-specified in SAP, this endpoint was not summarized and hence, no data was reported.

[63] - As pre-specified in SAP, this endpoint was not summarized and hence, no data was reported.

[64] - As pre-specified in SAP, this endpoint was not summarized and hence, no data was reported.

End point values	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa +Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[65]	0 ^[66]	0 ^[67]	0 ^[68]
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[65] - As pre-specified in SAP, this endpoint was not summarized and hence, no data was reported.

[66] - As pre-specified in SAP, this endpoint was not summarized and hence, no data was reported.

[67] - As pre-specified in SAP, this endpoint was not summarized and hence, no data was reported.

[68] - As pre-specified in SAP, this endpoint was not summarized and hence, no data was reported.

End point values	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[69]	0 ^[70]		
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)		

Notes:

[69] - As pre-specified in SAP, this endpoint was not summarized and hence, no data was reported.

[70] - As pre-specified in SAP, this endpoint was not summarized and hence, no data was reported.

Statistical analyses

Secondary: Part B and Part C Cohorts C5, C6, C7: Immune DRR (iDRR) Based on iRECIST

End point title	Part B and Part C Cohorts C5, C6, C7: Immune DRR (iDRR) Based on iRECIST ^[71]
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End point description:

iDRR was defined as the percentage of subjects with an objective response (complete or partial response per iRECIST) lasting continuously for 6 months and starting any time within 12 months of initiating the study drug. Data collection or analysis based on irRC and iRECIST was not performed as iRECIST was implemented during the middle of the study conduct to replace irRC. Hence, no data was reported in this endpoint.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 40.3 months for Part B; up to 50.5 months for Part C

Notes:

[71] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[72]	0 ^[73]	0 ^[74]	0 ^[75]
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[72] - Data collection or analysis based on irRC and iRECIST was not performed.

[73] - Data collection or analysis based on irRC and iRECIST was not performed.

[74] - Data collection or analysis based on irRC and iRECIST was not performed.

[75] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[76]	0 ^[77]	0 ^[78]	0 ^[79]
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[76] - Data collection or analysis based on irRC and iRECIST was not performed.

[77] - Data collection or analysis based on irRC and iRECIST was not performed.

[78] - Data collection or analysis based on irRC and iRECIST was not performed.

[79] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part C, Cohort 6: Nemvaleukin Alfa +	Part C, Cohort 7: Nemvaleukin Alfa +		
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	Pembrolizumab	Pembrolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[80]	0 ^[81]		
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)		

Notes:

[80] - Data collection or analysis based on irRC and iRECIST was not performed.

[81] - Data collection or analysis based on irRC and iRECIST was not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B and Part C Cohorts C5, C6, C7: Progression-free Survival (PFS) Based on RECIST v.1.1

End point title	Part B and Part C Cohorts C5, C6, C7: Progression-free Survival (PFS) Based on RECIST v.1.1 ^[82]
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End point description:

Progression-free survival was defined as the time from the first dose of nemvaleukin to the first documentation of objective tumor progression or death due to any cause. PD: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this included the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. The antitumor evaluable population consisted of subjects who complete 2 cycles of therapy and had at least one follow-up scan. "99999" means data could not be estimated due to insufficient events.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to the first documentation of objective tumor progression or death due to any cause (up to 40.3 months for Part B and up to 50.5 months for Part C)

Notes:

[82] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	22	3	18
Units: weeks				
median (confidence interval 95%)	16.14 (10.57 to 17.14)	12.43 (4.43 to 22.57)	99999 (10.29 to 99999)	18.64 (6.14 to 27.14)

End point values	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: weeks				
median (confidence interval 95%)	35.57 (18.71			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B and Part C Cohorts C5, C6, C7: Immune PFS (iPFS)

End point title	Part B and Part C Cohorts C5, C6, C7: Immune PFS (iPFS) ^[83]
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End point description:

iPFS was defined as the time from the first dose of study medication to the first documentation of objective tumor progression based on iRECIST (immune confirmed progressive disease [iCPD]) or death due to any cause. Data collection or analysis based on irRC and iRECIST was not performed as iRECIST was implemented during the middle of the study conduct to replace irRC. Hence, no data was reported in this endpoint.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 40.3 months for Part B; up to 50.5 months for Part C

Notes:

[83] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[84]	0 ^[85]	0 ^[86]	0 ^[87]
Units: weeks				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[84] - Data collection or analysis based on irRC and iRECIST was not performed.

[85] - Data collection or analysis based on irRC and iRECIST was not performed.

[86] - Data collection or analysis based on irRC and iRECIST was not performed.

[87] - Data collection or analysis based on irRC and iRECIST was not performed.

End point values	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[88]			
Units: weeks				
number (confidence interval 95%)	(to)			

Notes:

[88] - Data collection or analysis based on irRC and iRECIST was not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B and C: Maximum Cell Count of Whole Blood FoxP3+ T Cells (Tregs), Total Cluster of Differentiation (CD)8+ T Cells and Natural Killer (NK) Cells

End point title	Parts A, B and C: Maximum Cell Count of Whole Blood FoxP3+ T Cells (Tregs), Total Cluster of Differentiation (CD)8+ T Cells and Natural Killer (NK) Cells ^[89]
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End point description:

The pharmacodynamic (PD) population consisted of all subjects who received at least 1 dose of nemvaleukin alfa and had at least one available postbaseline PD measurement. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable at specified timepoints. Here, "99999" means data could not be calculated due to less subject. Whole Blood FoxP3+ T Cells (Tregs) (n=5,4,7,8,12,3,7,27,47,3,25,26,39,3,21,1,6,36); Total CD8+ T Cells (n=5,4,7,8,12,3,7,27,47,3,25,26,39,3,21,2,6,36); NK Cells (n=5,4,7,8,12,3,7,27,47,3,25,26,39,3,21,2,6,36).

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 (Cycle 1 length = 14 days for Part A and 21 days for Part B)

Notes:

[89] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	7	8
Units: cells per microliters (cells/mcL)				
arithmetic mean (standard deviation)				
Whole Blood FoxP3+ T Cells (Tregs)	32.0 (± 11.3)	50.5 (± 53.7)	56.6 (± 22.3)	46.3 (± 21.8)
Total CD8+ T Cells	247 (± 107)	204 (± 89.2)	262 (± 64.2)	466 (± 255)
NK Cells	197 (± 61.4)	343 (± 20.6)	467 (± 313)	685 (± 307)

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	3	7	47
Units: cells per microliters (cells/mcL)				
arithmetic mean (standard deviation)				
Whole Blood FoxP3+ T Cells (Tregs)	43.3 (± 28.2)	57.4 (± 14.4)	51.3 (± 36.0)	47.9 (± 24.0)
Total CD8+ T Cells	610 (± 570)	704 (± 559)	703 (± 502)	773 (± 422)
NK Cells	1053 (± 660)	978 (± 400)	1038 (± 1028)	1470 (± 873)

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	3	25	26
Units: cells per microliters (cells/mcL)				
arithmetic mean (standard deviation)				
Whole Blood FoxP3+ T Cells (Tregs)	40.3 (± 23.5)	27.4 (± 7.31)	37.8 (± 24.5)	41.6 (± 27.7)
Total CD8+ T Cells	1392 (± 1053)	262 (± 186)	533 (± 328)	688 (± 384)
NK Cells	1279 (± 642)	531 (± 296)	760 (± 458)	813 (± 436)

End point values	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	3	21	2
Units: cells per microliters (cells/mcL)				
arithmetic mean (standard deviation)				
Whole Blood FoxP3+ T Cells (Tregs)	44.3 (± 22.5)	51.1 (± 9.85)	52.6 (± 31.3)	33.1 (± 99999)
Total CD8+ T Cells	718 (± 567)	924 (± 638)	762 (± 538)	445 (± 349)
NK Cells	889 (± 438)	1081 (± 787)	1064 (± 445)	1298 (± 334)

End point values	Part C, Safety Run-in: Nemvaleukin Alfa 3 mcg/kg	Part C, Cohort 1: Nemvaleukin Alfa + Pembrolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	36		
Units: cells per microliters (cells/mcL)				
arithmetic mean (standard deviation)				
Whole Blood FoxP3+ T Cells (Tregs)	50.9 (± 23.9)	42.6 (± 28.3)		
Total CD8+ T Cells	551 (± 433)	562 (± 373)		
NK Cells	804 (± 196)	771 (± 503)		

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A, B and C: Maximum Cell Count of Interferon-gamma (INF-γ) and Interleukin 6 (IL-6)

End point title	Parts A, B and C: Maximum Cell Count of Interferon-gamma (INF-γ) and Interleukin 6 (IL-6) ^[90]
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End point description:

The PD population consisted of all subjects who received at least 1 dose of nemvaleukin alfa and had at least one available postbaseline PD measurement. Here, "99999" means data could not be calculated due to less subject. INF-γ: C1D1 (n=5,4,7,8,10,1,7,12,15,0,4,3,21,1,5,0,2,29); INF-γ: C1D5 (n=5,4,5,7,8,2,4,34,13,0,14,17, 17,2,17,2,4,29); INF-γ: C2D1 (n=4,4,5,5,1,2,1,16,4, 0,5,4,4,1,3,0,1,7); INF-γ: Cycle 2 Day 5 (n=3,4,6,5,6,2,3,33,10, 0,10,17,21,2,12,2,4,20); IL-6: C1D1 (n=5,3,7,8,10,2,6,29,13, 0,16,18,14,2,15,0,5,29); IL-6: C1D5 (n=5,4,7,7,9,2,4,33,15,1,17,20,16,2,18,2,5,31); IL-6: C2D1 (n=5,4,7,6,6,2,4,31,12,1,15, 12,11,2,12,0,6,23); IL-6: C2D5 (n=3,4,7,5,5,2,3,30,10, 3,17,12,15,2,12,2,6,21).

End point type Secondary

End point timeframe:

Cycle 1 Days 1 and 5; Cycle 2 Days 1 and 5 (Cycle 1 length = 14 days for Part A and 21 days for Part B and C; Cycle 2 length= 21 days for all parts)

Notes:

[90] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only descriptive data was planned.

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 0.1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 0.3 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 1 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 3 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	7	8
Units: nanogram per liter (ng/L)				
arithmetic mean (standard deviation)				
INF-γ: C1D1	23.0 (± 10.3)	19.8 (± 10.4)	14.9 (± 6.10)	31.3 (± 12.7)
INF-γ: C1D5	24.7 (± 10.8)	29.1 (± 10.7)	13.8 (± 7.71)	173 (± 199)
INF-γ: C2D1	28.0 (± 24.1)	18.3 (± 3.70)	12.2 (± 4.56)	43.3 (± 28.4)
INF-γ: C2D5	31.2 (± 19.2)	24.3 (± 10.8)	16.3 (± 8.03)	53.2 (± 15.3)
IL-6: C1D1	104 (± 61.8)	118 (± 33.0)	169 (± 280)	938 (± 845)
IL-6: C1D5	116 (± 121)	113 (± 51.9)	223 (± 229)	2022 (± 1491)
IL-6: C2D1	41.9 (± 14.7)	106 (± 76.4)	191 (± 240)	883 (± 570)
IL-6: C2D5	56.2 (± 19.1)	95.2 (± 45.3)	125 (± 89.3)	1145 (± 700)

End point values	Part A, Dose Escalation: Nemvaleukin Alfa 6 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 8 mcg/kg	Part A, Dose Escalation: Nemvaleukin Alfa 10 mcg/kg	Part B, Dose Expansion, Melanoma: Nemvaleukin Alfa 6 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	2	7
Units: nanogram per liter (ng/L)				
arithmetic mean (standard deviation)				
INF-γ: C1D1	108 (± 130)	26.4 (± 99999)	18.0 (± 99999)	34.7 (± 22.7)
INF-γ: C1D5	129 (± 84.1)	585 (± 313)	335 (± 74.3)	209 (± 191)
INF-γ: C2D1	33.9 (± 99999)	19.8 (± 4.81)	15.7 (± 99999)	43.3 (± 41.9)
INF-γ: C2D5	45.1 (± 28.5)	171 (± 78.4)	84.8 (± 58.6)	141 (± 139)
IL-6: C1D1	254 (± 177)	148 (± 14.6)	1826 (± 3474)	323 (± 630)
IL-6: C1D5	802 (± 797)	677 (± 751)	5240 (± 5279)	699 (± 538)
IL-6: C2D1	351 (± 448)	169 (± 18.1)	519 (± 475)	311 (± 447)
IL-6: C2D5	399 (± 243)	252 (± 124)	1372 (± 1841)	341 (± 252)

End point values	Part B, Dose Expansion, RCC: Nemvaleukin Alfa 6 mcg/kg	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	3	17	20
Units: nanogram per liter (ng/L)				
arithmetic mean (standard deviation)				
INF-γ: C1D1	18.6 (± 4.19)	99999 (± 99999)	34.5 (± 15.6)	18.9 (± 3.71)
INF-γ: C1D5	162 (± 183)	99999 (± 99999)	94.3 (± 103)	70.9 (± 54.7)
INF-γ: C2D1	50.4 (± 22.7)	99999 (± 99999)	21.1 (± 6.39)	19.7 (± 3.87)
INF-γ: C2D5	120 (± 178)	99999 (± 99999)	47.7 (± 43.5)	38.5 (± 22.2)
IL-6: C1D1	211 (± 143)	99999 (± 99999)	274 (± 234)	306 (± 181)
IL-6: C1D5	723 (± 1077)	151 (± 99999)	513 (± 585)	527 (± 538)
IL-6: C2D1	254 (± 151)	95.7 (± 99999)	276 (± 249)	372 (± 279)
IL-6: C2D5	318 (± 174)	116 (± 33.0)	290 (± 296)	269 (± 155)

End point values	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	2	18	2
Units: nanogram per liter (ng/L)				
arithmetic mean (standard deviation)				
INF-γ: C1D1	84.4 (± 87.8)	68.3 (± 99999)	31.7 (± 24.2)	99999 (± 99999)
INF-γ: C1D5	64.4 (± 61.5)	390 (± 530)	279 (± 526)	87.7 (± 42.1)
INF-γ: C2D1	62.4 (± 20.7)	43.5 (± 99999)	25.8 (± 1.04)	99999 (± 99999)
INF-γ: C2D5	54.0 (± 36.1)	326 (± 124)	101 (± 71.0)	41.9 (± 1.42)
IL-6: C1D1	706 (± 1757)	200 (± 101)	757 (± 2165)	99999 (± 99999)
IL-6: C1D5	273 (± 244)	1049 (± 1288)	635 (± 500)	232 (± 13.8)
IL-6: C2D1	282 (± 176)	718 (± 649)	264 (± 379)	99999 (± 99999)
IL-6: C2D5	269 (± 174)	165 (± 98.6)	267 (± 172)	123 (± 19.0)

End point values	Part C, Safety Run-in: Nemvaleukin	Part C, Cohort 1: Nemvaleukin		
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	Alfa 3 mcg/kg	Alfa + Pembrolizumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6	31		
Units: nanogram per liter (ng/L)				
arithmetic mean (standard deviation)				
INF-γ: C1D1	23.3 (± 7.40)	77.0 (± 106)		
INF-γ: C1D5	48.2 (± 30.3)	92.6 (± 86.4)		
INF-γ: C2D1	15.4 (± 99999)	70.9 (± 102)		
INF-γ: C2D5	60.3 (± 19.5)	73.3 (± 77.7)		
IL-6: C1D1	506 (± 137)	667 (± 1020)		
IL-6: C1D5	524 (± 180)	1269 (± 1807)		
IL-6: C2D1	254 (± 99.4)	669 (± 1075)		
IL-6: C2D5	425 (± 339)	929 (± 1962)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug until 30 days after last dose (up to 10 months for Part A; up to 41.3 months for Part B; up to 51.5 months for Part C)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	Part A: Nemvaleukin Alfa 0.1 mcg/kg
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.1 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Reporting group title	Part A: Nemvaleukin Alfa 0.3 mcg/kg
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.3 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Reporting group title	Part A: Nemvaleukin Alfa 1 mcg/kg
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 1 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Reporting group title	Part A: Nemvaleukin Alfa 3 mcg/kg
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Reporting group title	Part A: Nemvaleukin Alfa 6 mcg/kg
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Reporting group title	Part A: Nemvaleukin Alfa 8 mcg/kg
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 8 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Reporting group title	Part A: Nemvaleukin Alfa 10 mcg/kg
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 10 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Reporting group title	Part B, Melanoma: Nemvaleukin Alfa 6 mcg/kg
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Reporting group description:

Subjects with melanoma received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Reporting group title	Part B, RCC: Nemvaleukin Alfa 6 mcg/kg
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Reporting group description:

Subjects with RCC received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in Cycle 1 (Cycle length = 14 days) and then in Cycle 2 and subsequent cycles (each Cycle length = 21 days) until disease progression or the subject met any discontinuation criteria.

Reporting group title	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg
Reporting group description:	
Subjects with any tumor type received nemvaleukin alfa 1 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.	
Reporting group title	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab
Reporting group description:	
Subjects with PD-1/L1 unapproved tumor types (PD-1/L1 treatment naive) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation. The Safety Run-in for nemvaleukin alfa 3 mcg/kg was combined with Cohort 1 of Part C due to same dosing level and regimen.	
Reporting group title	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
Reporting group description:	
Subjects with PD-1/L1 approved tumor types (PD-1/L1 treatment pretreated) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.	
Reporting group title	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab
Reporting group description:	
Subjects with PD-1/L1 approved tumor types (PD-1/L1 treatment naive) received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.	
Reporting group title	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa +Pembrolizumab
Reporting group description:	
Subjects rollover from Parts A or B received nemvaleukin alfa 3 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.	
Reporting group title	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
Reporting group description:	
Subjects with melanoma received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.	
Reporting group title	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab
Reporting group description:	
Subjects with NSCLC received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.	

Reporting group title	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab
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Reporting group description:

Subjects with SCCHN received nemvaleukin alfa 6 mcg/kg IV infusion administration daily from Days 1 to 5 in combination with pembrolizumab 200 mg IV infusion on Day 1 in each Cycle (cycle length = 21 days) for a maximum of 2 years for as long as the subject appeared to be deriving clinical benefit (i.e., objective response or SD) and had tolerated therapy well. Subjects could continue nemvaleukin alfa as monotherapy beyond the maximum of 2 years of treatment by switching to monotherapy at the joint discretion of the Investigator and Sponsor and if they did not meet any other criteria for discontinuation.

Serious adverse events	Part A: Nemvaleukin Alfa 0.1 mcg/kg	Part A: Nemvaleukin Alfa 0.3 mcg/kg	Part A: Nemvaleukin Alfa 1 mcg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism arterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Extravasation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine release syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase			

increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram T wave abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaccination complication			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stomal hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Brain oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Iritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess neck			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A: Nemvaleukin Alfa 3 mcg/kg	Part A: Nemvaleukin Alfa 6 mcg/kg	Part A: Nemvaleukin Alfa 8 mcg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 8 (37.50%)	5 / 12 (41.67%)	0 / 3 (0.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic carcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bladder transitional cell carcinoma subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders Embolism arterial subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions Extravasation subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia subjects affected / exposed	1 / 8 (12.50%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine release syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive			

subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			

subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram T wave abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaccination complication			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomal hernia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			

subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Iritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess neck			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis infective			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyelonephritis acute			

subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A: Nemvaleukin Alfa 10 mcg/kg	Part B, Melanoma: Nemvaleukin Alfa 6 mcg/kg	Part B, RCC: Nemvaleukin Alfa 6 mcg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)	11 / 47 (23.40%)	12 / 27 (44.44%)
number of deaths (all causes)	3	7	7
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism arterial			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Extravasation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine release syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram T wave abnormal			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vaccination complication			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomal hernia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	2 / 27 (7.41%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			

subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	2 / 27 (7.41%)
occurrences causally related to treatment / all	0 / 0	1 / 4	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Iritis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitritis			

subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			

subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			

subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 47 (0.00%)	2 / 27 (7.41%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 7 (14.29%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 7 (14.29%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			

subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess neck			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	2 / 27 (7.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Catheter site infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	1 / 7 (14.29%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			

subjects affected / exposed	0 / 7 (0.00%)	1 / 47 (2.13%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 +Safety Run-in: Nemvaleukin Alfa+Pembrolizumab	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	19 / 42 (45.24%)	10 / 26 (38.46%)
number of deaths (all causes)	0	7	7
number of deaths resulting from adverse events	0	3	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism arterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	2 / 42 (4.76%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			

subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatinine increased subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram T wave abnormal subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction subjects affected / exposed	0 / 3 (0.00%)	2 / 42 (4.76%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaccination complication subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomal hernia subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			

subjects affected / exposed	0 / 3 (0.00%)	2 / 42 (4.76%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Iritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 42 (7.14%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	2 / 42 (4.76%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess neck			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal abscess			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 42 (7.14%)	2 / 26 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			

subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 42 (4.76%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa +Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 26 (42.31%)	14 / 43 (32.56%)	2 / 3 (66.67%)
number of deaths (all causes)	8	8	1
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic carcinoma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			

subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism arterial			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Extravasation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine release syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			

subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram T wave abnormal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Infusion related reaction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaccination complication			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomal hernia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			

subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			

subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	1 / 26 (3.85%)	4 / 43 (9.30%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	6 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			

subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Iritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			

subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			

subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			

subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess neck			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bacteraemia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal abscess			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			

subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	2 / 26 (7.69%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 26 (0.00%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			

subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			

subjects affected / exposed	1 / 26 (3.85%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 21 (57.14%)	2 / 2 (100.00%)	
number of deaths (all causes)	8	1	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic carcinoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 21 (4.76%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Embolism arterial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Extravasation			

subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytokine release syndrome			
subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Vaginal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 21 (0.00%)	1 / 2 (50.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	1 / 21 (4.76%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive			
subjects affected / exposed	1 / 21 (4.76%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pneumothorax			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood bilirubin increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram T wave abnormal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin I increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaccination complication			
subjects affected / exposed	1 / 21 (4.76%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomal hernia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	0 / 21 (0.00%)	1 / 2 (50.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular extrasystoles			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Depressed level of consciousness subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy subjects affected / exposed	1 / 21 (4.76%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope subjects affected / exposed	1 / 21 (4.76%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			

Febrile neutropenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Iritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ascites			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 21 (4.76%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertransaminaemia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hepatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Myositis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess neck			
subjects affected / exposed	0 / 21 (0.00%)	1 / 2 (50.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal abscess			

subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			

subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Starvation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 21 (4.76%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Part A: Nemvaleukin Alfa 0.1 mcg/kg	Part A: Nemvaleukin Alfa 0.3 mcg/kg	Part A: Nemvaleukin Alfa 1 mcg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	4 / 4 (100.00%)	7 / 7 (100.00%)
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	2 / 4 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Hypertension			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Hypotension			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 4 (25.00%) 2	0 / 7 (0.00%) 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Chills			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	2 / 4 (50.00%) 8	5 / 7 (71.43%) 16
Fatigue			
subjects affected / exposed occurrences (all)	4 / 5 (80.00%) 6	1 / 4 (25.00%) 1	2 / 7 (28.57%) 2
Malaise			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	2 / 7 (28.57%) 2
Oedema peripheral			
subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 2	1 / 4 (25.00%) 1	0 / 7 (0.00%) 0
Pain			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 4 (25.00%) 1	1 / 7 (14.29%) 1
Peripheral swelling			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0	0 / 7 (0.00%) 0
Pyrexia			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	2 / 4 (50.00%) 2	5 / 7 (71.43%) 8
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 4 (25.00%) 2	0 / 7 (0.00%) 0
Dyspnoea			
subjects affected / exposed occurrences (all)	2 / 5 (40.00%) 2	1 / 4 (25.00%) 1	1 / 7 (14.29%) 1
Dyspnoea exertional			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	3
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	4
Blood pressure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	3 / 7 (42.86%)
occurrences (all)	0	1	4
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	2 / 7 (28.57%)
occurrences (all)	0	2	3
Headache			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	3 / 7 (42.86%)
occurrences (all)	1	0	3
Iron deficiency anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Ascites			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Constipation			
subjects affected / exposed	2 / 5 (40.00%)	1 / 4 (25.00%)	2 / 7 (28.57%)
occurrences (all)	2	1	5
Diarrhoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	2
Dyspepsia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Nausea			
subjects affected / exposed	2 / 5 (40.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	3	1	4
Vomiting			
subjects affected / exposed	2 / 5 (40.00%)	2 / 4 (50.00%)	2 / 7 (28.57%)
occurrences (all)	4	2	2
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	3 / 7 (42.86%)
occurrences (all)	0	3	4
Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Arthralgia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Dehydration			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hypoalbuminaemia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1

Non-serious adverse events	Part A: Nemvaleukin Alfa 3 mcg/kg	Part A: Nemvaleukin Alfa 6 mcg/kg	Part A: Nemvaleukin Alfa 8 mcg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	12 / 12 (100.00%)	3 / 3 (100.00%)
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	2 / 8 (25.00%)	2 / 12 (16.67%)	2 / 3 (66.67%)
occurrences (all)	6	5	6
Hypotension			
subjects affected / exposed	3 / 8 (37.50%)	7 / 12 (58.33%)	1 / 3 (33.33%)
occurrences (all)	3	16	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	8 / 8 (100.00%)	11 / 12 (91.67%)	3 / 3 (100.00%)
occurrences (all)	29	52	32
Fatigue			

subjects affected / exposed	3 / 8 (37.50%)	4 / 12 (33.33%)	2 / 3 (66.67%)
occurrences (all)	4	5	9
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 8 (25.00%)	1 / 12 (8.33%)	1 / 3 (33.33%)
occurrences (all)	3	1	1
Pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	8 / 8 (100.00%)	12 / 12 (100.00%)	2 / 3 (66.67%)
occurrences (all)	24	59	10
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 8 (0.00%)	1 / 12 (8.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Dyspnoea			
subjects affected / exposed	3 / 8 (37.50%)	2 / 12 (16.67%)	1 / 3 (33.33%)
occurrences (all)	8	2	1
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	2 / 8 (25.00%)	3 / 12 (25.00%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
Insomnia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 12 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 8 (25.00%)	2 / 12 (16.67%)	1 / 3 (33.33%)
occurrences (all)	2	3	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	2 / 12 (16.67%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 8 (12.50%)	2 / 12 (16.67%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	3
Blood creatinine increased			
subjects affected / exposed	4 / 8 (50.00%)	0 / 12 (0.00%)	1 / 3 (33.33%)
occurrences (all)	4	0	2
Blood pressure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 12 (8.33%)	2 / 3 (66.67%)
occurrences (all)	1	1	2
Weight increased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 12 (8.33%)	1 / 3 (33.33%)
occurrences (all)	1	1	2
White blood cell count decreased			

subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all) Palpitations subjects affected / exposed occurrences (all) Sinus tachycardia subjects affected / exposed occurrences (all) Tachycardia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 2 / 8 (25.00%) 7 0 / 8 (0.00%) 0	0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 4 / 12 (33.33%) 23	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 1 / 3 (33.33%) 2 0 / 3 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 4 2 / 8 (25.00%) 2	0 / 12 (0.00%) 0 3 / 12 (25.00%) 3	1 / 3 (33.33%) 2 2 / 3 (66.67%) 2
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) Iron deficiency anaemia subjects affected / exposed occurrences (all) Lymphopenia subjects affected / exposed occurrences (all)	3 / 8 (37.50%) 12 0 / 8 (0.00%) 0 2 / 8 (25.00%) 3	1 / 12 (8.33%) 1 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0	2 / 3 (66.67%) 5 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0

Neutropenia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 8 (12.50%)	1 / 12 (8.33%)	1 / 3 (33.33%)
occurrences (all)	2	1	2
Abdominal pain			
subjects affected / exposed	2 / 8 (25.00%)	1 / 12 (8.33%)	3 / 3 (100.00%)
occurrences (all)	5	1	9
Abdominal pain upper			
subjects affected / exposed	2 / 8 (25.00%)	0 / 12 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	2
Ascites			
subjects affected / exposed	1 / 8 (12.50%)	0 / 12 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	2
Constipation			
subjects affected / exposed	4 / 8 (50.00%)	1 / 12 (8.33%)	3 / 3 (100.00%)
occurrences (all)	4	1	8
Diarrhoea			
subjects affected / exposed	2 / 8 (25.00%)	1 / 12 (8.33%)	1 / 3 (33.33%)
occurrences (all)	3	1	1
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 8 (12.50%)	1 / 12 (8.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed occurrences (all)	4 / 8 (50.00%) 8	5 / 12 (41.67%) 13	3 / 3 (100.00%) 6
Vomiting subjects affected / exposed occurrences (all)	4 / 8 (50.00%) 10	5 / 12 (41.67%) 9	3 / 3 (100.00%) 14
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 2	1 / 12 (8.33%) 2	0 / 3 (0.00%) 0
Skin and subcutaneous tissue disorders Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 12 (8.33%) 1	0 / 3 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Renal and urinary disorders Hydronephrosis subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 12 (0.00%) 0	1 / 3 (33.33%) 1
Musculoskeletal and connective tissue disorders Hypokalaemia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	3 / 12 (25.00%) 4	1 / 3 (33.33%) 4
Arthralgia subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	2 / 12 (16.67%) 3	1 / 3 (33.33%) 3
Back pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 12 (8.33%) 1	0 / 3 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0

Muscular weakness subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 4	1 / 12 (8.33%) 1	0 / 3 (0.00%) 0
Infections and infestations			
COVID-19 subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	3 / 8 (37.50%) 3	1 / 12 (8.33%) 1	1 / 3 (33.33%) 1
Dehydration subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 12 (0.00%) 0	0 / 3 (0.00%) 0
Hypophosphataemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 12 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	3 / 8 (37.50%)	0 / 12 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	2

Non-serious adverse events	Part A: Nemvaleukin Alfa 10 mcg/kg	Part B, Melanoma: Nemvaleukin Alfa 6 mcg/kg	Part B, RCC: Nemvaleukin Alfa 6 mcg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	46 / 47 (97.87%)	27 / 27 (100.00%)
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	4 / 47 (8.51%)	3 / 27 (11.11%)
occurrences (all)	0	15	3
Hypotension			
subjects affected / exposed	4 / 7 (57.14%)	20 / 47 (42.55%)	5 / 27 (18.52%)
occurrences (all)	7	65	8
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	3	0	0
Chills			
subjects affected / exposed	2 / 7 (28.57%)	21 / 47 (44.68%)	14 / 27 (51.85%)
occurrences (all)	2	226	47
Fatigue			
subjects affected / exposed	3 / 7 (42.86%)	11 / 47 (23.40%)	8 / 27 (29.63%)
occurrences (all)	7	28	14
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 7 (14.29%)	5 / 47 (10.64%)	1 / 27 (3.70%)
occurrences (all)	2	6	1
Pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 7 (0.00%)	2 / 47 (4.26%)	4 / 27 (14.81%)
occurrences (all)	0	2	6
Pyrexia			
subjects affected / exposed	3 / 7 (42.86%)	33 / 47 (70.21%)	17 / 27 (62.96%)
occurrences (all)	7	104	27
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 7 (0.00%)	6 / 47 (12.77%)	3 / 27 (11.11%)
occurrences (all)	0	13	4
Dyspnoea			
subjects affected / exposed	2 / 7 (28.57%)	5 / 47 (10.64%)	8 / 27 (29.63%)
occurrences (all)	2	6	9
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	4 / 47 (8.51%)	2 / 27 (7.41%)
occurrences (all)	0	4	2
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 47 (8.51%)	4 / 27 (14.81%)
occurrences (all)	0	10	7
Investigations			

Alanine aminotransferase increased subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 4	17 / 47 (36.17%) 27	6 / 27 (22.22%) 8
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 6	18 / 47 (38.30%) 27	7 / 27 (25.93%) 10
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	4 / 47 (8.51%) 4	2 / 27 (7.41%) 2
Blood bilirubin increased subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 3	4 / 47 (8.51%) 4	1 / 27 (3.70%) 9
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 47 (4.26%) 5	6 / 27 (22.22%) 8
Blood pressure subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	6 / 47 (12.77%) 25	6 / 27 (22.22%) 11
Weight decreased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 47 (0.00%) 0	0 / 27 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 47 (0.00%) 0	0 / 27 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 47 (4.26%) 9	2 / 27 (7.41%) 3
Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 47 (2.13%) 5	5 / 27 (18.52%) 17
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all) Palpitations	0 / 7 (0.00%) 0	2 / 47 (4.26%) 2	2 / 27 (7.41%) 2

subjects affected / exposed	0 / 7 (0.00%)	3 / 47 (6.38%)	1 / 27 (3.70%)
occurrences (all)	0	5	1
Sinus tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 47 (8.51%)	2 / 27 (7.41%)
occurrences (all)	0	5	4
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	7 / 47 (14.89%)	5 / 27 (18.52%)
occurrences (all)	0	10	18
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 7 (14.29%)	6 / 47 (12.77%)	1 / 27 (3.70%)
occurrences (all)	1	12	1
Headache			
subjects affected / exposed	1 / 7 (14.29%)	13 / 47 (27.66%)	6 / 27 (22.22%)
occurrences (all)	1	26	40
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 7 (71.43%)	15 / 47 (31.91%)	8 / 27 (29.63%)
occurrences (all)	7	38	17
Iron deficiency anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 47 (6.38%)	2 / 27 (7.41%)
occurrences (all)	0	7	2
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	31 / 47 (65.96%)	11 / 27 (40.74%)
occurrences (all)	0	152	49
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	5 / 47 (10.64%)	3 / 27 (11.11%)
occurrences (all)	0	8	4
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			

subjects affected / exposed	2 / 7 (28.57%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	2	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	3 / 47 (6.38%)	1 / 27 (3.70%)
occurrences (all)	0	4	1
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	6 / 47 (12.77%)	3 / 27 (11.11%)
occurrences (all)	1	12	3
Diarrhoea			
subjects affected / exposed	1 / 7 (14.29%)	6 / 47 (12.77%)	3 / 27 (11.11%)
occurrences (all)	1	26	3
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	5 / 47 (10.64%)	1 / 27 (3.70%)
occurrences (all)	0	5	1
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 47 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	24 / 47 (51.06%)	8 / 27 (29.63%)
occurrences (all)	0	90	10
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	13 / 47 (27.66%)	3 / 27 (11.11%)
occurrences (all)	0	29	3
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 47 (2.13%)	3 / 27 (11.11%)
occurrences (all)	4	1	3
Skin and subcutaneous tissue disorders			
Hyperhidrosis			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 47 (0.00%) 0	3 / 27 (11.11%) 9
Pruritus subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	4 / 47 (8.51%) 9	2 / 27 (7.41%) 7
Rash subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	5 / 47 (10.64%) 6	3 / 27 (11.11%) 3
Renal and urinary disorders Hydronephrosis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 47 (0.00%) 0	0 / 27 (0.00%) 0
Musculoskeletal and connective tissue disorders Hypokalaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	4 / 47 (8.51%) 7	2 / 27 (7.41%) 2
Arthralgia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	7 / 47 (14.89%) 19	3 / 27 (11.11%) 8
Back pain subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	7 / 47 (14.89%) 7	2 / 27 (7.41%) 2
Muscle spasms subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 47 (4.26%) 5	2 / 27 (7.41%) 6
Muscular weakness subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 47 (0.00%) 0	0 / 27 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	3 / 47 (6.38%) 14	1 / 27 (3.70%) 1
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 47 (4.26%) 2	3 / 27 (11.11%) 3
Pneumonia			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 47 (0.00%) 0	0 / 27 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 47 (4.26%) 2	3 / 27 (11.11%) 3
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	3 / 47 (6.38%) 3	3 / 27 (11.11%) 4
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 4	11 / 47 (23.40%) 21	7 / 27 (25.93%) 7
Dehydration subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 47 (0.00%) 0	0 / 27 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 47 (0.00%) 0	0 / 27 (0.00%) 0
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 47 (0.00%) 0	0 / 27 (0.00%) 0
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 47 (0.00%) 0	0 / 27 (0.00%) 0
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 47 (2.13%) 1	4 / 27 (14.81%) 7
Myalgia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	5 / 47 (10.64%) 18	3 / 27 (11.11%) 3

Non-serious adverse events	Part C, Safety Run-in: Nemvaleukin Alfa 1 mcg/kg	Part C, Cohort 1 + Safety Run-in: Nemvaleukin Alfa+Pembrolizumab	Part C, Cohort 2: Nemvaleukin Alfa + Pembrolizumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	42 / 42 (100.00%)	26 / 26 (100.00%)
Vascular disorders			

Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	4 / 42 (9.52%)	3 / 26 (11.54%)
occurrences (all)	0	5	6
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	18 / 42 (42.86%)	4 / 26 (15.38%)
occurrences (all)	0	67	4
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 42 (4.76%)	1 / 26 (3.85%)
occurrences (all)	0	5	2
Chills			
subjects affected / exposed	1 / 3 (33.33%)	32 / 42 (76.19%)	16 / 26 (61.54%)
occurrences (all)	3	171	62
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	19 / 42 (45.24%)	8 / 26 (30.77%)
occurrences (all)	2	33	8
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 3 (66.67%)	8 / 42 (19.05%)	3 / 26 (11.54%)
occurrences (all)	7	13	3
Pain			
subjects affected / exposed	0 / 3 (0.00%)	6 / 42 (14.29%)	3 / 26 (11.54%)
occurrences (all)	0	10	3
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	30 / 42 (71.43%)	17 / 26 (65.38%)
occurrences (all)	1	148	80
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	5 / 42 (11.90%) 5	2 / 26 (7.69%) 5
Dyspnoea subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	8 / 42 (19.05%) 10	4 / 26 (15.38%) 5
Dyspnoea exertional subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 42 (2.38%) 1	1 / 26 (3.85%) 1
Pleural effusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	5 / 42 (11.90%) 7	2 / 26 (7.69%) 2
Tachypnoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	3 / 42 (7.14%) 4	2 / 26 (7.69%) 4
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	5 / 42 (11.90%) 6	0 / 26 (0.00%) 0
Confusional state subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 42 (0.00%) 0	0 / 26 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	6 / 42 (14.29%) 7	1 / 26 (3.85%) 1
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	4 / 42 (9.52%) 11	3 / 26 (11.54%) 5
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	6 / 42 (14.29%) 9	3 / 26 (11.54%) 6
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	6 / 42 (14.29%) 20	0 / 26 (0.00%) 0
Blood bilirubin increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	8 / 42 (19.05%)	1 / 26 (3.85%)
occurrences (all)	0	17	2
Blood pressure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	7 / 42 (16.67%)	2 / 26 (7.69%)
occurrences (all)	0	28	2
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 3 (33.33%)	6 / 42 (14.29%)	1 / 26 (3.85%)
occurrences (all)	1	73	2
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	4 / 42 (9.52%)	4 / 26 (15.38%)
occurrences (all)	0	18	19
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 42 (7.14%)	3 / 26 (11.54%)
occurrences (all)	0	3	8
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	16 / 42 (38.10%)	2 / 26 (7.69%)
occurrences (all)	0	59	2
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	10 / 42 (23.81%)	8 / 26 (30.77%)
occurrences (all)	0	19	9
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	13 / 42 (30.95%)	5 / 26 (19.23%)
occurrences (all)	2	35	9
Iron deficiency anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 42 (2.38%)	1 / 26 (3.85%)
occurrences (all)	0	1	1
Lymphopenia			
subjects affected / exposed	1 / 3 (33.33%)	7 / 42 (16.67%)	3 / 26 (11.54%)
occurrences (all)	1	51	4
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	8 / 42 (19.05%)	4 / 26 (15.38%)
occurrences (all)	0	58	5
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	10 / 42 (23.81%)	1 / 26 (3.85%)
occurrences (all)	0	42	1
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	11 / 42 (26.19%)	3 / 26 (11.54%)
occurrences (all)	0	12	4
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Constipation			

subjects affected / exposed	0 / 3 (0.00%)	15 / 42 (35.71%)	5 / 26 (19.23%)
occurrences (all)	0	20	6
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	10 / 42 (23.81%)	5 / 26 (19.23%)
occurrences (all)	1	15	5
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 42 (9.52%)	2 / 26 (7.69%)
occurrences (all)	0	6	2
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	21 / 42 (50.00%)	13 / 26 (50.00%)
occurrences (all)	0	45	22
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	15 / 42 (35.71%)	8 / 26 (30.77%)
occurrences (all)	1	27	13
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	3 / 3 (100.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	4	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	3 / 42 (7.14%)	5 / 26 (19.23%)
occurrences (all)	0	6	6
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 42 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Hydronephrosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 42 (0.00%) 0	0 / 26 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	8 / 42 (19.05%) 24	8 / 26 (30.77%) 10
Arthralgia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	7 / 42 (16.67%) 9	2 / 26 (7.69%) 2
Back pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	6 / 42 (14.29%) 7	3 / 26 (11.54%) 3
Muscle spasms subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 42 (4.76%) 7	1 / 26 (3.85%) 1
Muscular weakness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	4 / 42 (9.52%) 6	1 / 26 (3.85%) 1
Pain in extremity subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	7 / 42 (16.67%) 9	0 / 26 (0.00%) 0
Infections and infestations			
COVID-19 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 42 (0.00%) 0	0 / 26 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	3 / 42 (7.14%) 3	2 / 26 (7.69%) 2
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 42 (0.00%) 0	0 / 26 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	3 / 42 (7.14%) 9	1 / 26 (3.85%) 3
Metabolism and nutrition disorders			

Decreased appetite subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	13 / 42 (30.95%) 15	3 / 26 (11.54%) 3
Dehydration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	3 / 42 (7.14%) 4	2 / 26 (7.69%) 2
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 42 (0.00%) 0	0 / 26 (0.00%) 0
Hypomagnesaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	2 / 42 (4.76%) 14	1 / 26 (3.85%) 1
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	5 / 42 (11.90%) 15	0 / 26 (0.00%) 0
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	4 / 42 (9.52%) 5	4 / 26 (15.38%) 5
Myalgia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	6 / 42 (14.29%) 13	1 / 26 (3.85%) 1

Non-serious adverse events	Part C, Cohort 3: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 4, Rolled Over: Nemvaleukin Alfa +Pembrolizumab	Part C, Cohort 5: Nemvaleukin Alfa + Pembrolizumab
Total subjects affected by non-serious adverse events subjects affected / exposed	26 / 26 (100.00%)	38 / 43 (88.37%)	3 / 3 (100.00%)
Vascular disorders Embolism subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	6 / 26 (23.08%) 18	1 / 43 (2.33%) 6	1 / 3 (33.33%) 2
Hypotension subjects affected / exposed occurrences (all)	6 / 26 (23.08%) 11	4 / 43 (9.30%) 7	0 / 3 (0.00%) 0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	1 / 26 (3.85%)	2 / 43 (4.65%)	2 / 3 (66.67%)
occurrences (all)	1	4	2
Chills			
subjects affected / exposed	18 / 26 (69.23%)	9 / 43 (20.93%)	3 / 3 (100.00%)
occurrences (all)	95	29	7
Fatigue			
subjects affected / exposed	11 / 26 (42.31%)	9 / 43 (20.93%)	3 / 3 (100.00%)
occurrences (all)	39	28	6
Malaise			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	5 / 26 (19.23%)	1 / 43 (2.33%)	2 / 3 (66.67%)
occurrences (all)	10	1	3
Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	16 / 26 (61.54%)	7 / 43 (16.28%)	2 / 3 (66.67%)
occurrences (all)	45	33	7
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 26 (7.69%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Dyspnoea			
subjects affected / exposed	6 / 26 (23.08%)	0 / 43 (0.00%)	1 / 3 (33.33%)
occurrences (all)	14	0	1
Dyspnoea exertional			
subjects affected / exposed	4 / 26 (15.38%)	2 / 43 (4.65%)	0 / 3 (0.00%)
occurrences (all)	5	2	0
Pleural effusion			

subjects affected / exposed	0 / 26 (0.00%)	2 / 43 (4.65%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Tachypnoea			
subjects affected / exposed	1 / 26 (3.85%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	4 / 26 (15.38%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences (all)	4	1	0
Confusional state			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	3 / 26 (11.54%)	3 / 43 (6.98%)	0 / 3 (0.00%)
occurrences (all)	3	4	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	8 / 26 (30.77%)	5 / 43 (11.63%)	1 / 3 (33.33%)
occurrences (all)	17	27	1
Aspartate aminotransferase increased			
subjects affected / exposed	8 / 26 (30.77%)	5 / 43 (11.63%)	1 / 3 (33.33%)
occurrences (all)	19	24	1
Blood alkaline phosphatase increased			
subjects affected / exposed	4 / 26 (15.38%)	2 / 43 (4.65%)	0 / 3 (0.00%)
occurrences (all)	7	2	0
Blood bilirubin increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	4 / 26 (15.38%)	4 / 43 (9.30%)	0 / 3 (0.00%)
occurrences (all)	5	6	0
Blood pressure			
subjects affected / exposed	0 / 26 (0.00%)	0 / 43 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed occurrences (all)	3 / 26 (11.54%) 15	3 / 43 (6.98%) 8	0 / 3 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	4 / 26 (15.38%) 53	0 / 43 (0.00%) 0	1 / 3 (33.33%) 1
Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2	1 / 43 (2.33%) 1	1 / 3 (33.33%) 3
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	3 / 26 (11.54%) 9	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	6 / 26 (23.08%) 24	4 / 43 (9.30%) 6	0 / 3 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	1 / 3 (33.33%) 1
Headache subjects affected / exposed occurrences (all)	9 / 26 (34.62%) 32	8 / 43 (18.60%) 15	2 / 3 (66.67%) 2
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	11 / 26 (42.31%) 32	13 / 43 (30.23%) 34	1 / 3 (33.33%) 1

Iron deficiency anaemia subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2	1 / 43 (2.33%) 1	0 / 3 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	4 / 26 (15.38%) 26	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	10 / 26 (38.46%) 68	15 / 43 (34.88%) 83	2 / 3 (66.67%) 15
Thrombocytopenia subjects affected / exposed occurrences (all)	3 / 26 (11.54%) 8	2 / 43 (4.65%) 2	2 / 3 (66.67%) 2
Gastrointestinal disorders			
Abdominal distension subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	5 / 26 (19.23%) 6	4 / 43 (9.30%) 6	0 / 3 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Ascites subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	5 / 26 (19.23%) 6	3 / 43 (6.98%) 6	0 / 3 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	8 / 26 (30.77%) 13	11 / 43 (25.58%) 20	0 / 3 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2	1 / 43 (2.33%) 1	0 / 3 (0.00%) 0
Flatulence			

subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	9 / 26 (34.62%) 36	8 / 43 (18.60%) 64	1 / 3 (33.33%) 1
Vomiting subjects affected / exposed occurrences (all)	10 / 26 (38.46%) 23	4 / 43 (9.30%) 49	2 / 3 (66.67%) 2
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Skin and subcutaneous tissue disorders Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	6 / 26 (23.08%) 8	4 / 43 (9.30%) 5	0 / 3 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Renal and urinary disorders Hydronephrosis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal and connective tissue disorders Hypokalaemia subjects affected / exposed occurrences (all)	5 / 26 (19.23%) 7	2 / 43 (4.65%) 3	0 / 3 (0.00%) 0
Arthralgia subjects affected / exposed occurrences (all)	4 / 26 (15.38%) 6	4 / 43 (9.30%) 7	0 / 3 (0.00%) 0

Back pain subjects affected / exposed occurrences (all)	7 / 26 (26.92%) 26	7 / 43 (16.28%) 15	1 / 3 (33.33%) 1
Muscle spasms subjects affected / exposed occurrences (all)	3 / 26 (11.54%) 3	3 / 43 (6.98%) 7	0 / 3 (0.00%) 0
Muscular weakness subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 5	1 / 43 (2.33%) 1	0 / 3 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 6	3 / 43 (6.98%) 4	0 / 3 (0.00%) 0
Infections and infestations			
COVID-19 subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	3 / 26 (11.54%) 4	5 / 43 (11.63%) 8	0 / 3 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	13 / 26 (50.00%) 15	2 / 43 (4.65%) 5	1 / 3 (33.33%) 2
Dehydration subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 43 (0.00%) 0	0 / 3 (0.00%) 0
Hypomagnesaemia			

subjects affected / exposed	3 / 26 (11.54%)	3 / 43 (6.98%)	0 / 3 (0.00%)
occurrences (all)	5	4	0
Hyponatraemia			
subjects affected / exposed	2 / 26 (7.69%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences (all)	5	1	0
Hypophosphataemia			
subjects affected / exposed	2 / 26 (7.69%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Myalgia			
subjects affected / exposed	3 / 26 (11.54%)	1 / 43 (2.33%)	0 / 3 (0.00%)
occurrences (all)	3	1	0

Non-serious adverse events	Part C, Cohort 6: Nemvaleukin Alfa + Pembrolizumab	Part C, Cohort 7: Nemvaleukin Alfa + Pembrolizumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 21 (100.00%)	2 / 2 (100.00%)	
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	4 / 21 (19.05%)	0 / 2 (0.00%)	
occurrences (all)	7	0	
Hypotension			
subjects affected / exposed	6 / 21 (28.57%)	1 / 2 (50.00%)	
occurrences (all)	54	4	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences (all)	5	0	
Chills			
subjects affected / exposed	13 / 21 (61.90%)	2 / 2 (100.00%)	
occurrences (all)	65	42	
Fatigue			
subjects affected / exposed	6 / 21 (28.57%)	2 / 2 (100.00%)	
occurrences (all)	11	18	
Malaise			

subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	2 / 21 (9.52%)	1 / 2 (50.00%)	
occurrences (all)	2	1	
Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Peripheral swelling			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	10 / 21 (47.62%)	2 / 2 (100.00%)	
occurrences (all)	37	29	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 21 (14.29%)	0 / 2 (0.00%)	
occurrences (all)	4	0	
Dyspnoea			
subjects affected / exposed	11 / 21 (52.38%)	0 / 2 (0.00%)	
occurrences (all)	40	0	
Dyspnoea exertional			
subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences (all)	2	0	
Pleural effusion			
subjects affected / exposed	5 / 21 (23.81%)	1 / 2 (50.00%)	
occurrences (all)	7	1	
Tachypnoea			
subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences (all)	10	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Confusional state			

subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	5 / 21 (23.81%)	1 / 2 (50.00%)	
occurrences (all)	9	3	
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 21 (14.29%)	1 / 2 (50.00%)	
occurrences (all)	5	2	
Blood alkaline phosphatase increased			
subjects affected / exposed	5 / 21 (23.81%)	1 / 2 (50.00%)	
occurrences (all)	14	1	
Blood bilirubin increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	3 / 21 (14.29%)	0 / 2 (0.00%)	
occurrences (all)	3	0	
Blood pressure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	4 / 21 (19.05%)	1 / 2 (50.00%)	
occurrences (all)	24	3	
Weight increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
White blood cell count decreased			
subjects affected / exposed	6 / 21 (28.57%)	1 / 2 (50.00%)	
occurrences (all)	35	2	
Injury, poisoning and procedural complications			

Infusion related reaction subjects affected / exposed occurrences (all)	2 / 21 (9.52%) 8	0 / 2 (0.00%) 0	
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 2 (0.00%) 0	
Palpitations subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 2 (0.00%) 0	
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0	0 / 2 (0.00%) 0	
Tachycardia subjects affected / exposed occurrences (all)	6 / 21 (28.57%) 20	1 / 2 (50.00%) 2	
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	6 / 21 (28.57%) 8	1 / 2 (50.00%) 2	
Headache subjects affected / exposed occurrences (all)	4 / 21 (19.05%) 7	0 / 2 (0.00%) 0	
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	9 / 21 (42.86%) 38	0 / 2 (0.00%) 0	
Iron deficiency anaemia subjects affected / exposed occurrences (all)	4 / 21 (19.05%) 12	1 / 2 (50.00%) 3	
Lymphopenia subjects affected / exposed occurrences (all)	8 / 21 (38.10%) 72	1 / 2 (50.00%) 10	
Neutropenia subjects affected / exposed occurrences (all)	7 / 21 (33.33%) 33	1 / 2 (50.00%) 1	
Thrombocytopenia			

subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences (all)	7	0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences (all)	3	0	
Abdominal pain upper			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Ascites			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	5 / 21 (23.81%)	0 / 2 (0.00%)	
occurrences (all)	5	0	
Diarrhoea			
subjects affected / exposed	4 / 21 (19.05%)	1 / 2 (50.00%)	
occurrences (all)	6	1	
Dyspepsia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	12 / 21 (57.14%)	1 / 2 (50.00%)	
occurrences (all)	29	1	
Vomiting			
subjects affected / exposed	8 / 21 (38.10%)	2 / 2 (100.00%)	
occurrences (all)	13	2	

Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	3 / 21 (14.29%)	0 / 2 (0.00%)	
occurrences (all)	5	0	
Rash			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Hypokalaemia			
subjects affected / exposed	4 / 21 (19.05%)	0 / 2 (0.00%)	
occurrences (all)	5	0	
Arthralgia			
subjects affected / exposed	4 / 21 (19.05%)	1 / 2 (50.00%)	
occurrences (all)	10	1	
Back pain			
subjects affected / exposed	4 / 21 (19.05%)	0 / 2 (0.00%)	
occurrences (all)	4	0	
Muscle spasms			
subjects affected / exposed	1 / 21 (4.76%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Muscular weakness			
subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences (all)	5	0	
Pain in extremity			

subjects affected / exposed occurrences (all)	2 / 21 (9.52%) 11	0 / 2 (0.00%) 0	
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	3 / 21 (14.29%)	1 / 2 (50.00%)	
occurrences (all)	5	1	
Upper respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	4 / 21 (19.05%)	1 / 2 (50.00%)	
occurrences (all)	6	1	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	6 / 21 (28.57%)	0 / 2 (0.00%)	
occurrences (all)	6	0	
Dehydration			
subjects affected / exposed	4 / 21 (19.05%)	1 / 2 (50.00%)	
occurrences (all)	6	1	
Hypoalbuminaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypomagnesaemia			
subjects affected / exposed	2 / 21 (9.52%)	0 / 2 (0.00%)	
occurrences (all)	2	0	
Hyponatraemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Hypophosphataemia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 2 (0.00%)	
occurrences (all)	2	0	
Myalgia			

subjects affected / exposed	1 / 21 (4.76%)	1 / 2 (50.00%)	
occurrences (all)	1	6	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 October 2015	Protocol Version 2: <ul style="list-style-type: none">• Updated the Schedule of Assessments and study visits for PK and extent of disease assessment.• Further clarified the definition and criteria for DLTs.• Further clarified additional dose escalations via formal protocol amendment, if required.
10 February 2016	Protocol Version 3: <ul style="list-style-type: none">• Updated the number of subjects planned for Part B to 84 (21 subjects in each of the 4 cohorts).• Modified the nemvaleukin dosing schedule in Cycle 1 to permit the closest possible matching of exposure for nemvaleukin as compared with IL-2 during Days 1 to 28.• Updated the RCC tumor type to include 2 cohorts (subjects who received prior treatment with anti-PD-1 or anti-PD-L1 therapy and subjects who received no prior checkpoint inhibitor therapy).• Deleted the NSCLC, bladder cancer, and triple negative breast cancer from solid tumor types to be studied.• Clarified study procedures.
11 October 2016	Protocol Version 4: <ul style="list-style-type: none">• Revised or clarified inclusion criteria #4 and #10 and exclusion criterion #7.• Removed PD according to both irRC and RECIST from the reasons for withdrawal or discontinuation from study and added clinical progression as a criterion. The protocol then stated that PD (according to irRC), or clinical progression (worsening of symptoms or declining performance status), would result in subject discontinuation.• Revised the DLT definition from "febrile neutropenia" to "Grade 3 febrile neutropenia (ie, ANC <1,000/mm³ with a single temperature >38.3°C [101°F] or a sustained temperature of ≥38°C [100.4°F] for more than 1 hour)."• Clarified throughout the document that all 16-hour PK and cytokine samples and Day 6 (ie, Day 5, 24-hour) PK samples were optional.• Added language and guidance around inpatient dose escalation.• Added details regarding determination of sample size for Part B, based on methodology described by Simon regarding optimal 2-stage designs for Phase 2 trials. Also added details regarding uninteresting and desirable response rates, number of subjects, and number of responders needed for Part B.
08 June 2017	Protocol Version 5: <ul style="list-style-type: none">• Increased number of subjects enrolled from 6 to 7, in Cohorts 3 and beyond of Part A, and increased number of participating sites from "3 to 8 in the US" to "up to 20 in North America".• Clarified that the minimum number of DLT-evaluable subjects for Part A remained at 6.• Clarified that subjects deemed not evaluable for DLTs in Part A of the study could be replaced, resulting in enrollment beyond the 7 subjects planned in each cohort.• Included analysis of CA125 tumor marker in serum chemistry panel for ovarian cancer subjects only. The Schedule of Assessments and serum chemistry panel were updated accordingly.• Corrected the definition of PK and Pharmacodynamics Populations.

06 October 2017	<p>Protocol Version 6:</p> <ul style="list-style-type: none"> • Two DLT criteria were revised in order to more clearly define what would pose a true risk to subjects who experienced AEs meeting these criteria; Grade 4 hypoalbuminemia was added as a DLT criterion. • Restrictions around pretreatment with certain medications beginning on Cycle 1 Day 1 were revised. • Clarified the reporting period for SAEs and pregnancies, and clarified language around the permissible length of cycle delay for AE resolution. • Revised dose levels (added 6 mcg/kg and 15 mcg/kg, and removed 30 mcg/kg).
20 December 2017	<p>Protocol Version 7:</p> <ul style="list-style-type: none"> • Clarified DLT criteria for Grade 4 neutropenia and for febrile neutropenia. • Added language detailing the hospitalization and monitoring of subjects who experienced Grade 4 neutropenia or Grade 3 febrile neutropenia. • Included language around the recording of results from microbiology specimens that were cultured to investigate potential infections.
12 January 2018	<p>Protocol Version 8:</p> <ul style="list-style-type: none"> • Clarified that Grade 4 neutropenia requiring hospitalization was specific to instances of Grade 4 neutropenia where ANC <100/mm³. • Included language allowing for the outpatient treatment of subjects who experienced Grade 4 neutropenia if ANC was between 100 and 500/mm³.
22 May 2018	<p>Protocol Version 9:</p> <ul style="list-style-type: none"> • A Part C dose-expansion cohort was added to explore administration of nemvaleukin in combination with a PD-1 inhibitor (pembrolizumab). The implementation of combination therapy included a safety lead-in of 3 to 6 subjects at a dose that was adequately tolerated in a monotherapy setting for nemvaleukin (1 mcg/kg). Revisions were made to indicate that once safety was demonstrated, an expanded number of subjects were to be enrolled at an increased dose level of nemvaleukin (3 mcg/kg). Both nemvaleukin dose levels were to be administered in combination with pembrolizumab, and pembrolizumab was to be used in accordance with the FDA-approved label. • Revisions were made to indicate that the ovarian and immunotherapy treatment-naïve renal cell carcinoma expansion cohorts in Part B would no longer be explored, and ovarian carcinoma would be included in a Part C cohort in combination with pembrolizumab.
09 August 2018	<p>Protocol Version 10:</p> <ul style="list-style-type: none"> • The DLT criteria were revised to reflect the investigators' opinions and to bring the definitions in line with other cytokine-based agents in development. • The timeframe for administration of nemvaleukin after completion of the pembrolizumab infusion in Part C was adjusted to a range, rather than a specific amount of time, to provide greater flexibility in the timing of nemvaleukin administration and prevent unnecessary protocol deviations due to overly specific dosing instructions. • Further explanation of the definition and considerations surrounding AEs was included.
01 May 2019	<p>Protocol Version 11:</p> <ul style="list-style-type: none"> • Updated the global reach of the study, sample size, inclusion and exclusion criteria, study requirements and restrictions, schedules of procedures and assessments, study objectives and endpoints, methodology, planned statistical analyses to be used during and after the study, and types of tumors being studied.

20 February 2020	<p>Protocol Version 12:</p> <ul style="list-style-type: none"> • Clarified primary objectives for Part B and specified that antitumor activity would be characterized by ORR for Parts B and C; and clarified that the incidence and severity of AEs was a primary endpoint in all 3 parts of the study. • Additional inclusion criteria for Part B melanoma and RCC expansion cohorts specified the allowed prior therapies. • Exclusion criteria were updated to include clarifications on prior therapies and treatments, exclusionary conditions, and exclusion due to association with the site or Sponsor/CRO. • Added 12 and 14 mcg/kg dose levels (Cohorts 8 and 9) to Part A. • Updated assessments for blood-based biomarkers and added circulating tumor DNA assessment. • Updates to reflect changes in sample size calculation. • Clarified study procedures.
08 September 2022	<p>Protocol Version 13:</p> <ul style="list-style-type: none"> • The addition of an Extension Phase (aimed at assessing long-term effectiveness and safety, while minimizing the burden of repeated assessments), including the definition of procedures and clarification of treatment duration, for subjects completing or who had completed 1 year of treatment in Part B or in Part C of the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported