



Clinical trial results:

Clinical and Immunologic Activity of Nemvaleukin Alfa With a Less Frequent IV Dosing Schedule as Monotherapy and in Combination With Pembrolizumab and Impact on Tumor Microenvironment in Solid Tumor Patients (ARTISTRY-3)

Summary

EudraCT number	2022-003662-21
Trial protocol	ES
Global end of trial date	11 June 2024

Results information

Result version number	v1 (current)
This version publication date	17 July 2025
First version publication date	17 July 2025

Trial information

Trial identification

Sponsor protocol code	ALKS4230-003
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04592653
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Alkermes, Inc.
Sponsor organisation address	852 Winter Street, Waltham, United States, 02451-1420
Public contact	Richard Campbell, Alkermes, Inc., +1 781786-1058, richard.campbell@muraloncology.com
Scientific contact	Richard Campbell, Alkermes, Inc., +1 781786-1058, richard.campbell@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	11 June 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	11 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Cohort 1 (TME):

- To evaluate the effects of nemvaleukin alfa ('nemvaleukin,' 'ALKS 4230') monotherapy on the TME of a variety of advanced, malignant solid tumors.

Cohort 2 (Less Frequent IV Dosing):

- To investigate the safety and tolerability of less frequent IV dosing schedules of nemvaleukin to identify and determine a recommended phase 2 dose (RP2D) of nemvaleukin monotherapy.
- To determine the maximum tolerated dose (MTD) of nemvaleukin monotherapy and in combination with pembrolizumab.

Protection of trial subjects:

This study was conducted in accordance with the protocol, the ICH Guideline E6, and all applicable local regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 September 2020
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	United States: 44
Country: Number of subjects enrolled	Spain: 17
Worldwide total number of subjects	61
EEA total number of subjects	17

Notes:

Subjects enrolled per age group

In utero	0
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)	36
From 65 to 84 years	25
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 6 investigative sites in Spain and the United States. This study was conducted in two cohorts: Cohort 1 (Tumor Microenvironment [TME]) and Cohort 2 (Less Frequent Dosing). Cohort 2 consisted of Part A (monotherapy with nemvaleukin) and Part B (combination therapy with nemvaleukin and pembrolizumab).

Pre-assignment

Screening details:

As pre-specified in statistical analysis plan (SAP), Part B of Cohort 2 was not conducted and no subject was enrolled, therefore, no data was collected and reported for Cohort 2 Part B.

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	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg

Arm description:

Subjects received nemvaleukin alfa 6 micrograms per kilogram (mcg/kg), intravenous (IV) infusion, once daily for 5 consecutive days, followed by 9 days off during Cycle 1 (Cycle 1 length=14 days) and 16 days off during Cycle 2 (Cycle 2 length=21 days), then a single dose on Day 1 of each 21-day cycle in combination with pembrolizumab 200 milligrams (mg), IV infusion until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other 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 administered as 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 administered as IV infusion.

Arm title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg
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Arm description:

Subjects received nemvaleukin alfa 10 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subject derived clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg
Arm description:	
Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Arm description:	
Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subject deriving clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Arm description:	
Subjects received nemvaleukin alfa 35 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subject deriving clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg
Arm description:	
Subjects received nemvaleukin alfa 40 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg
Arm description: Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Arm description: Subjects received nemvaleukin alfa 25 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
Arm description: Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg
Arm description: Subjects received nemvaleukin alfa 15 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg
Arm description:	
Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Arm description:	
Subjects received nemvaleukin alfa 25 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg
Arm description:	
Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.	
Arm title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg
Arm description:	
Subjects received nemvaleukin alfa 35 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other 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 administered as IV infusion.

Number of subjects in period 1	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg
Started	9	1	1
Completed	0	0	0
Not completed	9	1	1
Consent withdrawn by subject	7	-	1
Death	1	1	-
Lost to follow-up	1	-	-

Number of subjects in period 1	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg
Started	5	6	4
Completed	1	0	2
Not completed	4	6	2
Consent withdrawn by subject	1	-	-
Death	3	6	2
Lost to follow-up	-	-	-

Number of subjects in period 1	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
Started	5	5	3
Completed	0	0	2
Not completed	5	5	1
Consent withdrawn by subject	1	1	-
Death	3	4	1
Lost to follow-up	1	-	-

Number of subjects in period 1	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Started	3	3	6
Completed	1	0	0
Not completed	2	3	6

Consent withdrawn by subject	1	-	2
Death	-	3	1
Lost to follow-up	1	-	3

Number of subjects in period 1	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg
Started	3	7
Completed	1	2
Not completed	2	5
Consent withdrawn by subject	1	1
Death	-	4
Lost to follow-up	1	-

Baseline characteristics

Reporting groups

Reporting group title	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg
Reporting group description: Subjects received nemvaleukin alfa 6 micrograms per kilogram (mcg/kg), intravenous (IV) infusion, once daily for 5 consecutive days, followed by 9 days off during Cycle 1 (Cycle 1 length=14 days) and 16 days off during Cycle 2 (Cycle 2 length=21 days), then a single dose on Day 1 of each 21-day cycle in combination with pembrolizumab 200 milligrams (mg), IV infusion until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 10 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subject derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subject deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 35 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subject deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 40 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 25 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 15 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg

Reporting group description:

Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 25 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 35 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg
Number of subjects	9	1	1
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	6	1	1
>=65 years	3	0	0
Gender categorical Units: Subjects			
Female	8	0	1
Male	1	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	9	1	1
Race (NIH/OMB) Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0
White	9	1	1
Unknown or Not Reported	0	0	0

Reporting group values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg
Number of subjects	5	6	4
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	3	1	2

>=65 years	2	5	2
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Gender categorical Units: Subjects			
Female	3	5	2
Male	2	1	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	5	6	4
Race (NIH/OMB) Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0
White	5	6	4
Unknown or Not Reported	0	0	0

Reporting group values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
Number of subjects	5	5	3
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	3	2	3
>=65 years	2	3	0
Gender categorical Units: Subjects			
Female	2	5	3
Male	3	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	0	0
Not Hispanic or Latino	3	5	3
Race (NIH/OMB) Units: Subjects			
Asian	1	0	0
Black or African American	0	0	0
White	2	5	3
Unknown or Not Reported	2	0	0

Reporting group values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Number of subjects	3	3	6
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	3	1	5
>=65 years	0	2	1

Gender categorical Units: Subjects			
Female	3	2	3
Male	0	1	3
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	3	6
Race (NIH/OMB) Units: Subjects			
Asian	0	1	1
Black or African American	0	1	0
White	3	1	5
Unknown or Not Reported	0	0	0

Reporting group values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg	Total
Number of subjects	3	7	61
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	2	5	38
>=65 years	1	2	23
Gender categorical Units: Subjects			
Female	2	6	45
Male	1	1	16
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	2
Not Hispanic or Latino	3	7	59
Race (NIH/OMB) Units: Subjects			
Asian	0	0	3
Black or African American	0	0	1
White	3	7	55
Unknown or Not Reported	0	0	2

End points

End points reporting groups

Reporting group title	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg
Reporting group description: Subjects received nemvaleukin alfa 6 micrograms per kilogram (mcg/kg), intravenous (IV) infusion, once daily for 5 consecutive days, followed by 9 days off during Cycle 1 (Cycle 1 length=14 days) and 16 days off during Cycle 2 (Cycle 2 length=21 days), then a single dose on Day 1 of each 21-day cycle in combination with pembrolizumab 200 milligrams (mg), IV infusion until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 10 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subject derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subject deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 35 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subject deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 40 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 25 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg
Reporting group description: Subjects received nemvaleukin alfa 15 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.	
Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg

Reporting group description:

Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 25 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 35 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Subject analysis set title	Cohort 1, Monotherapy: Nemvaleukin Alfa 6 mcg/kg
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Subject analysis set type	Safety analysis
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Subject analysis set description:

The safety population included all subjects who received any exposure to nemvaleukin alfa.

Primary: Cohort 1: Change From Baseline in Density of Immune Cells: Total T Cells, Cluster of Differentiation (CD)8+ T Cells, CD56+ Cells, and Regulatory T Cells (Tregs) at Cycle 2 Day 8 in Paired Tumor Biopsies

End point title	Cohort 1: Change From Baseline in Density of Immune Cells: Total T Cells, Cluster of Differentiation (CD)8+ T Cells, CD56+ Cells, and Regulatory T Cells (Tregs) at Cycle 2 Day 8 in Paired Tumor Biopsies ^[1]
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End point description:

The biopsies samples were collected and analyzed by immunohistochemistry (IHC) and/or immunofluorescence (IF). TME-evaluable population included subjects who had a confirmed diagnosis of one of included tumor types; had received specified minimum 4 out of 5 doses of nemvaleukin alfa (6 mcg/kg/day) during each of the first 2 cycles and completed doses of assigned less frequent IV dosing recommended phase 2 dose (RP2D) in the first 2 cycles; had contributed paired biopsies; and had not received any confounding therapies before the second biopsy (Cycle 2).

End point type	Primary
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End point timeframe:

Baseline, at Cycle 2 Day 8 (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.

End point values	Cohort 1, Monotherapy: Nemvaleukin Alfa 6 mcg/kg			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: cell counts per millimeter square				
arithmetic mean (standard deviation)				
Total T Cells: Total Region of Interest (ROI)	108.5 (± 474.87)			
Total T Cells: Within Tumor	-11.4 (± 158.27)			

Total T Cells: Outside Tumor	113.4 (± 630.59)			
CD8+: Total ROI	-72.6 (± 209.82)			
CD8+: Within Tumor	-39.3 (± 78.65)			
CD8+: Outside Tumor	-84.4 (± 258.03)			
CD56+: Total ROI	-196.1 (± 568.90)			
CD56+: Within Tumor	-221.4 (± 696.71)			
CD56+: Outside Tumor	-97.0 (± 332.26)			
Treg: Total ROI	7.2 (± 57.16)			
Treg: Within Tumor	-1.0 (± 10.44)			
Treg: Outside Tumor	9.2 (± 67.46)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 1: Change From Baseline in Ratio of T/Treg, CD8+/Treg, CD56+/Tregs at Cycle 2 Day 8 in Paired Tumor Biopsies

End point title	Cohort 1: Change From Baseline in Ratio of T/Treg, CD8+/Treg, CD56+/Tregs at Cycle 2 Day 8 in Paired Tumor Biopsies ^[2]
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End point description:

The biopsies samples were collected and analyzed by immunohistochemist. TME-evaluable population included subjects who had a confirmed diagnosis of one of included tumor types; had received specified minimum 4 out of 5 doses of nemvaleukin (6 mcg/kg/day) during each of the first 2 cycles and completed doses of assigned less frequent IV dosing RP2D in the first 2 cycles; had contributed paired biopsies; and had not received any confounding therapies before the second biopsy (Cycle 2).

End point type	Primary
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End point timeframe:

Baseline, at Cycle 2 Day 8 (Cycle 2 length=21 days)

Notes:

[2] - 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	Cohort 1, Monotherapy: Nemvaleukin Alfa 6 mcg/kg			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: ratio				
arithmetic mean (standard deviation)				
T/Treg: Total ROI	11.1 (± 57.05)			
T/Treg: Within Tumor	53.8 (± 144.88)			
T/Treg: Outside Tumor	3.3 (± 45.73)			
CD8+/Treg: Total ROI	-1.0 (± 4.21)			
CD8+/Treg: Within Tumor	-2.1 (± 5.00)			

CD8+/Treg: Outside Tumor	-1.0 (± 4.48)			
CD56+/Treg: Total ROI	4.6 (± 43.69)			
CD56+/Treg: Within Tumor	-212.9 (± 1096.11)			
CD56+/Treg: Outside Tumor	-20.3 (± 87.39)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohort 2 (Less Frequent IV Dosing): Number of Participants With of Dose-limiting Toxicity (DLT)

End point title	Cohort 2 (Less Frequent IV Dosing): Number of Participants With of Dose-limiting Toxicity (DLT) ^{[3][4]}
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End point description:

DLTs was defined by any of the following events with some exceptions that were observed during the interval from Cycle 1 Day 1 through Cycle 1 Day 21 and were deemed as possibly, probably, or definitely related to nemvaleukin alfa: Hematologic: Grade 4 neutropenia or thrombocytopenia lasting greater than (>) 7 days and Grade 3 thrombocytopenia with bleeding requiring transfusion or medical intervention; Non-hematologic: Any Grade greater than or equal to (>=) 3 nonhematologic adverse events (AEs) that did not resolve to Grade 2 or lower within 7 days. The DLT-evaluable population included subjects who had a confirmed diagnosis of one of the included tumor types, had received the specified dose of nemvaleukin during the first cycle as per schedule assigned and had completed 21-day follow-up in Cycle 1.

End point type	Primary
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End point timeframe:

Cycle 1 Day 1 through Cycle 1 Day 21 (Cycle 1 length =14 days)

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.

[4] - 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	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	5	6
Units: participants	0	0	0	0

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	3
Units: participants	0	0	0	0

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	3
Units: participants	0	0	0	0

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) Based on RECIST 1.1

End point title	Overall Response Rate (ORR) Based on RECIST 1.1
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End point description:

ORR was defined as the percentage of participants with confirmed complete response (CR) or partial response (PR) based on Investigator review of the radiographic or photographic images, as defined according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. CR: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 millimeter (mm). PR: At least a 30 percentage (%) decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. The safety population included all subjects who received any exposure to nemvaleukin alfa.

End point type	Secondary
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End point timeframe:

From time of initiation of therapy until the date of first documented tumor progression (up to 12 weeks for Cohort 1; up to 39 weeks for Cohort 2)

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	1	1	5
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to	0.0 (0.0 to	0.0 (0.0 to	0.0 (0.0 to

33.6)	97.5)	97.5)	52.2)
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End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	4	5	5
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 45.9)	0.00 (0.0 to 60.2)	0.00 (0.00 to 52.2)	0.00 (0.00 to 52.2)

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	6
Units: percentage of participants				
number (confidence interval 95%)	0.00 (0.00 to 70.8)	0.00 (0.00 to 70.8)	0.00 (0.00 to 70.8)	0.00 (0.00 to 45.9)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	3		
Units: percentage of participants				
number (confidence interval 95%)	0.00 (0.00 to 70.8)	0.00 (0.00 to 41.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) Based on iRECIST

End point title	Overall Response Rate (ORR) Based on iRECIST
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End point description:

ORR was defined as the percentage of participants with confirmed immune complete response (iCR) or immune partial response (iPR) based on Investigator review of the radiographic or photographic images, as defined according to immune Response Evaluation Criteria in Solid Tumors (iRECIST) v1.1. iCR was defined as disappearance of all target and non-target lesions and any pathological lymph nodes must be <10 mm in the short axis. iPR was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters. The safety population included all subjects who received any exposure to nemvaleukin alfa.

End point type	Secondary
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End point timeframe:

From time of initiation of therapy until the date of first documented tumor progression (up to 12 weeks for Cohort 1; up to 39 weeks for Cohort 2)

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	1	1	5
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 33.6)	0.0 (0.0 to 97.5)	0.0 (0.0 to 97.5)	0.0 (0.0 to 52.2)

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	4	5	5
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 45.9)	0.00 (0.00 to 60.2)	0.00 (0.00 to 52.2)	0.00 (0.00 to 52.2)

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	6
Units: percentage of participants				
number (confidence interval 95%)	0.00 (0.00 to 70.8)	0.00 (0.00 to 70.8)	0.00 (0.00 to 70.8)	0.00 (0.00 to 45.9)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: percentage of participants				
number (confidence interval 95%)	0.00 (0.00 to 70.8)	0.00 (0.00 to 41.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) Among Confirmed Responders Based on RECIST 1.1

End point title	Duration of Response (DOR) Among Confirmed Responders Based on RECIST 1.1
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End point description:

The DOR was defined as the time from the first documentation of response (PR or CR) to the first documentation of objective tumor progression or death due to any cause based on RECIST 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. The safety population included all subjects who received any exposure to nemvaleukin alfa. Here, "Overall Number of Participants Analyzed" signifies participants who had confirmed response (CR or PR).

End point type	Secondary
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End point timeframe:

From the first documentation of response (PR or CR) to the first documentation of objective tumor progression or death due to any cause (up to 12 weeks for Cohort 1; up to 39 weeks for Cohort 2)

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[5]	0 ^[6]	0 ^[7]	0 ^[8]
Units: months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[5] - Endpoint has zero total participants analyzed.

[6] - Endpoint has zero total participants analyzed.

[7] - Endpoint has zero total participants analyzed.

[8] - Endpoint has zero total participants analyzed.

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[9]	0 ^[10]	0 ^[11]	0 ^[12]
Units: months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[9] - Endpoint has zero total participants analyzed.

[10] - Endpoint has zero total participants analyzed.

[11] - Endpoint has zero total participants analyzed.

[12] - Endpoint has zero total participants analyzed.

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 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: months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[13] - Endpoint has zero total participants analyzed.

[14] - Endpoint has zero total participants analyzed.

[15] - Endpoint has zero total participants analyzed.

[16] - Endpoint has zero total participants analyzed.

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[17]	0 ^[18]		
Units: months				
median (full range (min-max))	(to)	(to)		

Notes:

[17] - Endpoint has zero total participants analyzed.

[18] - Endpoint has zero total participants analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) Among Confirmed Responders Based on iRECIST 1.1

End point title	Duration of Response (DOR) Among Confirmed Responders Based on iRECIST 1.1
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End point description:

The DOR was defined as the time from the first documentation of response (iPR or iCR) to the first documentation of objective tumor progression or death due to any cause based on iRECIST 1.1. iCR was defined as disappearance of all target and non-target lesions and any pathological lymph nodes must be <10 mm in the short axis. iPR was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters. The safety population included all subjects who received any exposure to nemvaleukin alfa. Here, "Overall Number of Participants Analyzed" signifies participants who had confirmed response (CR or PR).

End point type	Secondary
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End point timeframe:

From the first documentation of response (iPR or iCR) to the first documentation of objective tumor progression or death due to any cause (up to 12 weeks for Cohort 1; up to 39 weeks for Cohort 2)

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[19]	0 ^[20]	0 ^[21]	0 ^[22]
Units: months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

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

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

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

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

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[23]	0 ^[24]	0 ^[25]	0 ^[26]
Units: months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

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

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

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

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

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[27]	0 ^[28]	0 ^[29]	0 ^[30]
Units: months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

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

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

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

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

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[31]	0 ^[32]		
Units: months				
median (full range (min-max))	(to)	(to)		

Notes:

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

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

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment-Emergent Adverse Events (TEAEs) and TEAEs Severity Grade 3 or Higher

End point title	Number of Subjects With Treatment-Emergent Adverse Events (TEAEs) and TEAEs Severity Grade 3 or Higher
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End point description:

TEAEs were defined as AEs that occur or worsen after the first dose of study drug(s). An AE was any untoward medical occurrence in a subject or clinical investigation subject who had been administered a pharmaceutical product. Severity was evaluated according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v5.0, where Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living (ADL). Grade 4: Life-threatening consequences; urgent intervention indicated. Grade 5: Death related to AE. The safety population included all subjects who received any exposure to nemvaleukin alfa

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 30 days after last dose (up to 16 weeks for Cohort 1; up to 43 weeks for Cohort 2)

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	1	1	5
Units: participants				
TEAEs	4	1	1	5
TEAEs Severity Grade 3 or Higher	2	1	1	3

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	4	5	5
Units: participants				
TEAEs	6	4	5	5
TEAEs Severity Grade 3 or Higher	2	2	2	3

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	6

Units: participants				
TEAEs	3	3	3	6
TEAEs Severity Grade 3 or Higher	2	1	2	4

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg	Cohort 1, Monotherapy: Nemvaleukin Alfa 6 mcg/kg	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	3	7	9	
Units: participants				
TEAEs	3	7	9	
TEAEs Severity Grade 3 or Higher	2	3	8	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Potentially Clinically Significant Change From Baseline in Vital Signs Values

End point title	Number of Participants With Potentially Clinically Significant Change From Baseline in Vital Signs Values
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End point description:

Potentially clinically significant criteria in vital sign were defined as systolic blood pressure (SBP) ≥ 160 or diastolic blood pressure (DBP) ≥ 100 , or SBP less than or equal to (\leq) 90 or DBP ≤ 60 , or Temperature > 40 degree centigrade ($^{\circ}$). The safety population included all subjects who received any exposure to nemvaleukin alfa

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 30 days after last dose (up to 16 weeks for Cohort 1; up to 43 weeks for Cohort 2)

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	1	1	5
Units: participants				
SBP ≥ 160	2	0	0	0
DBP ≥ 100	1	0	0	0
SBP ≤ 90	7	0	0	0
DBP ≤ 60	0	0	1	3
Temperature > 40	0	0	0	0

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	4	5	5
Units: participants				
SBP >=160	0	0	0	3
DBP >=100	0	0	0	1
SBP <=90	3	2	2	1
DBP <=60	4	3	4	4
Temperature >40	0	0	0	0

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	6
Units: participants				
SBP >=160	2	0	0	0
DBP >=100	0	0	0	0
SBP <=90	2	1	1	4
DBP <=60	3	3	3	4
Temperature >40	0	0	0	0

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: participants				
SBP >=160	0	1		
DBP >=100	0	0		
SBP <=90	3	3		
DBP <=60	3	5		
Temperature >40	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Clinically Significant Abnormal Changes From Baseline in Laboratory Tests

End point title	Number of Participants With Clinically Significant Abnormal Changes From Baseline in Laboratory Tests
End point description: Laboratory tests hematology, serum chemistry, and urinalysis assessment. Any clinically significant abnormality was based on Investigator's assessment. The safety population included all subjects who received any exposure to nemvaleukin alfa.	
End point type	Secondary
End point timeframe: Laboratory tests hematology, serum chemistry, and urinalysis assessment. Any clinically significant abnormality was based on Investigator's assessment.	

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	1	1	5
Units: participants	0	0	0	0

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	4	5	5
Units: participants	0	0	0	0

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	6
Units: participants	0	0	0	0

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Clinically Significant Change From Baseline in Electrocardiograms (ECGs) Values

End point title	Number of Participants With Clinically Significant Change From Baseline in Electrocardiograms (ECGs) Values
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End point description:

Any clinically significant abnormality was based on Investigator's assessment. The safety population included all subjects who received any exposure to nemvaleukin alfa.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 30 days after last dose (up to 16 weeks for Cohort 1; up to 43 weeks for Cohort 2)

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	1	1	5
Units: participants	0	0	0	0

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	4	5	5
Units: participants	0	0	0	0

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	6
Units: participants	0	0	0	0

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Concentrations of Nemvaleukin in Serum

End point title	Cohort 1: Concentrations of Nemvaleukin in Serum ^[33]
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End point description:

The pharmacokinetic (PK) population included subjects who received at least 1 dose of nemvaleukin and have at least 1 measurable serum concentration of nemvaleukin at any scheduled PK time point. Here, "Number Analyzed" signifies subjects evaluable at given timepoints. "99999" means data could not be estimated due to insufficient events.

End point type	Secondary
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End point timeframe:

At pre-dose and within 5 minutes of End of Infusion (EOI) on Days 1 and 5 of Cycles 1 and 2; At pre-dose and within 5 minutes of EOI on Day 1 of Cycles 3 and 4 (Cycle 1 length = 14 days; Cycle 2, 3 and 4 length= 21 days)

Notes:

[33] - 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	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: nanograms per milliliter (ng/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1: Predose (n=9)	0 (± 99999)			
Cycle 1 Day 1: Within 5 minutes of EOI (n=9)	114.1 (± 62.47)			
Cycle 1 Day 5: Predose (n=8)	3.0 (± 1.50)			
Cycle 1 Day 5: Within 5 minutes of EOI (n=8)	125.4 (± 41.39)			
Cycle 2 Day 1: Predose (n=9)	0 (± 99999)			
Cycle 2 Day 1: Within 5 minutes of EOI (n=9)	120.3 (± 14.44)			
Cycle 2 Day 5: Predose (n=9)	2.7 (± 1.31)			

Cycle 2 Day 5: Within 5 minutes of EOI (n=9)	105.0 (± 26.67)			
Cycle 3 Day 1: Predose (n=4)	0 (± 99999)			
Cycle 3 Day 1: Within 5 minutes of EOI (n=4)	83.6 (± 33.54)			
Cycle 4 Day 1: Predose (n=2)	0 (± 99999)			
Cycle 4 Day 1: Within 5 minutes of EOI (n=2)	90.2 (± 22.72)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2: Concentrations of Nemvaleukin in Serum

End point title	Cohort 2: Concentrations of Nemvaleukin in Serum ^[34]
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End point description:

The PK population included 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 and "9999" means data could not be evaluated as no subject was evaluated.

End point type	Secondary
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End point timeframe:

Cycle 1 and 2 Day 1: Pre-dose, 1, 2, 4, 8 hours post-dose and within 5 minutes from the EOI; Cycle 1 and 2 Day 4; Cycle 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 and 13: Pre-dose and within 5 minutes from the EOI (Cycle 1 = 14 days; other Cycles = 21 days)

Notes:

[34] - 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	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	5	6
Units: ng/mL				
arithmetic mean (standard deviation)				
C1 D1: Predose (n=1,1,5,6,4,5,5,3,3,3,6,3, 7)	0 (± 99999)	0 (± 99999)	0 (± 99999)	0 (± 99999)
C1 D1:1 Hr Post Inf (n=1,1,5,6,4,5,5,3,3,3,6,3,7)	81.7 (± 99999)	512.7 (± 99999)	536.5 (± 149.89)	511.2 (± 248.50)
C1 D1:2 Hr Post Inf (n=1,1,5,6,4,4,5,3,3,3,6,3,7)	161.6 (± 99999)	413.6 (± 99999)	723.0 (± 669.04)	568.3 (± 525.29)
C1 D1:4 Hr Post Inf (n=1,1,5,6,4,4,5,3,3,3,6,3,7)	92.5 (± 9999)	103.3 (± 99999)	456.5 (± 301.13)	269.5 (± 143.16)
C1 D1:8 Hr Post Inf (n=1,1,3,6,4,4,5,3,3,3,6,3,7)	33.2 (± 9999)	110.5 (± 99999)	226.4 (± 146.60)	108.8 (± 62.05)
C1D1: In 5m from EOI(n=1,1,4,6,4,5,5,3,3,3,6,3,7)	174.7 (± 9999)	546.7 (± 99999)	906.3 (± 662.31)	662.0 (± 442.53)
C1 D4 (n=1,1,5,5,4,5,5,3,0,0,0,0,0)	9999 (± 99999)	0 (± 99999)	2.9 (± 1.62)	1.9 (± 0.86)
C2 D1: Predose (n=0,1,3,4,2,4,4,3,3,3,6,3,6)	9999 (± 99999)	0 (± 99999)	0 (± 99999)	0 (± 99999)

C2 D1: 1 Hr Post Inf (n=0,1,3,4,2,5,4,3,3,3,6,3,6)	9999 (± 9999)	363.9 (± 99999)	669.4 (± 314.87)	583.8 (± 279.09)
C2 D1: 2 Hr Post Inf (n=0,1,3,4,2,5,5,3,3,3,6,3,6)	9999 (± 9999)	306.1 (± 99999)	535.9 (± 101.44)	497.0 (± 251.06)
C2 D1: 4 Hr Post Inf (n=0,1,3,4,2,5,4,3,3,3,6,3,6)	9999 (± 9999)	182.5 (± 99999)	408.0 (± 154.81)	306.7 (± 275.77)
C2 D1: 8 Hr Post Inf (n=0,1,3,4,2,4,4,3,3,3,5,2,6)	9999 (± 9999)	68.7 (± 99999)	244.8 (± 20.43)	213.0 (± 250.36)
C2D1: In 5m from EOI(n=0,1,3,4,2,5,5,3,3,3,6,3,6)	9999 (± 9999)	426.4 (± 99999)	784.4 (± 251.81)	622.5 (± 241.93)
C2 D4 (n=0,1,2,4,2,0,0,0,0,0,0,0,0)	9999 (± 9999)	0.5 (± 99999)	1.1 (± 0.27)	1.5 (± 0.79)
C3 D1: Predose (n=0,0,1,1,0,1,2,1,0,1,3,3,4)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)	0 (± 99999)
C3D1:In 5m from EOI(n=0,0,1,1,0,1,2,1,0,1,3,3,4)	9999 (± 9999)	9999 (± 9999)	741.5 (± 99999)	504.2 (± 99999)
C4 D1: Predose (n=0,0,1,1,0,1,2,1,0,0,2,3,3)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)	0 (± 99999)
C4 D1:In 5m from EOI(n=0,0,1,1,0,1,2,1,0,0,2,3,3)	9999 (± 9999)	9999 (± 9999)	898.2 (± 99999)	1408.0 (± 99999)
C5 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,1,1,1)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)	9999 (± 9999)
C5D1: In 5m from EOI (n=0,0,1,0,0,1,2,0,0,0,1,1,1)	9999 (± 9999)	9999 (± 9999)	574.3 (± 99999)	9999 (± 9999)
C6 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,6,3,7)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)	9999 (± 9999)
C6 D1: In 5m from EOI(n=0,0,1,0,0,1,2,0,0,0,1,1,1)	9999 (± 9999)	9999 (± 9999)	581.6 (± 99999)	9999 (± 9999)
C7 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)	9999 (± 9999)
C7D1:In 5m from EOI(n=0,0,0,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C8 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)	9999 (± 9999)
C8D1:In 5m from EOI(n=0,0,0,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C9 D1: Predose (n=0,0,0,0,0,0,1,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C9D1:In 5m from EOI(n=0,0,0,0,0,0,1,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C10 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C10D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C11 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C11D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C12 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C12D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C13 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C13D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin	Cohort 2, Part A, Schedule 2: Nemvaleukin	Cohort 2, Part A, Schedule 2: Nemvaleukin	Cohort 2, Part A, Schedule 2: Nemvaleukin
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	Alfa 40 mcg/kg	Alfa 20 mcg/kg	Alfa 25 mcg/kg	Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: ng/mL				
arithmetic mean (standard deviation)				
C1 D1: Predose (n=1,1,5,6,4,5,5,3,3,3,6,3, 7)	0 (± 99999)	3 (± 99999)	0 (± 99999)	0 (± 99999)
C1 D1:1 Hr Post Inf (n=1,1,5,6,4,5,5,3,3,3,6,3,7)	749.9 (± 327.76)	271.0 (± 94.88)	345.1 (± 63.24)	467.0 (± 27.70)
C1 D1:2 Hr Post Inf (n=1,1,5,6,4,4,5,3,3,3,6,3,7)	885.7 (± 570.36)	249.1 (± 126.02)	283.3 (± 34.21)	308.5 (± 87.35)
C1 D1:4 Hr Post Inf (n=1,1,5,6,4,4,5,3,3,3,6,3,7)	423.6 (± 220.23)	140.5 (± 59.78)	190.1 (± 44.29)	229.4 (± 6.81)
C1 D1:8 Hr Post Inf (n=1,1,3,6,4,4,5,3,3,3,6,3,7)	309.9 (± 130.26)	78.9 (± 30.91)	97.1 (± 16.04)	116.7 (± 54.26)
C1D1: In 5m from EOI(n=1,1,4,6,4,5,5,3,3,3,6,3,7)	999.4 (± 543.38)	338.3 (± 129.85)	412.3 (± 66.88)	436.1 (± 140.65)
C1 D4 (n=1,1,5,5,4,5,5,3,0,0,0,0,0)	2.7 (± 0.90)	1.0 (± 0.71)	1.2 (± 0.16)	12.3 (± 18.58)
C2 D1: Predose (n=0,1,3,4,2,4,4,3,3,3,6,3,6)	0 (± 99999)	0 (± 99999)	3 (± 99999)	1 (± 99999)
C2 D1: 1 Hr Post Inf (n=0,1,3,4,2,5,4,3,3,3,6,3,6)	884.2 (± 201.52)	283.7 (± 83.75)	332.8 (± 83.19)	375.6 (± 62.23)
C2 D1: 2 Hr Post Inf (n=0,1,3,4,2,5,5,3,3,3,6,3,6)	605.0 (± 58.50)	215.2 (± 81.02)	235.0 (± 16.58)	272.1 (± 56.15)
C2 D1: 4 Hr Post Inf (n=0,1,3,4,2,5,4,3,3,3,6,3,6)	270.6 (± 290.31)	130.7 (± 52.81)	128.7 (± 86.16)	193.4 (± 37.63)
C2 D1: 8 Hr Post Inf (n=0,1,3,4,2,4,4,3,3,3,5,2,6)	180.4 (± 55.37)	61.9 (± 17.64)	82.1 (± 9.47)	88.1 (± 29.48)
C2D1: In 5m from EOI(n=0,1,3,4,2,5,5,3,3,3,6,3,6)	929.8 (± 334.10)	306.1 (± 134.02)	330.7 (± 18.08)	476.5 (± 133.60)
C2 D4 (n=0,1,2,4,2,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C3 D1: Predose (n=0,0,1,1,0,1,2,1,0,1,3,3,4)	9999 (± 9999)	0 (± 99999)	0 (± 99999)	0.6 (± 99999)
C3D1:In 5m from EOI(n=0,0,1,1,0,1,2,1,0,1,3,3,4)	9999 (± 9999)	282.6 (± 99999)	331.8 (± 49.78)	575.1 (± 99999)
C4 D1: Predose (n=0,0,1,1,0,1,2,1,0,0,2,3,3)	9999 (± 9999)	0 (± 99999)	0 (± 99999)	0 (± 99999)
C4 D1:In 5m from EOI(n=0,0,1,1,0,1,2,1,0,0,2,3,3)	9999 (± 9999)	275.2 (± 99999)	297.1 (± 0.05)	637.2 (± 99999)
C5 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,1,1,1)	9999 (± 9999)	0 (± 99999)	0 (± 99999)	9999 (± 9999)
C5D1: In 5m from EOI (n=0,0,1,0,0,1,2,0,0,0,1,1,1)	9999 (± 9999)	340.5 (± 99999)	365.6 (± 117.78)	9999 (± 9999)
C6 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,6,3,7)	9999 (± 9999)	0 (± 99999)	0 (± 99999)	9999 (± 9999)
C6 D1: In 5m from EOI(n=0,0,1,0,0,1,2,0,0,0,1,1,1)	9999 (± 9999)	289.4 (± 99999)	331.9 (± 157.69)	9999 (± 9999)
C7 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	0 (± 99999)	0 (± 99999)	9999 (± 9999)
C7D1:In 5m from EOI(n=0,0,0,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	396.6 (± 99999)	358.6 (± 35.74)	9999 (± 9999)
C8 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	0 (± 99999)	0 (± 99999)	9999 (± 9999)
C8D1:In 5m from EOI(n=0,0,0,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	436.0 (± 99999)	311.9 (± 103.16)	9999 (± 9999)
C9 D1: Predose (n=0,0,0,0,0,0,1,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)	9999 (± 9999)
C9D1:In 5m from EOI(n=0,0,0,0,0,0,1,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	362.8 (± 99999)	9999 (± 9999)

C10 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C10D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C11 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C11D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C12 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C12D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C13 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C13D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	6	3
Units: ng/mL				
arithmetic mean (standard deviation)				
C1 D1: Predose (n=1,1,5,6,4,5,5,3,3,6,3, 7)	0 (± 99999)	0 (± 99999)	0 (± 99999)	0 (± 99999)
C1 D1:1 Hr Post Inf (n=1,1,5,6,4,5,5,3,3,6,3,7)	375.9 (± 15.55)	475.3 (± 292.23)	392.0 (± 117.51)	407.4 (± 40.52)
C1 D1:2 Hr Post Inf (n=1,1,5,6,4,4,5,3,3,6,3,7)	321.2 (± 123.50)	329.6 (± 136.55)	313.5 (± 74.34)	339.6 (± 65.43)
C1 D1:4 Hr Post Inf (n=1,1,5,6,4,4,5,3,3,6,3,7)	142.6 (± 154.06)	227.0 (± 102.52)	231.8 (± 70.63)	226.3 (± 34.19)
C1 D1:8 Hr Post Inf (n=1,1,3,6,4,4,5,3,3,6,3,7)	118.9 (± 92.98)	120.8 (± 75.18)	108.3 (± 21.65)	80.1 (± 34.07)
C1D1: In 5m from EOI(n=1,1,4,6,4,5,5,3,3,6,3,7)	427.8 (± 30.36)	456.1 (± 178.76)	401.2 (± 76.75)	461.4 (± 76.94)
C1 D4 (n=1,1,5,5,4,5,5,3,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2 D1: Predose (n=0,1,3,4,2,4,4,3,3,6,3,6)	0 (± 99999)	0 (± 99999)	0 (± 99999)	0 (± 99999)
C2 D1: 1 Hr Post Inf (n=0,1,3,4,2,5,4,3,3,6,3,6)	431.8 (± 162.46)	407.3 (± 228.72)	246.5 (± 82.08)	396.4 (± 66.90)
C2 D1: 2 Hr Post Inf (n=0,1,3,4,2,5,5,3,3,6,3,6)	317.6 (± 75.80)	383.0 (± 188.02)	237.9 (± 127.98)	369.1 (± 60.21)
C2 D1: 4 Hr Post Inf (n=0,1,3,4,2,5,4,3,3,6,3,6)	189.8 (± 32.43)	238.9 (± 172.54)	188.0 (± 148.09)	221.1 (± 52.34)
C2 D1: 8 Hr Post Inf (n=0,1,3,4,2,4,4,3,3,5,2,6)	88.4 (± 18.40)	120.1 (± 73.13)	66.1 (± 19.39)	106.9 (± 2.28)
C2D1: In 5m from EOI(n=0,1,3,4,2,5,5,3,3,6,3,6)	336.0 (± 106.98)	536.0 (± 391.82)	306.8 (± 113.96)	458.3 (± 121.75)
C2 D4 (n=0,1,2,4,2,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C3 D1: Predose (n=0,0,1,1,0,1,2,1,0,1,3,3,4)	9999 (± 9999)	0 (± 99999)	0 (± 99999)	0 (± 99999)
C3D1:In 5m from EOI(n=0,0,1,1,0,1,2,1,0,1,3,3,4)	9999 (± 9999)	769.5 (± 99999)	404.3 (± 253.19)	269 (± 99999)
C4 D1: Predose (n=0,0,1,1,0,1,2,1,0,0,2,3,3)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)	0 (± 99999)

C4 D1: In 5m from EOI(n=0,0,1,1,0,1,2,1,0,0,2,3,3)	9999 (± 9999)	9999 (± 9999)	437.1 (± 147.32)	384.7 (± 62.27)
C5 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,1,1,1)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)	0 (± 99999)
C5D1: In 5m from EOI (n=0,0,1,0,0,1,2,0,0,0,1,1,1)	9999 (± 9999)	9999 (± 9999)	262.1 (± 99999)	712.3 (± 99999)
C6 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,6,3,7)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)	0 (± 99999)
C6 D1: In 5m from EOI(n=0,0,1,0,0,1,2,0,0,0,1,1,1)	9999 (± 9999)	9999 (± 9999)	257.8 (± 99999)	358.8 (± 99999)
C7 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	1.2 (± 99999)
C7D1: In 5m from EOI(n=0,0,0,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	334.1 (± 99999)
C8 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)
C8D1: In 5m from EOI(n=0,0,0,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	431.6 (± 99999)
C9 D1: Predose (n=0,0,0,0,0,0,1,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	571.0 (± 99999)
C9D1: In 5m from EOI(n=0,0,0,0,0,0,1,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)
C10 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)
C10D1: In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	480.1 (± 99999)
C11 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)
C11D1: In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	487.4 (± 99999)
C12 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)
C12D1: In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	602.1 (± 99999)
C13 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	0 (± 99999)
C13D1: In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	488.8 (± 99999)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: ng/mL				
arithmetic mean (standard deviation)				
C1 D1: Predose (n=1,1,5,6,4,5,5,3,3,6,3, 7)	0 (± 99999)			
C1 D1:1 Hr Post Inf (n=1,1,5,6,4,5,5,3,3,6,3,7)	590.9 (± 128.85)			
C1 D1:2 Hr Post Inf (n=1,1,5,6,4,4,5,3,3,6,3,7)	502.6 (± 141.64)			
C1 D1:4 Hr Post Inf (n=1,1,5,6,4,4,5,3,3,6,3,7)	287.3 (± 88.88)			
C1 D1:8 Hr Post Inf (n=1,1,3,6,4,4,5,3,3,6,3,7)	208.5 (± 96.99)			

C1D1: In 5m from EOI(n=1,1,4,6,4,5,5,3,3,6,3,7)	670.9 (± 186.47)			
C1 D4 (n=1,1,5,5,4,5,5,3,0,0,0,0)	9999 (± 9999)			
C2 D1: Predose (n=0,1,3,4,2,4,4,3,3,6,3,6)	0 (± 99999)			
C2 D1: 1 Hr Post Inf (n=0,1,3,4,2,5,4,3,3,6,3,6)	575.3 (± 186.18)			
C2 D1: 2 Hr Post Inf (n=0,1,3,4,2,5,5,3,3,6,3,6)	479.7 (± 179.55)			
C2 D1: 4 Hr Post Inf (n=0,1,3,4,2,5,4,3,3,6,3,6)	308.6 (± 81.55)			
C2 D1: 8 Hr Post Inf (n=0,1,3,4,2,4,4,3,3,5,2,6)	161.5 (± 58.04)			
C2D1: In 5m from EOI(n=0,1,3,4,2,5,5,3,3,6,3,6)	692.3 (± 209.98)			
C2 D4 (n=0,1,2,4,2,0,0,0,0,0,0,0)	9999 (± 9999)			
C3 D1: Predose (n=0,0,1,1,0,1,2,1,0,1,3,3,4)	0 (± 99999)			
C3D1:In 5m from EOI(n=0,0,1,1,0,1,2,1,0,1,3,3,4)	697.9 (± 187.85)			
C4 D1: Predose (n=0,0,1,1,0,1,2,1,0,0,2,3,3)	0 (± 99999)			
C4 D1:In 5m from EOI(n=0,0,1,1,0,1,2,1,0,0,2,3,3)	781.7 (± 62.17)			
C5 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,1,1,1)	0 (± 99999)			
C5D1: In 5m from EOI (n=0,0,1,0,0,1,2,0,0,0,1,1,1)	776.4 (± 99999)			
C6 D1: Predose (n=0,0,1,0,0,1,2,0, 0,0,6,3,7)	0 (± 99999)			
C6 D1: In 5m from EOI(n=0,0,1,0,0,1,2,0,0,0,1,1,1)	757.0 (± 99999)			
C7 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)			
C7D1:In 5m from EOI(n=0,0,0,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)			
C8 D1: Predose (n=0,0,1,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)			
C8D1:In 5m from EOI(n=0,0,0,0,0,1,2,0,0,0,0,1,0)	9999 (± 9999)			
C9 D1: Predose (n=0,0,0,0,0,0,1,0,0,0,0,1,0)	9999 (± 9999)			
C9D1:In 5m from EOI(n=0,0,0,0,0,0,1,0,0,0,0,1,0)	9999 (± 9999)			
C10 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)			
C10D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)			
C11 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)			
C11D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)			
C12 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)			
C12D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)			
C13 D1: Predose (n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)			
C13D1:In 5m from EOI(n=0,0,0,0,0,0,0,0,0,0,0,1,0)	9999 (± 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2, Cmax: Maximum Observed Serum Concentration of Nemvaleukin Alfa

End point title	Cohort 2, Cmax: Maximum Observed Serum Concentration of Nemvaleukin Alfa ^[35]
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End point description:

Noncompartmental PK analysis was performed. The PK population included 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 evaluable for this outcome measure and "n" signifies subjects evaluable at given timepoints. As planned, this PK parameter was assessed in Cohort 2 only. Here, "99999" means data could not be calculated due to less subject and "9999" means data could not be evaluated as no subject was evaluated for the specified endpoint.

End point type	Secondary
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End point timeframe:

Cycles 1 and 2: Day 1 (Schedules 1, 2 and 3), Day 4 (Schedule 3 only), and Day 8 (Schedule 2 only): Pre-dose, and within 5 minutes, 1, 2, 4, and 8 hours post-dose (each Cycle length=21 days)

Notes:

[35] - 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	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	5	6
Units: micrograms per liter (mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,6,3,7)	175 (± 99999)	547 (± 99999)	769 (± 57.7)	601 (± 61.0)
C1D4 (n=0,0,0,0,0,0,0,3,3,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	9999 (± 9999)	426 (± 99999)	760 (± 31.1)	596 (± 38.0)
C2D4 (n=0,0,0,0,0,0,0,3,4,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3

Units: micrograms per liter (mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,3,6,3,7)	925 (± 47.6)	339 (± 42.0)	415 (± 15.7)	490 (± 9.9)
C1D4 (n=0,0,0,0,0,0,0,0,3,3,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0,0)	9999 (± 9999)	298 (± 35.0)	342 (± 14.4)	558 (± 46.7)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	930 (± 32.8)	316 (± 44.7)	353 (± 17.5)	463 (± 31.4)
C2D4 (n=0,0,0,0,0,0,0,0,3,4,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0,0)	9999 (± 9999)	307 (± 14.9)	353 (± 7.3)	646 (± 30.3)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	6	3
Units: micrograms per liter (mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,3,6,3,7)	430 (± 7.9)	466 (± 51.2)	408 (± 25.5)	457 (± 17.1)
C1D4 (n=0,0,0,0,0,0,0,0,3,3,4,3,5)	304 (± 24.3)	456 (± 45.5)	358 (± 25.9)	400 (± 13.9)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	446 (± 34.1)	362 (± 69.4)	339 (± 46.6)	492 (± 16.6)
C2D4 (n=0,0,0,0,0,0,0,0,3,4,4,3,5)	441 (± 57.1)	309 (± 57.5)	316 (± 85.1)	401 (± 18.7)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: micrograms per liter (mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,3,6,3,7)	656 (± 27.7)			
C1D4 (n=0,0,0,0,0,0,0,0,3,3,4,3,5)	632 (± 25.3)			
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0,0)	9999 (± 9999)			
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	665 (± 32.5)			
C2D4 (n=0,0,0,0,0,0,0,0,3,4,4,3,5)	652 (± 32.0)			
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0,0)	9999 (± 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2, Tmax: Time to Reach Cmax of Nemvaleukin Alfa

End point title	Cohort 2, Tmax: Time to Reach Cmax of Nemvaleukin Alfa ^[36]
End point description:	
Noncompartmental PK analysis was performed. The PK population included 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 evaluable for this outcome measure and "n" signifies subjects evaluable at given timepoints. As planned, this PK parameter was assessed in Cohort 2 only. Here, "99999" means data could not be calculated due to less subject and "9999" means data could not be evaluated as no subject was evaluated for the specified endpoint.	
End point type	Secondary
End point timeframe:	
Cycles 1 and 2: Day 1 (Schedules 1, 2 and 3), Day 4 (Schedule 3 only), and Day 8 (Schedule 2 only): Pre-dose, and within 5 minutes, 1, 2, 4, and 8 hours post-dose (each Cycle length=21 days)	
Notes:	
[36] - 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	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	4	6
Units: hours				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,4,6,4,5,5,3,3,6,3,7)	0.673 (± 99999)	1.05 (± 99999)	1.25 (± 102.0)	1.10 (± 55.5)
C1D4 (n=0,0,0,0,0,0,0,3,3,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,6,3,7)	9999 (± 9999)	0.913 (± 99999)	0.589 (± 1.6)	0.748 (± 53.5)
C2D4 (n=0,0,0,0,0,0,0,3,4,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: hours				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,4,6,4,5,5,3,3,6,3,7)	1.12 (± 45.7)	0.807 (± 61.9)	0.614 (± 29.1)	0.682 (± 36.4)
C1D4 (n=0,0,0,0,0,0,0,3,3,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0)	9999 (± 9999)	0.612 (± 19.8)	0.707 (± 41.7)	0.531 (± 10.6)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,6,3,7)	0.775 (± 37.3)	0.747 (± 27.7)	0.654 (± 34.5)	0.526 (± 8.9)
C2D4 (n=0,0,0,0,0,0,0,3,4,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0)	9999 (± 9999)	0.589 (± 4.3)	0.572 (± 18.3)	0.563 (± 16.8)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	6	3
Units: hours				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,4,6,4,5,5,3,3,3,6,3,7)	0.908 (± 75.2)	0.705 (± 31.1)	0.757 (± 64.2)	0.536 (± 12.2)
C1D4 (n=0,0,0,0,0,0,0,0,3,3,4,3,5)	1.21 (± 88.1)	0.695 (± 33.9)	0.917 (± 30.9)	0.574 (± 14.5)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,6,3,7)	0.716 (± 48.5)	0.754 (± 59.6)	0.901 (± 130.6)	1.00 (± 78.5)
C2D4 (n=0,0,0,0,0,0,0,0,3,4,4,3,5)	0.901 (± 87.4)	0.820 (± 86.3)	0.991 (± 73.3)	0.691 (± 33.2)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: hours				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,4,6,4,5,5,3,3,3,6,3,7)	0.610 (± 24.1)			
C1D4 (n=0,0,0,0,0,0,0,0,3,3,4,3,5)	1.04 (± 99.7)			
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0,0)	9999 (± 9999)			
C2D1 (n=0,1,3,4,2,5,4,3,3,5,6,3,7)	0.556 (± 9.4)			
C2D4 (n=0,0,0,0,0,0,0,0,3,4,4,3,5)	0.596 (± 26.7)			
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0,0)	9999 (± 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2, AUClast: Area Under the Serum Concentration–Time Curve From Zero Time to Time of Last Quantifiable Concentration of Nemvaleukin Alfa

End point title	Cohort 2, AUClast: Area Under the Serum Concentration–Time Curve From Zero Time to Time of Last Quantifiable Concentration of Nemvaleukin Alfa ^[37]
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End point description:

Noncompartmental PK analysis was performed. The PK population included 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 evaluable for this outcome measure and "n" signifies subjects evaluable at given timepoints. As planned, this PK parameter was assessed in Cohort 2 only. Here, "99999" means data could not be calculated due to less

subject and "9999" means data could not be evaluated as no subject was evaluated for the specified endpoint.

End point type	Secondary
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End point timeframe:

Cycles 1 and 2: Day 1 (Schedules 1, 2 and 3), Day 4 (Schedule 3 only), and Day 8 (Schedule 2 only): Pre-dose, and within 5 minutes, 1, 2, 4, and 8 hours post-dose (each Cycle length=21 days)

Notes:

[37] - 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	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	4	6
Units: hour micrograms per liter (h*mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,4,6,4,4,5,3,3,6,3,7)	677 (± 99999)	1700 (± 99999)	2870 (± 71.8)	2120 (± 59.0)
C1D4 (n=0,0,0,0,0,0,0,3,3,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	9999 (± 9999)	1520 (± 99999)	2930 (± 35.9)	2290 (± 67.2)
C2D4 (n=0,0,0,0,0,0,0,3,4,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: hour micrograms per liter (h*mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,4,6,4,4,5,3,3,6,3,7)	3790 (± 46.8)	1180 (± 50.1)	1560 (± 12.4)	1860 (± 20.4)
C1D4 (n=0,0,0,0,0,0,0,3,3,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0)	9999 (± 9999)	1040 (± 65.1)	1350 (± 6.5)	1930 (± 33.1)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	2800 (± 59.2)	987 (± 60.5)	1390 (± 5.2)	1600 (± 22.3)
C2D4 (n=0,0,0,0,0,0,0,3,4,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0)	9999 (± 9999)	1190 (± 26.6)	1150 (± 15.7)	2100 (± 2.7)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	6	3
Units: hour micrograms per liter (h*mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,4,6,4,4,5,3,3,3,6,3,7)	1490 (± 47.8)	1780 (± 45.9)	1790 (± 28.4)	1770 (± 10.2)
C1D4 (n=0,0,0,0,0,0,0,0,3,3,4,3,5)	821 (± 32.0)	1720 (± 50.2)	1440 (± 30.0)	1420 (± 17.4)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	1560 (± 11.4)	1360 (± 64.1)	1290 (± 59.0)	1670 (± 13.7)
C2D4 (n=0,0,0,0,0,0,0,0,3,4,4,3,5)	1860 (± 52.2)	1280 (± 62.8)	1100 (± 80.9)	1590 (± 3.9)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: hour micrograms per liter (h*mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,4,6,4,4,5,3,3,3,6,3,7)	2620 (± 27.1)			
C1D4 (n=0,0,0,0,0,0,0,0,3,3,4,3,5)	2590 (± 24.6)			
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0,0)	9999 (± 9999)			
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	2490 (± 30.4)			
C2D4 (n=0,0,0,0,0,0,0,0,3,4,4,3,5)	2210 (± 27.0)			
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0,0)	9999 (± 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2, Clast: Last Quantifiable Serum Concentration of Nemvaleukin Alfa

End point title	Cohort 2, Clast: Last Quantifiable Serum Concentration of Nemvaleukin Alfa ^[38]
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End point description:

Noncompartmental PK analysis was performed. The PK population included 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 evaluable for this outcome measure and "n" signifies subjects evaluable at given timepoints. As planned, this PK parameter was assessed in Cohort 2 only. Here, "99999" means data could not be calculated due to less subject and "9999" means data could not be evaluated as no subject was evaluated for the specified endpoint.

End point type	Secondary
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End point timeframe:

Cycles 1 and 2: Day 1 (Schedules 1, 2 and 3), Day 4 (Schedule 3 only), and Day 8 (Schedule 2 only): Pre-dose, and within 5 minutes, 1, 2, 4, and 8 hours post-dose (each Cycle length=21 days)

Notes:

[38] - 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	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	5	6
Units: micrograms per liter (mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,5,6,3,7)	33.2 (± 99999)	111 (± 99999)	260 (± 61.8)	96.4 (± 56.8)
C1D4 (n=0,0,0,0,0,0,0,0,3,3,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	9999 (± 9999)	68.7 (± 99999)	244 (± 8.6)	136 (± 140.0)
C2D4 (n=0,0,0,0,0,0,0,0,3,4,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D8 (n=0,0,0,0,0,5,5,3,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: micrograms per liter (mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,5,6,3,7)	288 (± 48.4)	98.3 (± 85.3)	96.1 (± 16.7)	106 (± 63.3)
C1D4 (n=0,0,0,0,0,0,0,0,3,3,4,3,5)	9999 (± 9999)	80.0 (± 17.0)	9999 (± 9999)	9999 (± 9999)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0,0)	9999 (± 9999)	62.7 (± 26.6)	70.7 (± 9.6)	92.4 (± 48.6)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	176 (± 32.0)	9999 (± 9999)	81.7 (± 11.8)	84.6 (± 37.2)
C2D4 (n=0,0,0,0,0,0,0,0,3,4,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D8 (n=0,0,0,0,0,5,5,3,0,0,0,0,0)	9999 (± 9999)	84.5 (± 83.8)	85.4 (± 50.6)	117 (± 8.6)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	6	3
Units: micrograms per liter (mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,5,6,3,7)	98.3 (± 84.1)	107 (± 62.7)	106 (± 20.7)	74.4 (± 52.8)
C1D4 (n=0,0,0,0,0,0,0,0,3,3,4,3,5)	129 (± 37.9)	77.0 (± 58.6)	72.6 (± 30.7)	54.5 (± 48.5)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	87.0 (± 22.7)	84.3 (± 62.2)	86.1 (± 57.4)	147 (± 59.7)

C2D4 (n=0,0,0,0,0,0,0,0,3,4,4,3,5)	132 (± 132.7)	76.9 (± 83.3)	87.5 (± 98.5)	111 (± 59.1)
C2D8 (n=0,0,0,0,0,5,5,3,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: micrograms per liter (mcg/L)				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,5,6,3,7)	191 (± 48.1)			
C1D4 (n=0,0,0,0,0,0,0,0,3,3,4,3,5)	125 (± 38.8)			
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0,0)	9999 (± 9999)			
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	153 (± 36.1)			
C2D4 (n=0,0,0,0,0,0,0,0,3,4,4,3,5)	107 (± 37.0)			
C2D8 (n=0,0,0,0,0,5,5,3,0,0,0,0,0)	9999 (± 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2, T1ast: Time to the Last Quantifiable Concentration of Nemvaleukin Alfa

End point title	Cohort 2, T1ast: Time to the Last Quantifiable Concentration of Nemvaleukin Alfa ^[39]
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End point description:

Noncompartmental PK analysis was performed. The PK population included 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 evaluable for this outcome measure and "n" signifies subjects evaluable at given timepoints. As planned, this PK parameter was assessed in Cohort 2 only. Here, "99999" means data could not be calculated due to less subject and "9999" means data could not be evaluated as no subject was evaluated for the specified endpoint.

End point type	Secondary
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End point timeframe:

Cycles 1 and 2: Day 1 (Schedules 1, 2 and 3), Day 4 (Schedule 3 only), and Day 8 (Schedule 2 only): Pre-dose, and within 5 minutes, 1, 2, 4, and 8 hours post-dose (each Cycle length=21 days)

Notes:

[39] - 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	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	5	6
Units: hours				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,6,3,7)	7.52 (± 99999)	7.88 (± 99999)	6.15 (± 34.7)	7.81 (± 2.1)
C1D4 (n=0,0,0,0,0,0,0,3,3,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	9999 (± 9999)	9999 (± 9999)	6.99 (± 12.3)	7.64 (± 3.1)
C2D4 (n=0,0,0,0,0,0,0,3,4,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	5	3
Units: hours				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,6,3,7)	7.93 (± 3.7)	5.51 (± 102.1)	7.56 (± 13.0)	7.95 (± 1.1)
C1D4 (n=0,0,0,0,0,0,0,3,3,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0)	9999 (± 9999)	6.77 (± 33.0)	7.96 (± 1.1)	8.01 (± 0.1)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	7.89 (± 3.7)	6.81 (± 32.8)	7.96 (± 1.1)	7.85 (± 3.0)
C2D4 (n=0,0,0,0,0,0,0,3,4,4,3,5)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0)	9999 (± 9999)	7.84 (± 1.7)	6.73 (± 31.9)	7.87 (± 2.2)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	6	3
Units: hours				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,6,3,7)	7.79 (± 3.6)	7.87 (± 1.1)	7.88 (± 5.8)	7.91 (± 4.8)
C1D4 (n=0,0,0,0,0,0,0,3,3,4,3,5)	5.09 (± 41.6)	7.90 (± 1.7)	7.93 (± 3.6)	7.94 (± 2.1)
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	7.31 (± 8.9)	7.88 (± 1.4)	6.67 (± 38.9)	6.38 (± 40.9)
C2D4 (n=0,0,0,0,0,0,0,3,4,4,3,5)	7.79 (± 3.5)	7.95 (± 5.4)	6.78 (± 33.4)	7.76 (± 3.3)
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: hours				
geometric mean (geometric coefficient of variation)				
C1D1 (n=1,1,5,6,4,5,5,3,3,6,3,7)	7.77 (± 4.7)			
C1D4 (n=0,0,0,0,0,0,0,3,3,4,3,5)	7.95 (± 1.4)			
C1D8 (n=0,0,0,0,0,4,4,3,0,0,0,0)	9999 (± 9999)			
C2D1 (n=0,1,3,4,2,5,4,3,3,5,4,3,6)	7.68 (± 7.7)			
C2D4 (n=0,0,0,0,0,0,0,3,4,4,3,5)	8.01 (± 1.2)			
C2D8 (n=0,0,0,0,0,3,4,2,0,0,0,0)	9999 (± 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Positive Anti-nemvaleukin Antibodies (ADA)

End point title	Number of Participants With Positive Anti-nemvaleukin Antibodies (ADA)
End point description:	
Positive ADA were defined as sample with a positive result in the screen and the confirmatory assays. The immunogenicity population included all subjects who received at least one dose of nemvaleukin alfa and has a baseline and at least 1 post-treatment sample for ADA analysis.	
End point type	Secondary
End point timeframe:	
Baseline up to 12 weeks for Cohort A; up to 39 weeks for Cohort 2	

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	1	1	3
Units: participants	0	0	0	0

End point values	Cohort 2, Part A, Schedule 1:	Cohort 2, Part A, Schedule 1:	Cohort 2, Part A, Schedule 2:	Cohort 2, Part A, Schedule 2:
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	Nemvaleukin Alfa 35 mcg/kg	Nemvaleukin Alfa 40 mcg/kg	Nemvaleukin Alfa 20 mcg/kg	Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	4
Units: participants	0	0	0	1

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	5
Units: participants	1	0	0	0

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: participants	2	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Total T Cells, CD8+ T Cells, CD56+ Cells, and Treg Cells in Peripheral Blood

End point title	Change From Baseline in Number of Total T Cells, CD8+ T Cells, CD56+ Cells, and Treg Cells in Peripheral Blood
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End point description:

The circulating total T Cells, CD8+ T cells, CD56+ cells, and Treg cells in peripheral whole blood were measured using a validated biomarker assay. The peripheral blood PD population included subjects who received at least 1 dose of nemvaleukin alfa and had at least 1 post-baseline available peripheral blood PD measurement. 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 and "9999" means data could not be evaluated as no subject was evaluated for the specified endpoint.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 5; Cycle 2 Day 1; Cycle 3 Day 1 (each Cycle length = 21 days)

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	0 ^[40]	1	3
Units: cells count				
arithmetic mean (standard deviation)				
Total T:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0)	-25.3 (± 231.55)	()	9999 (± 9999)	9999 (± 9999)
Total T:C2D1 (n=8,0,1,3,4,2,5,4,3,3,3,6,2,6)	224.8 (± 246.65)	()	29.0 (± 99999)	14.3 (± 180.06)
Total T:C3D1 (n=4,0,0,1,1,0,1,2,1,0,1,3,3,4)	-226.0 (± 99999)	()	9999 (± 9999)	375.0 (± 99999)
CD8+ T Cells:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0,0,0)	-15.3 (± 84.27)	()	9999 (± 9999)	9999 (± 9999)
CD8+ T Cells:C2D1 (n=9,0,1,3,4,2,5,4,3,3,3,6,2,6)	117.0 (± 112.97)	()	8.0 (± 99999)	161.0 (± 119.00)
CD8+ T Cells:C3D1 (n=4,0,0,1,1,0,1,2,1,1,1,6,3,4)	42.5 (± 204.82)	()	9999 (± 9999)	173.0 (± 99999)
CD56+ Cells:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0,0,0)	156.9 (± 253.59)	()	9999 (± 9999)	9999 (± 9999)
CD56+ Cells:C2D1 (n=8,0,1,3,4,2,5,4,3,3,3,6,2,6)	294.1 (± 213.25)	()	6.0 (± 99999)	166.0 (± 140.81)
CD56+ Cells:C3D1 (n=4,0,0,1,1,0,1,2,1,0,1,3,3,4)	123.3 (± 167.07)	()	9999 (± 9999)	239.0 (± 99999)
Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0,0,0)	14.7 (± 9.99)	()	9999 (± 9999)	9999 (± 9999)
Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,3,5,3,6)	-0.7 (± 10.41)	()	8.4 (± 99999)	-0.6 (± 99999)
Treg:C3D1 (n=3,0,0,0,0,0,0,1,2,1,0,1,2,3,4)	-5.7 (± 5.91)	()	9999 (± 9999)	9999 (± 9999)

Notes:

[40] - No subjects were evaluable.

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	5	4
Units: cells count				
arithmetic mean (standard deviation)				
Total T:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Total T:C2D1 (n=8,0,1,3,4,2,5,4,3,3,3,6,2,6)	69.3 (± 92.10)	-129.5 (± 338.70)	-89.2 (± 61.92)	236.8 (± 188.54)
Total T:C3D1 (n=4,0,0,1,1,0,1,2,1,0,1,3,3,4)	199.0 (± 99999)	9999 (± 9999)	619.0 (± 99999)	307.0 (± 271.53)
CD8+ T Cells:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
CD8+ T Cells:C2D1 (n=9,0,1,3,4,2,5,4,3,3,3,6,2,6)	58.8 (± 48.82)	-64.5 (± 222.74)	-13.8 (± 58.94)	144.8 (± 115.22)
CD8+ T Cells:C3D1 (n=4,0,0,1,1,0,1,2,1,1,1,6,3,4)	110.0 (± 99999)	9999 (± 9999)	524.0 (± 99999)	191.0 (± 250.32)
CD56+ Cells:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

CD56+ Cells:C2D1 (n=8,0,1,3,4,2,5,4,3,3,3,6,2,6)	42.5 (± 57.23)	133.0 (± 277.19)	75.0 (± 46.73)	267.8 (± 177.05)
CD56+ Cells:C3D1 (n=4,0,0,1,1,0,1,2,1,0,1,3,3,4)	-67.0 (± 99999)	9999 (± 9999)	653.0 (± 99999)	584.0 (± 967.32)
Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,3,5,3,6)	1.3 (± 6.25)	-22.3 (± 30.78)	3.3 (± 16.32)	-0.1 (± 17.50)
Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	9999 (± 9999)	9999 (± 9999)	22.3 (± 99999)	-9.3 (± 20.06)

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: cells count				
arithmetic mean (standard deviation)				
Total T:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Total T:C2D1 (n=8,0,1,3,4,2,5,4,3,3,3,6,2,6)	328.0 (± 392.49)	370.3 (± 453.35)	98.0 (± 277.64)	140.3 (± 159.32)
Total T:C3D1 (n=4,0,0,1,1,0,1,2,1,0,1,3,3,4)	150.0 (± 99999)	9999 (± 9999)	55.0 (± 99999)	267.7 (± 194.04)
CD8+ T Cells:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
CD8+ T Cells:C2D1 (n=9,0,1,3,4,2,5,4,3,3,3,6,2,6)	157.7 (± 122.60)	160.0 (± 136.52)	61.3 (± 20.53)	81.7 (± 66.55)
CD8+ T Cells:C3D1 (n=4,0,0,1,1,0,1,2,1,1,1,6,3,4)	549.0 (± 99999)	0 (± 99999)	161.0 (± 99999)	518.7 (± 338.54)
CD56+ Cells:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
CD56+ Cells:C2D1 (n=8,0,1,3,4,2,5,4,3,3,3,6,2,6)	123.7 (± 76.49)	82.0 (± 51.51)	104.0 (± 62.22)	110.2 (± 44.51)
CD56+ Cells:C3D1 (n=4,0,0,1,1,0,1,2,1,0,1,3,3,4)	1284.0 (± 99999)	9999 (± 9999)	435.0 (± 99999)	138.0 (± 23.81)
Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,3,5,3,6)	-5.0 (± 17.54)	-10.4 (± 17.91)	-11.8 (± 20.11)	5.8 (± 15.61)
Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	7.7 (± 99999)	9999 (± 9999)	-22.6 (± 99999)	7.0 (± 6.85)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: cells count				
arithmetic mean (standard deviation)				
Total T:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)		

Total T:C2D1 (n=8,0,1,3,4,2,5,4,3,3,6,2,6)	252.0 (± 26.87)	459.8 (± 405.86)		
Total T:C3D1 (n=4,0,0,1,1,0,1,2,1,0,1,3,3,4)	31.0 (± 660.80)	324.8 (± 216.97)		
CD8+ T Cells:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)		
CD8+ T Cells:C2D1 (n=9,0,1,3,4,2,5,4,3,3,6,2,6)	148.0 (± 53.74)	226.5 (± 215.80)		
CD8+ T Cells:C3D1 (n=4,0,0,1,1,0,1,2,1,1,1,6,3,4)	99.3 (± 367.75)	166.5 (± 107.07)		
CD56+ Cells:C1D5 (n=8,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)		
CD56+ Cells:C2D1 (n=8,0,1,3,4,2,5,4,3,3,6,2,6)	556.5 (± 792.67)	280.8 (± 207.80)		
CD56+ Cells:C3D1 (n=4,0,0,1,1,0,1,2,1,0,1,3,3,4)	-220.3 (± 604.21)	303.0 (± 197.05)		
Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)		
Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,5,3,6)	-3.3 (± 8.94)	4.6 (± 13.25)		
Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	-8.4 (± 8.68)	-0.5 (± 6.88)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Ratio of T Cells/Treg, CD8+/Treg, CD56+/Treg in Peripheral Blood

End point title	Change From Baseline in Ratio of T Cells/Treg, CD8+/Treg, CD56+/Treg in Peripheral Blood
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End point description:

The circulating CD8+ T cells, Tregs, and NK cells in peripheral whole blood were measured using a validated biomarker assays and ratio of T Cells/Treg, CD8+/Treg, CD56+/Treg was calculated and reported. The peripheral blood PD population included subjects who received at least 1 dose of nemvaleukin alfa and had at least 1 post-baseline available peripheral blood PD measurement. 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 and "9999" means data could not be evaluated as no subject was evaluated for the specified endpoint.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 5; Cycle 2 Day 1; Cycle 3 Day 1 (each Cycle length = 21 days)

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	0 ^[41]	1	1
Units: ratio				
arithmetic mean (standard deviation)				

T/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0,0)	-19.5 (± 15.90)	()	9999 (± 9999)	9999 (± 9999)
T/Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,3,5,2,6)	25.6 (± 25.50)	()	-22.5 (± 99999)	11.9 (± 99999)
T/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	12.8 (± 9.96)	()	9999 (± 9999)	9999 (± 9999)
CD8+/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0,0)	-6.5 (± 6.26)	()	9999 (± 9999)	9999 (± 9999)
CD8+/Treg:C2D1 (n=8,0,1,1,4,3,4,4,3,3,3,5,2,6)	9.8 (± 9.61)	()	-5.9 (± 99999)	3.6 (± 99999)
CD8+/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	7.5 (± 9.78)	()	9999 (± 9999)	9999 (± 9999)
CD56+/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0,0)	1.8 (± 9.25)	()	9999 (± 9999)	9999 (± 9999)
CD56+/Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,3,5,2,6)	21.2 (± 15.65)	()	-7.4 (± 99999)	11.4 (± 99999)
CD56+/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	10.8 (± 8.57)	()	9999 (± 9999)	9999 (± 9999)

Notes:

[41] - No subjects were evaluable.

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	4
Units: ratio				
arithmetic mean (standard deviation)				
T/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
T/Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,3,5,2,6)	-78.9 (± 170.65)	26.2 (± 56.16)	34.9 (± 208.05)	7.1 (± 21.31)
T/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	9999 (± 9999)	9999 (± 9999)	-89.3 (± 99999)	33.8 (± 58.63)
CD8+/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
CD8+/Treg:C2D1 (n=8,0,1,1,4,3,4,4,3,3,3,5,2,6)	23.4 (± 57.43)	3.8 (± 16.98)	30.1 (± 120.44)	6.5 (± 6.15)
CD8+/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	9999 (± 9999)	9999 (± 9999)	-35.8 (± 99999)	10.4 (± 15.70)
CD56+/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
CD56+/Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,3,5,2,6)	-11.3 (± 33.71)	12.3 (± 20.76)	45.5 (± 112.43)	10.5 (± 5.16)
CD56+/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	9999 (± 9999)	9999 (± 9999)	-4.7 (± 99999)	10.0 (± 2.73)

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	5
Units: ratio				
arithmetic mean (standard deviation)				

T/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
T/Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,5,2,6)	1.0 (± 96.36)	105.4 (± 159.69)	-382.1 (± 1019.06)	-17.5 (± 47.99)
T/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	21.2 (± 99999)	9999 (± 9999)	264.3 (± 99999)	17.3 (± 0.33)
CD8+/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
CD8+/Treg:C2D1 (n=8,0,1,1,4,3,4,4,3,3,5,2,6)	-7.6 (± 46.42)	39.2 (± 52.39)	-166.3 (± 380.84)	-2.9 (± 19.58)
CD8+/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	9.8 (± 99999)	9999 (± 9999)	59.7 (± 99999)	10.1 (± 0.68)
CD56+/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
CD56+/Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,5,2,6)	0.8 (± 34.35)	14.2 (± 12.09)	7.3 (± 109.52)	3.1 (± 14.01)
CD56+/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	1.8 (± 99999)	9999 (± 9999)	286.8 (± 99999)	5.1 (± 5.37)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: ratio				
arithmetic mean (standard deviation)				
T/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)		
T/Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,5,2,6)	5.5 (± 10.32)	15.4 (± 28.86)		
T/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	333.2 (± 589.70)	28.6 (± 33.91)		
CD8+/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)		
CD8+/Treg:C2D1 (n=8,0,1,1,4,3,4,4,3,3,5,2,6)	4.1 (± 7.03)	9.2 (± 13.48)		
CD8+/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	182.8 (± 319.89)	11.2 (± 11.08)		
CD56+/Treg:C1D5 (n=4,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)		
CD56+/Treg:C2D1 (n=8,0,1,1,4,2,4,4,3,3,5,2,6)	10.8 (± 15.01)	15.0 (± 19.08)		
CD56+/Treg:C3D1 (n=3,0,0,0,0,0,1,2,1,0,1,2,3,4)	101.7 (± 184.75)	19.9 (± 14.82)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Absolute Numbers of Circulating Leukocytes Subtypes Cells

End point title	Change From Baseline in Absolute Numbers of Circulating Leukocytes Subtypes Cells
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End point description:

The interpretation of the TME data was limited by the small sample size in individual cohorts and schedules and by the wide variability in expression of the biomarkers. Since it was planned to not summarize data when number of samples is small. Therefore, the data was not summarized and reported in this endpoint.

End point type	Secondary
End point timeframe:	
Baseline up to Week 39	

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[42]	0 ^[43]	0 ^[44]	0 ^[45]
Units: participants				

Notes:

[42] - No subject was evaluated.

[43] - No subject was evaluated.

[44] - No subject was evaluated.

[45] - No subject was evaluated.

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[46]	0 ^[47]	0 ^[48]	0 ^[49]
Units: participants				

Notes:

[46] - No subject was evaluated.

[47] - No subject was evaluated.

[48] - No subject was evaluated.

[49] - No subject was evaluated.

End point values	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[50]	0 ^[51]	0 ^[52]	0 ^[53]
Units: participants				

Notes:

[50] - No subject was evaluated.

[51] - No subject was evaluated.

[52] - No subject was evaluated.

[53] - No subject was evaluated.

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[54]	0 ^[55]		
Units: participants				

Notes:

[54] - No subject was evaluated.

[55] - No subject was evaluated.

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentrations of Interferon Gamma (IFN-γ), Tumor Necrosis Factor-alpha (TNF-α), Interleukin (IL)-1 Beta, IL-6, and IL-10 Cytokines

End point title	Serum Concentrations of Interferon Gamma (IFN-γ), Tumor Necrosis Factor-alpha (TNF-α), Interleukin (IL)-1 Beta, IL-6, and IL-10 Cytokines
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End point description:

Serum concentrations of IFN-γ, TNF-α, IL-1 beta, IL-6, and IL-10 were determined using a validated soluble protein assay kit. Here, in timeframe 'C' stands for Cycle, 'D' for Day and 'h' for hours. Cycle 1 length was 14 days and length of other specified cycle was 21 days. The peripheral blood PD population included subjects who received at least 1 dose of nemvaleukin alfa and had at least 1 post-baseline available peripheral blood PD measurement. Here, "Number Analyzed" signifies subjects evaluable at given timepoints. "99999" means data could not be estimated due to insufficient events. "9999" means data could not be evaluated as no subject was evaluated.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1: Pre-dose, 4 and 8 hours post-dose; Cycle 1 Day 8 (Cycle length = 21 days)

End point values	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	1	1	2
Units: picograms per milliliters (pg/mL)				
arithmetic mean (standard deviation)				
IFN-γ:C1D1:Pre dose(n=9,1,1,1,2,1,5,5,3,1,3,6,3,6)	9.5 (± 5.84)	15.0 (± 99999)	4.9 (± 9999)	27.7 (± 99999)
IFN-γ:C1D1:4h PD(n=9,1,1,2,2,1,4,5,3,1,3,6,3,6)	1263.2 (± 1114.35)	1925.7 (± 99999)	4968.0 (± 99999)	3990.1 (± 3714.49)
IFN-γ:C1D1:8h PD(n=0,1,1,1,2,1,4,5,3,1,3,6,3,6)	9999 (± 9999)	653.4 (± 99999)	852.4 (± 99999)	11483.0 (± 99999)
IFN- γ:C1D8(n=6,0,0,0,0,0,0,0,0,0,0,1,6)	20.0 (± 7.22)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
IL-10 :C1D1:Predose(n=9,1,1,1,2,1,5,5,3,1,3,	1.9 (± 0.75)	1.6 (± 99999)	1.6 (± 99999)	1.6 (± 99999)
IL-10 :C1D1:4h PD(n=9,1,1,2,2,1,5,5,3,1,3,6,3,6)	5.0 (± 8.69)	3.8 (± 99999)	1.6 (± 99999)	3.9 (± 3.03)
IL-10 :C1D1:8h PD(n=0,1,1,1,2,1,4,5,3,1,3,6,3,6)	9999 (± 9999)	7.4 (± 99999)	2.9 (± 99999)	12.1 (± 99999)
IL-10 :C1D8(n=6,0,0,0,0,0,0,0,0,0,0,1,0,6)	1.6 (± 0.00)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
IL1beta:C1D1Predose(n=9,1,1,1,2,1,5,5, ,3,1,3,6,3,6)	3.0 (± 0.00)	3.0 (± 99999)	3.0 (± 99999)	3.0 (± 99999)

IL1beta:C1D1:4h PD(n=9,1,1,2,2,1,4,5,3,1,3,6,3,6)	3.0 (± 0.00)	3.0 (± 99999)	3.0 (± 99999)	3.0 (± 0.00)
IL1beta:C1D1:8h PD(n=0,1,1,1,2,1,4,5,3,1,3,6,3,6)	9999 (± 9999)	3.0 (± 99999)	3.0 (± 99999)	3.0 (± 99999)
IL1beta:C1D8(n=6,0,0,0,0,0,0,0,0,0,0,0,0,0)	3.0 (± 0.00)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
IL- 6:C1D1:Predose(n=9,1,1,1,2,1,5,5,3,1,3,6,3,6)	7.5 (± 5.88)	10.8 (± 99999)	2.0 (± 99999)	7.6 (± 99999)
IL-6:C1D1:4h PD(n=9,1,1,2,2,1,4,5,3,1,3,6,3,6)	156.4 (± 188.57)	274.7 (± 99999)	363.5 (± 99999)	475.2 (± 208.66)
IL-6:C1D1:8h PD(n=0,1,1,1,2,1,4,5,3,1,3,6,3,6)	9999 (± 9999)	40.9 (± 99999)	37.9 (± 99999)	566.2 (± 99999)
IL- 6:C1D8(n=6,0,0,0,0,0,0,0,0,0,0,0,0,0)	6.2 (± 4.70)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
TNF- α:C1D1:Predose(n=9,1,1,2,5,4,5,5,3,3,3,6,3,6)	4.6 (± 1.77)	2.8 (± 99999)	1.1 (± 99999)	4.7 (± 2.36)
TNF-α:C1D1:4h PD(n=0,1,1,3,5,4,4,5,3,3,3,6,3,6)	9999 (± 9999)	9.5 (± 99999)	11.3 (± 99999)	10.2 (± 8.44)
TNF-α:C1D1:8h PD(n=0,1,1,2,5,4,4,5,3,3,3,6,3,1)	9999 (± 9999)	5.8 (± 99999)	4.7 (± 99999)	19.8 (± 2.54)
TNF- α:C1D8(n=6,0,0,0,0,0,0,0,0,0,0,1,0,6)	6.7 (± 3.04)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	5	5
Units: picograms per milliliters (pg/mL)				
arithmetic mean (standard deviation)				
IFN-γ:C1D1:Pre dose(n=9,1,1,1,2,1,5,5,3,1,3,6,3,6)	9.5 (± 10.85)	2.7 (± 99999)	4.9 (± 3.19)	7.0 (± 3.46)
IFN-γ:C1D1:4h PD(n=9,1,1,2,2,1,4,5,3,1,3,6,3,6)	1442.0 (± 256.73)	2825.2 (± 99999)	737.0 (± 403.60)	2841.2 (± 2548.13)
IFN-γ:C1D1:8h PD(n=0,1,1,1,2,1,4,5,3,1,3,6,3,6)	467.9 (± 391.92)	6018.8 (± 99999)	293.4 (± 99.52)	1578.0 (± 1700.82)
IFN- γ:C1D8(n=6,0,0,0,0,0,0,0,0,0,0,0,1,6)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
IL-10 :C1D1:Predose(n=9,1,1,1,2,1,5,5,3,1,3,6,3,6)	1.7 (± 0.05)	1.6 (± 99999)	1.6 (± 0.00)	1.6 (± 0.00)
IL-10 :C1D1:4h PD(n=9,1,1,2,2,1,5,5,3,1,3,6,3,6)	4.7 (± 0.95)	1.8 (± 99999)	2.7 (± 0.78)	2.7 (± 1.04)
IL-10 :C1D1:8h PD(n=0,1,1,1,2,1,4,5,3,1,3,6,3,6)	10.6 (± 1.73)	4.6 (± 99999)	8.5 (± 5.22)	7.2 (± 4.55)
IL-10 :C1D8(n=6,0,0,0,0,0,0,0,0,0,0,0,1,0,6)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
IL1beta:C1D1Predose(n=9,1,1,1,2,1,5,5,3,1,3,6,3,6)	3.0 (± 0.00)	3.0 (± 99999)	3.0 (± 0.00)	3.1 (± 0.27)
IL1beta:C1D1:4h PD(n=9,1,1,2,2,1,4,5,3,1,3,6,3,6)	3.0 (± 0.00)	3.0 (± 99999)	3.0 (± 0.00)	3.4 (± 0.76)
IL1beta:C1D1:8h PD(n=0,1,1,1,2,1,4,5,3,1,3,6,3,6)	3.0 (± 0.00)	3.0 (± 99999)	3.0 (± 0.00)	3.0 (± 0.00)
IL1beta:C1D8(n=6,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)
IL- 6:C1D1:Predose(n=9,1,1,1,2,1,5,5,3,1,3,6,3,6)	27.4 (± 28.63)	1.5 (± 99999)	8.3 (± 10.97)	5.7 (± 4.57)

TNF-α:C1D1:4h PD(n=0,1,1,3,5,4,4,5,3,3,3,6,3,6)	15.4 (± 1.78)	13.9 (± 7.35)	14.3 (± 3.58)	14.8 (± 9.52)
TNF-α:C1D1:8h PD(n=0,1,1,2,5,4,4,5,3,3,3,6,3,1)	13.5 (± 3.79)	10.3 (± 3.38)	25.0 (± 12.71)	17.5 (± 17.58)
TNF- α:C1D8(n=6,0,0,0,0,0,0,0,0,0,1,0,6)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	1.7 (± 99999)

End point values	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: picograms per milliliters (pg/mL)				
arithmetic mean (standard deviation)				
IFN-γ:C1D1:Pre dose(n=9,1,1,1,2,1,5,5,3,1,3,6,3,6)	7.4 (± 5.40)	19.7 (± 30.84)		
IFN-γ:C1D1:4h PD(n=9,1,1,2,2,1,4,5,3,1,3,6,3,6)	1883.1 (± 711.64)	3309.7 (± 1431.11)		
IFN-γ:C1D1:8h PD(n=0,1,1,1,2,1,4,5,3,1,3,6,3,6)	1568.8 (± 244.11)	2586.2 (± 1800.74)		
IFN- γ:C1D8(n=6,0,0,0,0,0,0,0,0,0,0,1,6)	5.2 (± 99999)	78.7 (± 115.98)		
IL-10 :C1D1:Predose(n=9,1,1,1,2,1,5,5,3,1,3,6,3,6)	1.6 (± 0.00)	2.0 (± 0.82)		
IL-10 :C1D1:4h PD(n=9,1,1,2,2,1,5,5,3,1,3,6,3,6)	2.9 (± 0.75)	7.0 (± 10.20)		
IL-10 :C1D1:8h PD(n=0,1,1,1,2,1,4,5,3,1,3,6,3,6)	11.8 (± 10.11)	14.1 (± 9.63)		
IL-10 :C1D8(n=6,0,0,0,0,0,0,0,0,0,0,1,0,6)	9999 (± 9999)	1.7 (± 0.08)		
IL1beta:C1D1Predose(n=9,1,1,1,2,1,5,5,3,1,3,6,3,6)	3.0 (± 0.00)	3.0 (± 0.00)		
IL1beta:C1D1:4h PD(n=9,1,1,2,2,1,4,5,3,1,3,6,3,6)	3.0 (± 0.00)	3.0 (± 0.00)		
IL1beta:C1D1:8h PD(n=0,1,1,1,2,1,4,5,3,1,3,6,3,6)	3.0 (± 0.00)	3.0 (± 0.00)		
IL1beta:C1D8(n=6,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)		
IL- 6:C1D1:Predose(n=9,1,1,1,2,1,5,5,3,1,3,6,3,6)	2.2 (± 0.51)	5.8 (± 3.68)		
IL-6:C1D1:4h PD(n=9,1,1,2,2,1,4,5,3,1,3,6,3,6)	137.9 (± 74.25)	287.6 (± 147.72)		
IL-6:C1D1:8h PD(n=0,1,1,1,2,1,4,5,3,1,3,6,3,6)	107.8 (± 57.89)	223.0 (± 196.59)		
IL- 6:C1D8(n=6,0,0,0,0,0,0,0,0,0,0,0,0,0)	9999 (± 9999)	9999 (± 9999)		
TNF- α:C1D1:Predose(n=9,1,1,2,5,4,5,5,3,3,3,6,3,6)	2.3 (± 0.57)	2.4 (± 0.92)		
TNF-α:C1D1:4h PD(n=0,1,1,3,5,4,4,5,3,3,3,6,3,6)	15.9 (± 4.88)	16.1 (± 6.86)		
TNF-α:C1D1:8h PD(n=0,1,1,2,5,4,4,5,3,3,3,6,3,1)	14.9 (± 6.05)	15.5 (± 99999)		
TNF- α:C1D8(n=6,0,0,0,0,0,0,0,0,0,0,1,0,6)	9999 (± 9999)	3.2 (± 1.09)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Change From Baseline in Density of Immune Cells: Total T Cells, CD8+ T Cells, CD56+ Cells, and Tregs in Tumor Biopsies

End point title	Cohort 1: Change From Baseline in Density of Immune Cells: Total T Cells, CD8+ T Cells, CD56+ Cells, and Tregs in Tumor Biopsies ^[56]
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End point description:

TME-evaluable population. As pre-specified in protocol, tumor biopsies were optional at Day 8 of Cycles 4 and 5, and these optional assessments were not performed. Hence, no data was collected to be reported in this outcome measure.

End point type	Secondary
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End point timeframe:

Baseline, at Day 8 of Cycles 4 and 5 (each Cycle length=21 days)

Notes:

[56] - 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	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[57]			
Units: participants				

Notes:

[57] - No subjects evaluated for this endpoint

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 1: Change From Baseline in Ratio of T/Treg, CD8+/Treg, CD56+/Tregs in Tumor Biopsies

End point title	Cohort 1: Change From Baseline in Ratio of T/Treg, CD8+/Treg, CD56+/Tregs in Tumor Biopsies ^[58]
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End point description:

TME-evaluable population. As pre-specified in protocol, tumor biopsies were optional at Day 8 of Cycles 4 and 5, and these optional assessments were not performed. Hence, no data was collected to be reported in this outcome measure.

End point type	Secondary
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End point timeframe:

Baseline, at Day 8 of Cycle 4 and 5 (each Cycle length=21 days)

Notes:

[58] - 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	Cohort 1: Nemvaleukin Alfa 6 mcg/kg + Pembrolizumab 200 mg			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[59]			
Units: ratio				
arithmetic mean (standard deviation)	()			

Notes:

[59] - no data was collected to be reported in this endpoint.

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 up to 30 days after last dose (up to 16 weeks for Cohort 1; up to 43 weeks for Cohort 2)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.1
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Reporting groups

Reporting group title	Cohort 1, Monotherapy: Nemvaleukin Alfa 6 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 6 mcg/kg, IV infusion, once daily for 5 consecutive days, followed by 9 days off during Cycle 1 (Cycle 1 length=14 days) and 16 days off during Cycle 2 (Cycle 2 length=21 days).

Reporting group title	Cohort 1, Combination: Nemvaleukin Alfa 6 mcg/kg+Pembrolizumab
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Reporting group description:

Subjects received nemvaleukin alfa 6 mcg/kg, as a single dose, IV infusion, on Day 1 of each 21-day cycle in combination with pembrolizumab 200 mg, IV infusion until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 10 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 35 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 40 mcg/kg, IV infusion, once on Day 1 of each 21-day cycle until subjects deriving clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 25 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other

discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Days 1 and 8 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 15 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 20 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 25 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 30 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Reporting group title	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg
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Reporting group description:

Subjects received nemvaleukin alfa 35 mcg/kg, IV infusion, once on Days 1 and 4 of each 21-day cycle until subjects derived clinical benefit (i.e., stable disease or better) or they met any other discontinuation criteria.

Serious adverse events	Cohort 1, Monotherapy: Nemvaleukin Alfa 6 mcg/kg	Cohort 1, Combination: Nemvaleukin Alfa 6 mcg/kg+Pembrolizu mab	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 9 (22.22%)	1 / 4 (25.00%)	1 / 1 (100.00%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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			
Haemorrhage			

subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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			
Cytokine release syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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 disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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			
Capillary permeability increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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			
Heat exhaustion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (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
Fall			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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			
Pericardial effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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			
Cerebral haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uraemic encephalopathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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 / 9 (11.11%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	1 / 9 (11.11%)	1 / 4 (25.00%)	0 / 1 (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
Vomiting			
subjects affected / exposed	1 / 9 (11.11%)	1 / 4 (25.00%)	0 / 1 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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			
Photosensitivity reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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			
Lumbar spinal stenosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			

subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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 escherichia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
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	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	2 / 5 (40.00%)	1 / 6 (16.67%)
number of deaths (all causes)	0	3	6
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Cytokine release syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			

Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 6 (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
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Capillary permeability increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Heat exhaustion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Pericardial effusion			

subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Cerebral haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 6 (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
Headache			
subjects affected / exposed	1 / 1 (100.00%)	0 / 5 (0.00%)	0 / 6 (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
Uraemic encephalopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			

Photosensitivity reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Lumbar spinal stenosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 escherichia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	2 / 5 (40.00%)	3 / 5 (60.00%)
number of deaths (all causes)	2	3	4
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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			
Haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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			
Cytokine release syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	2 / 5 (40.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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 disorder			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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			
Capillary permeability increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Heat exhaustion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 5 (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 disorders			
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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			
Cerebral haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uraemic encephalopathy			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (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
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (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			
Photosensitivity reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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			
Lumbar spinal stenosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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			
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
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 escherichia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (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

Serious adverse events	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	1 / 3 (33.33%)
number of deaths (all causes)	1	0	3
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Capillary permeability increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Heat exhaustion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Cerebral haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Uraemic encephalopathy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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			
Photosensitivity reaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Lumbar spinal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Pneumonia escherichia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)	1 / 3 (33.33%)	3 / 7 (42.86%)
number of deaths (all causes)	1	0	4
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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
Vascular disorders			
Haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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 / 6 (0.00%)	0 / 3 (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	1 / 6 (16.67%)	0 / 3 (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
Respiratory disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Investigations			
Capillary permeability increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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			
Heat exhaustion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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			
Pericardial effusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (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
Nervous system disorders			
Cerebral haemorrhage			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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
Uraemic encephalopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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	0 / 6 (0.00%)	0 / 3 (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 / 6 (0.00%)	0 / 3 (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 / 6 (0.00%)	1 / 3 (33.33%)	0 / 7 (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 / 6 (0.00%)	0 / 3 (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			
Photosensitivity reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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 / 6 (0.00%)	0 / 3 (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
Musculoskeletal and connective tissue disorders			
Lumbar spinal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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			
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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 escherichia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (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

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

Non-serious adverse events	Cohort 1, Monotherapy: Nemvaleukin Alfa 6 mcg/kg	Cohort 1, Combination: Nemvaleukin Alfa 6 mcg/kg+Pembrolizu mab	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 10 mcg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	4 / 4 (100.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to peritoneum			
subjects affected / exposed	0 / 9 (0.00%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Tumour pain			

subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Cancer pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 9 (44.44%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Pelvic venous thrombosis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	4 / 9 (44.44%)	2 / 4 (50.00%)	0 / 1 (0.00%)
occurrences (all)	4	2	0
Chills			
subjects affected / exposed	5 / 9 (55.56%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	9	0	0
Pyrexia			
subjects affected / exposed	3 / 9 (33.33%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Oedema peripheral			
subjects affected / exposed	2 / 9 (22.22%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Asthenia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Catheter site pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Early satiety			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 4 (25.00%) 1	0 / 1 (0.00%) 0
Non-cardiac chest pain subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Immune system disorders Cytokine release syndrome subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Reproductive system and breast disorders Vulvovaginal burning sensation subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Vulvovaginal pruritus subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	3 / 9 (33.33%) 3	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 4 (25.00%) 2	0 / 1 (0.00%) 0
Pleural effusion subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 4 (25.00%) 2	0 / 1 (0.00%) 0
Bronchostenosis subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory tract congestion			

subjects affected / exposed	0 / 9 (0.00%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 9 (55.56%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	10	0	0
Alanine aminotransferase increased			
subjects affected / exposed	4 / 9 (44.44%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Blood creatinine increased			
subjects affected / exposed	3 / 9 (33.33%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	5	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 9 (22.22%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
White blood cell count decreased			
subjects affected / exposed	2 / 9 (22.22%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Bacterial test positive			

subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 9 (11.11%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eastern Cooperative Oncology Group performance status			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 9 (0.00%)	2 / 4 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	5 / 9 (55.56%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	8	1	0
Bradycardia			

subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 9 (44.44%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	7 / 9 (77.78%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	22	0	0
Anaemia			
subjects affected / exposed	4 / 9 (44.44%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	4	1	0
Neutropenia			
subjects affected / exposed	4 / 9 (44.44%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Leukopenia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Thrombocytopenia			

subjects affected / exposed	2 / 9 (22.22%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Eosinophilia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Leukocytosis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Thrombocytosis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	3 / 9 (33.33%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Abdominal distension			
subjects affected / exposed	2 / 9 (22.22%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	2 / 4 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Abdominal pain upper			
subjects affected / exposed	2 / 9 (22.22%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Diarrhoea			
subjects affected / exposed	2 / 9 (22.22%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Anal haemorrhage			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Ascites			

subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Large intestinal obstruction			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Retching			
subjects affected / exposed	0 / 9 (0.00%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Angioedema subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Photosensitivity reaction subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Renal and urinary disorders			
Dysuria subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Urinary tract disorder subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Muscle spasms subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	2 / 4 (50.00%) 2	0 / 1 (0.00%) 0
Muscular weakness subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 4 (25.00%) 1	0 / 1 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Flank pain subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Musculoskeletal stiffness subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 4 (0.00%) 0	0 / 1 (0.00%) 0
Myopathy subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 4 (25.00%) 1	0 / 1 (0.00%) 0
Neck pain			

subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Muscle atrophy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 9 (22.22%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Hyperuricaemia			

subjects affected / exposed	2 / 9 (22.22%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Appetite disorder			
subjects affected / exposed	1 / 9 (11.11%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Hyperkalaemia			
subjects affected / exposed	2 / 9 (22.22%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Hyponatraemia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Malnutrition			
subjects affected / exposed	0 / 9 (0.00%)	1 / 4 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 4 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 35 mcg/kg
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	1 / 1 (100.00%)	4 / 5 (80.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to peritoneum			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic venous thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Asthenia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 1 (100.00%)	0 / 5 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Reproductive system and breast disorders			
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Bronchostenosis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 5 (40.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 5 (40.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Eastern Cooperative Oncology Group performance status			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Bilirubin conjugated increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 1 (100.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Fall			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Seizure			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Neutropenia			

subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Eosinophilia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Thrombocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	3 / 5 (60.00%)	1 / 6 (16.67%)
occurrences (all)	0	4	1
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	3 / 6 (50.00%)
occurrences (all)	0	1	3
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			

subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Anal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Large intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	3 / 5 (60.00%)	1 / 6 (16.67%)
occurrences (all)	0	4	1
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Angioedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			

subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle atrophy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Appetite disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 5 (40.00%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Malnutrition			
subjects affected / exposed	0 / 1 (0.00%)	2 / 5 (40.00%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypomagnesaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 2, Part A, Schedule 1: Nemvaleukin Alfa 40 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 20 mcg/kg	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 25 mcg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	5 / 5 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to peritoneum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pelvic venous thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	2 / 5 (40.00%)	1 / 5 (20.00%)
occurrences (all)	1	2	3
Chills			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Pyrexia			

subjects affected / exposed	1 / 4 (25.00%)	2 / 5 (40.00%)	1 / 5 (20.00%)
occurrences (all)	1	2	1
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences (all)	0	2	1
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	2 / 4 (50.00%)	2 / 5 (40.00%)	0 / 5 (0.00%)
occurrences (all)	2	3	0
Reproductive system and breast disorders			
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Dyspnoea			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Bronchostenosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eastern Cooperative Oncology Group performance status			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Weight decreased			

subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	1 / 5 (20.00%) 1	1 / 5 (20.00%) 1
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	3 / 5 (60.00%)
occurrences (all)	0	1	3
Fall			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	3	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Eosinophilia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 4 (50.00%)	0 / 5 (0.00%)	2 / 5 (40.00%)
occurrences (all)	4	0	2
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences (all)	0	2	1
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Large intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	0 / 5 (0.00%) 0
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Angioedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle atrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Viral infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1

Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Appetite disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dehydration			

subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Cohort 2, Part A, Schedule 2: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 15 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 20 mcg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to peritoneum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic venous thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	3
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	2	3	2
Reproductive system and breast disorders			
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchostenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Anxiety subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Investigations			
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Bacterial test positive subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Electrocardiogram PR prolongation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Electrocardiogram QT prolonged subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Eastern Cooperative Oncology Group performance status			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Bilirubin conjugated increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Injury, poisoning and procedural complications			
Infusion related reaction subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 4	0 / 3 (0.00%) 0	2 / 3 (66.67%) 2
Fall subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 2	0 / 3 (0.00%) 0
Bradycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Hypoaesthesia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Seizure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Eosinophilia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Nausea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	3
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Large intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Vomiting subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1
Skin and subcutaneous tissue disorders			
Night sweats subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Angioedema subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Photosensitivity reaction subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Renal and urinary disorders			
Dysuria subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0
Urinary tract disorder subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal and connective tissue disorders			

Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle atrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Clostridium difficile colitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Appetite disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 25 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 30 mcg/kg	Cohort 2, Part A, Schedule 3: Nemvaleukin Alfa 35 mcg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	3 / 3 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to peritoneum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic venous thrombosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	3	0	3
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 6 (50.00%)	1 / 3 (33.33%)	2 / 7 (28.57%)
occurrences (all)	5	1	2
Chills			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	3	2	1
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 3 (66.67%)	2 / 7 (28.57%)
occurrences (all)	1	3	4
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Asthenia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Catheter site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Cytokine release syndrome subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 4	0 / 3 (0.00%) 0	3 / 7 (42.86%) 8
Reproductive system and breast disorders			
Vulvovaginal burning sensation subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Vulvovaginal pruritus subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Pleural effusion subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Bronchostenosis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Respiratory tract congestion subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Respiratory tract infection subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Epistaxis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 6 (50.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	4	2	0
Alanine aminotransferase increased			
subjects affected / exposed	3 / 6 (50.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	4	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Eastern Cooperative Oncology Group performance status subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Bilirubin conjugated increased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	1 / 3 (33.33%) 1	0 / 7 (0.00%) 0
Injury, poisoning and procedural complications			
Infusion related reaction subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 3	1 / 3 (33.33%) 2	2 / 7 (28.57%) 3
Fall subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 6	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Bradycardia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 3 (0.00%) 0	1 / 7 (14.29%) 1
Hypoaesthesia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Dizziness			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	3 / 6 (50.00%)	2 / 3 (66.67%)	1 / 7 (14.29%)
occurrences (all)	4	3	1
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Eosinophilia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	4	0	3
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Large intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retching			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Angioedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Urinary tract disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle atrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 6 (33.33%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Appetite disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Malnutrition			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported