



Clinical trial results:

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

Summary

EudraCT number	2019-002013-20
Trial protocol	GB DE ES NL FR
Global end of trial date	01 March 2023

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	ALKS4230-001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03861793
WHO universal trial number (UTN)	-
Other trial identifiers	IND: 128,159

Notes:

Sponsors

Sponsor organisation name	Mural Oncology, Inc
Sponsor organisation address	10 Earlsfort Terrace, Dublin, Ireland, D02 T380
Public contact	Study Director, Mural Oncology, Inc, +1 (781) 614-0100, clinicaltrials@muraloncology.com
Scientific contact	Study Director, Mural Oncology, Inc, +1 (781) 614-0100, clinicaltrials@muraloncology.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 March 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	01 March 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To characterize the safety and tolerability and to identify the recommended Phase 2 dose (RP2D) of ALKS 4230 administered subcutaneously (SC) as lead-in monotherapy and in combination with pembrolizumab in subjects with advanced solid tumors (Phase 1)
- To characterize the safety profile of SC ALKS 4230 at the RP2D in combination with pembrolizumab in subjects with advanced solid tumors (Phase 2)
- To estimate the clinical activity of combination treatment with ALKS 4230 and pembrolizumab in terms of objective response rate (ORR) as assessed by Response Evaluation Criteria in Solid Tumors (RECIST) guidelines version 1.1 separately for non-small-cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck (SCCHN), squamous tumor agnostic, hepatocellular carcinoma (HCC), and small-cell lung cancer (SCLC) (Phase 2)

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 March 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 16
Country: Number of subjects enrolled	United States: 81
Country: Number of subjects enrolled	Canada: 10
Country: Number of subjects enrolled	China: 1
Country: Number of subjects enrolled	Taiwan: 5
Country: Number of subjects enrolled	Korea, Republic of: 3
Worldwide total number of subjects	116
EEA total number of subjects	16

Notes:

Subjects enrolled per age group

In utero	0
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Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	69
From 65 to 84 years	47
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 50 investigative sites globally from 06 March 2019 to 01 March 2023.

Pre-assignment

Screening details:

Subjects were enrolled in this 2 phases study (Phase 1 and 2) to receive nemvaleukin alfa (ALKS 4230) either as monotherapy or in combination with pembrolizumab.

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	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D

Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.3 milligram (mg) monotherapy, subcutaneous (SC) injection, every 7 days (Q7D). After 6 weeks of monotherapy, if tolerated, then pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation or study discontinuation or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.6 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
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Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 1 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:	
Nemvaleukin alfa administration via subcutaneous (SC) injection	
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 6 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 1 mg monotherapy, SC injection, every 21 days (Q21D). After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Pembrolizumab administration via IV infusion.	

Arm title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 3 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 6 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion over 30 minutes in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D
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Arm description:

Subjects with advanced solid tumors received nemvaleukin alfa 10 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 2, Dose Expansion Phase, NSCLC
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Arm description:

Subjects with non-small-cell lung cancer (NSCLC) received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 2, Dose Expansion Phase, SCCHN
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Arm description:

Subjects with squamous cell carcinoma of the head and neck (SCCHN) received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the

subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
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Arm description:

Subjects with gastric/gastroesophageal junction (GEJ) adenocarcinoma received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1
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Arm description:

Subjects with ovarian cancer (OC) in cohort 1 received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
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Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Arm title	Phase 2, Dose Expansion Phase, OC Cohort 2
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Arm description:

Subjects with ovarian cancer (OC) in cohort 2 received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Arm type	Experimental
Investigational medicinal product name	Nemvaleukin Alfa
Investigational medicinal product code	
Other name	ALKS 4230
Pharmaceutical forms	Injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Nemvaleukin alfa administration via subcutaneous (SC) injection

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

Dosage and administration details:

Pembrolizumab administration via IV infusion.

Number of subjects in period 1	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D
Started	7	3	7
Completed	1	1	0
Not completed	6	2	7
Consent withdrawn by subject	1	1	1
Adverse Event	-	-	-
Death	4	1	4

Lost to Follow-up	-	-	-
Progressive Disease	-	-	1
Unspecified	1	-	1
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D
Started	7	8	4
Completed	0	0	0
Not completed	7	8	4
Consent withdrawn by subject	-	2	-
Adverse Event	-	-	-
Death	7	5	2
Lost to Follow-up	-	-	-
Progressive Disease	-	-	-
Unspecified	-	1	2
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D
Started	4	8	9
Completed	2	0	0
Not completed	2	8	9
Consent withdrawn by subject	-	2	-
Adverse Event	-	-	-
Death	2	3	5
Lost to Follow-up	-	-	-
Progressive Disease	-	1	-
Unspecified	-	2	3
Lost to follow-up	-	-	1

Number of subjects in period 1	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Started	11	10	13
Completed	0	0	0
Not completed	11	10	13
Consent withdrawn by subject	-	2	1
Adverse Event	-	-	-
Death	5	4	10
Lost to Follow-up	-	-	-
Progressive Disease	-	2	-

Unspecified	6	2	2
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2
Started	17	8
Completed	0	0
Not completed	17	8
Consent withdrawn by subject	3	2
Adverse Event	-	2
Death	10	1
Lost to Follow-up	-	1
Progressive Disease	2	-
Unspecified	2	2
Lost to follow-up	-	-

Baseline characteristics

Reporting groups

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.3 milligram (mg) monotherapy, subcutaneous (SC) injection, every 7 days (Q7D). After 6 weeks of monotherapy, if tolerated, then pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation or study discontinuation or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.6 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 1 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 6 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 1 mg monotherapy, SC injection, every 21 days (Q21D). After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment

discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 3 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 6 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion over 30 minutes in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 10 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, NSCLC
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Reporting group description:

Subjects with non-small-cell lung cancer (NSCLC) received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, SCCHN
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Reporting group description:

Subjects with squamous cell carcinoma of the head and neck (SCCHN) received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
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Reporting group description:

Subjects with gastric/gastroesophageal junction (GEJ) adenocarcinoma received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1
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Reporting group description:

Subjects with ovarian cancer (OC) in cohort 1 received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received

combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, OC Cohort 2
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Reporting group description:

Subjects with ovarian cancer (OC) in cohort 2 received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D
Number of subjects	7	3	7
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	3	4
From 65-84 years	4	0	3
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	5	1	4
Male	2	2	3
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	7	3	7
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	7	2	7
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Phase 1, Dose Escalation Phase:	Phase 1, Dose Escalation Phase:	Phase 1, Dose Escalation Phase:
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	Nemvaleukin Alfa 3mg Q7D	Nemvaleukin Alfa 6mg Q7D	Nemvaleukin Alfa 1mg Q21D
Number of subjects	7	8	4
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	6	2
From 65-84 years	3	2	2
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	6	4	0
Male	1	4	4
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	7	7	4
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	1	0	0
White	6	6	4
More than one race	0	0	0
Unknown or Not Reported	0	1	0

Reporting group values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D
Number of subjects	4	8	9
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	4	4
From 65-84 years	1	4	5
85 years and over	0	0	0

Gender categorical			
Units: Subjects			
Female	3	1	5
Male	1	7	4
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	0	1
Not Hispanic or Latino	3	8	8
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	4	0
White	4	4	7
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Number of subjects	11	10	13
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	3	10
From 65-84 years	6	7	3
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	3	1	1
Male	8	9	12
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	11	10	13
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	5	0	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0

White	6	10	10
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2	Total
Number of subjects	17	8	116
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	12	6	69
From 65-84 years	5	2	47
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	17	8	59
Male	0	0	57
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	3
Not Hispanic or Latino	17	8	113
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	11
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	1	2	9
White	15	6	94
More than one race	0	0	0
Unknown or Not Reported	0	0	1

End points

End points reporting groups

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.3 milligram (mg) monotherapy, subcutaneous (SC) injection, every 7 days (Q7D). After 6 weeks of monotherapy, if tolerated, then pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation or study discontinuation or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.6 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 1 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 6 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 1 mg monotherapy, SC injection, every 21 days (Q21D). After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment

discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 3 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 6 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion over 30 minutes in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 10 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, NSCLC
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Reporting group description:

Subjects with non-small-cell lung cancer (NSCLC) received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, SCCHN
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Reporting group description:

Subjects with squamous cell carcinoma of the head and neck (SCCHN) received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
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Reporting group description:

Subjects with gastric/gastroesophageal junction (GEJ) adenocarcinoma received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1
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Reporting group description:

Subjects with ovarian cancer (OC) in cohort 1 received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received

combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, OC Cohort 2
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Reporting group description:

Subjects with ovarian cancer (OC) in cohort 2 received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Primary: Phase 1 and 2: Number of Subjects With Treatment-emergent Adverse Events (TEAEs)

End point title	Phase 1 and 2: Number of Subjects With Treatment-emergent Adverse Events (TEAEs) ^[1]
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End point description:

TEAEs were defined as AEs that were newly occurring or worsening from the time of the first dose of study drug. An AE was any untoward medical occurrence in a participant or clinical investigation subject administered a pharmaceutical product. Safety population included all subjects who received any exposure to study drug (SC ALKS 4230 in Phase 1 and SC ALKS 4230 or pembrolizumab in Phase 2).

End point type	Primary
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End point timeframe:

From first dose of study drug until 30 days after last dose (up to 23.3 months for Phase 1 and up to 21.2 months for Phase 2)

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: No statistical analysis was performed for this endpoint.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	7	7
Units: Subjects	7	3	7	7

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	4	4	8
Units: Subjects	8	4	4	8

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	11	10	13
Units: Subjects	9	11	10	13

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	8		
Units: Subjects	17	8		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1 and 2: Number of Subjects With TEAEs by Severity Grading

End point title	Phase 1 and 2: Number of Subjects With TEAEs by Severity Grading ^[2]
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End point description:

TEAEs were defined as AEs that were newly occurring or worsening from the time of the first dose of study drug. Severity was graded according to the National Cancer Institute (NCI) CTCAE (version 4.03) where, Grade 1: Mild- asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. Grade 2: Moderate- minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living (ADL) Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL. Grade 4: Life-threatening consequences; urgent intervention indicated. Grade 5: Death related to AE. As planned, subjects experienced grade 3 or more were reported. Safety population included all subjects who received any exposure to study drug (SC ALKS 4230 in Phase 1 and SC ALKS 4230 or pembrolizumab in Phase 2).

End point type	Primary
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End point timeframe:

From first dose of study drug until 30 days after last dose (up to 23.3 months for Phase 1 and up to 21.2 months for Phase 2)

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: No statistical analysis was performed for this endpoint.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	7	7

Units: Subjects	2	2	3	7
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End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	4	4	8
Units: Subjects	7	3	1	3

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	11	10	13
Units: Subjects	6	7	7	10

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	8		
Units: Subjects	12	7		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Overall Response Rate (ORR) Based on Response Evaluation Criteria in Solid Tumors (RECIST) v1.1

End point title	Phase 2: Overall Response Rate (ORR) Based on Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 ^{[3][4]}
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End point description:

ORR rate was defined as the percentage of subjects with objective evidence of CR or PR based on RECIST v1.1. Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<) 10 millimeters (mm). Partial Response (PR): At least a 30 percent (%) decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. The antitumor evaluable population consisted of subjects who complete 2 cycles of therapy and had at least one follow-up scan. Antitumor evaluable population included of all subjects who had at least one assessment of tumor size after exposure to ALKS 4230.

End point type	Primary			
End point timeframe:				
From first dose of study drug up to 20.2 months for Phase 2				
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: No statistical analysis was performed for this endpoint.				
[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: ORR was assessed in Part 1 arms only.				
End point values	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	13	14
Units: percentage of subjects				
number (confidence interval 95%)	10.0 (0.25 to 44.50)	14.3 (0.36 to 57.87)	0 (0.00 to 24.71)	14.3 (1.78 to 42.81)

End point values	Phase 2, Dose Expansion Phase, OC Cohort 2			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: percentage of subjects				
number (confidence interval 95%)	0 (0.00 to 45.93)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Number of Subjects With Dose-limiting Toxicities (DLTs)

End point title	Phase 1: Number of Subjects With Dose-limiting Toxicities (DLTs) ^[5]
End point description:	
DLT was defined by any of following events possibly, probably, or definitely related to ALKS 4230: Grade 4 neutrophil count decreased (neutropenia); Febrile neutropenia; CTCAE Grade 4 thrombocytopenia; Thrombocytopenia; Any Grade 3 cardiac or central nervous system toxicity; Liver transaminase elevation higher than 8*upper limit of normal (ULN) or total bilirubin higher than 6*ULN; Grade 4 hypoalbuminemia; Fever more than (>) 40 degree Celsius (°C) sustained for >24 hours; Hypotension required the use of pressors or prolonged hospitalization (>48 hours) for hypotension requiring medical intervention; Grade 3 or higher electrolyte abnormalities; Increase in amylase or lipase; Grade 3 or higher nausea, vomiting, or diarrhea; Any other Grade 4 nonhematologic toxicity or any other Grade 3 nonhematologic toxicity; Any other toxicity or adverse event (AE) not defined above that resulted in subject removal from the study or discontinuation of dosing by the Investigator.	
End point type	Secondary
End point timeframe:	
Phase 1: Cycle 1 Day 1 through Cycle 2 Day 15 (Cycle 1 length = 14 days; Cycle 2 length= 21 days)	

Notes:

[5] - 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: DLT was assessed in Part 1 arms only.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	7	7
Units: Subjects	0	0	0	0

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	4	4	8
Units: Subjects	2	0	0	0

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Subjects	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Serum Concentrations of ALKS 4230 and Descriptive PK Parameters

End point title	Phase 1 and 2: Serum Concentrations of ALKS 4230 and Descriptive PK Parameters
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End point description:

The PK population consists of all subjects who received at least 1 dose of ALKS 4230 and had at least 1 measurable serum concentration of ALKS 4230 at any scheduled PK time point. This outcome measure was planned but due to a decision to prioritize less frequent IV dosing, data are not available, and no analyses were performed.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[6]	0 ^[7]	0 ^[8]	0 ^[9]
Units: Micrograms per milliliter				
geometric mean (standard deviation)	()	()	()	()

Notes:

[6] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[7] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[8] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[9] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[10]	0 ^[11]	0 ^[12]	0 ^[13]
Units: Micrograms per milliliter				
geometric mean (standard deviation)	()	()	()	()

Notes:

[10] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[11] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[12] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[13] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[14]	0 ^[15]	0 ^[16]	0 ^[17]
Units: Micrograms per milliliter				
geometric mean (standard deviation)	()	()	()	()

Notes:

[14] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[15] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[16] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[17] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[18]	0 ^[19]		
Units: Micrograms per milliliter				
geometric mean (standard deviation)	()	()		

Notes:

[18] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[19] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Presence of Anti-ALKS 4230 Antibodies in Serum

End point title	Phase 1 and 2: Presence of Anti-ALKS 4230 Antibodies in Serum
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End point description:

The efficacy population will consist of all subjects who had at least one assessment of tumor size after exposure to ALKS 4230. This endpoint was planned but due to a decision to prioritize less frequent IV dosing, data are not available, and no analyses were performed.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[20]	0 ^[21]	0 ^[22]	0 ^[23]
Units: subjects				

Notes:

[20] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[21] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[22] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[23] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[24]	0 ^[25]	0 ^[26]	0 ^[27]
Units: subjects				

Notes:

[24] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[25] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[26] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[27] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[28]	0 ^[29]	0 ^[30]	0 ^[31]
Units: subjects				

Notes:

[28] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[29] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[30] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[31] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[32]	0 ^[33]		
Units: subjects				

Notes:

[32] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[33] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Numbers of Circulating CD8+ T Cells, Tregs, and NK Cells in Peripheral Blood

End point title	Phase 1 and 2: Numbers of Circulating CD8+ T Cells, Tregs, and NK Cells in Peripheral Blood
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End point description:

The efficacy population will consist of all subjects who had at least one assessment of tumor size after exposure to ALKS 4230. This endpoint was planned but due to a decision to prioritize less frequent IV dosing, data are not available, and no analyses were performed.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[34]	0 ^[35]	0 ^[36]	0 ^[37]
Units: subjects				

Notes:

- [34] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.
 [35] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.
 [36] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.
 [37] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[38]	0 ^[39]	0 ^[40]	0 ^[41]
Units: subjects				

Notes:

- [38] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.
 [39] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.
 [40] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.
 [41] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[42]	0 ^[43]	0 ^[44]	0 ^[45]
Units: subjects				

Notes:

- [42] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.
 [43] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.
 [44] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.
 [45] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[46]	0 ^[47]		
Units: subjects				

Notes:

- [46] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.
 [47] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Serum Concentrations of IL-6 and Other Cytokines

End point title	Phase 1 and 2: Serum Concentrations of IL-6 and Other Cytokines
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End point description:

The PK population consists of all subjects who received at least 1 dose of ALKS 4230 and had at least 1 measurable serum concentration of ALKS 4230 at any scheduled PK time point. This endpoint was

planned but due to a decision to prioritize less frequent IV dosing, data are not available, and no analyses were performed.

End point type	Secondary
End point timeframe:	
From first dose of study drug up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2	

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[48]	0 ^[49]	0 ^[50]	0 ^[51]
Units: Micrograms per milliliter				
geometric mean (standard deviation)	()	()	()	()

Notes:

[48] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[49] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[50] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[51] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[52]	0 ^[53]	0 ^[54]	0 ^[55]
Units: Micrograms per milliliter				
geometric mean (standard deviation)	()	()	()	()

Notes:

[52] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[53] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[54] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[55] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[56]	0 ^[57]	0 ^[58]	0 ^[59]
Units: Micrograms per milliliter				
geometric mean (standard deviation)	()	()	()	()

Notes:

[56] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[57] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[58] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[59] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[60]	0 ^[61]		
Units: Micrograms per milliliter				
geometric mean (standard deviation)	()	()		

Notes:

[60] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[61] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: ORR Based on RECIST v1.1

End point title	Phase 1: ORR Based on RECIST v1.1 ^[62]
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End point description:

ORR rate was defined as the percentage of subjects with objective evidence of CR or PR based on RECIST v1.1. Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<) 10 millimeters (mm). Partial Response (PR): At least a 30 percent (%) decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 22.3 months for Phase 1

Notes:

[62] - 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: ORR was assessed in Part 1 arms only.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	6	6
Units: percentage of subjects				
number (confidence interval 95%)	0 (0.00 to 40.96)	0 (0.00 to 70.76)	0 (0.00 to 45.93)	0 (0.00 to 45.93)

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	4	8
Units: percentage of subjects				
number (confidence interval 95%)	0 (0.00 to	0 (0.00 to	0 (0.00 to	1 (0.32 to

40.96)	70.76)	60.24)	52.65)
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End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: percentage of subjects				
number (confidence interval 95%)	0 (0.00 to 36.94)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Disease Control Rate (DCR) Based on RECIST v1.1

End point title	Phase 1 and 2: Disease Control Rate (DCR) Based on RECIST v1.1
End point description:	
Disease control rate was defined as the percentage of participants with objective evidence of CR, PR, or SD based on RECIST v.1.1. CR: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<) 10 millimeters (mm). Partial Response (PR): At least a 30 percent (%) decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.	
End point type	Secondary
End point timeframe:	
From first dose of study drug up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2	

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	6	6
Units: percentage of subjects				
number (confidence interval 95%)	14.3 (0.36 to 57.87)	33.3 (0.84 to 90.57)	0 (0.00 to 45.93)	33.3 (4.33 to 77.72)

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin	Phase 1, Dose Escalation Phase: Nemvaleukin	Phase 1, Dose Escalation Phase: Nemvaleukin	Phase 1, Dose Escalation Phase: Nemvaleukin
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	Alfa 6mg Q7D	Alfa 1mg Q21D	Alfa 3mg Q21D	Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	4	8
Units: percentage of subjects				
number (confidence interval 95%)	0 (0.00 to 40.96)	33.3 (0.84 to 90.57)	0 (0.00 to 60.24)	12.5 (0.32 to 52.65)

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	10	7	13
Units: percentage of subjects				
number (confidence interval 95%)	0 (0.00 to 36.94)	40.0 (12.16 to 73.76)	28.6 (3.67 to 70.96)	30.8 (9.09 to 61.43)

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	6		
Units: percentage of subjects				
number (confidence interval 95%)	28.6 (8.39 to 58.10)	16.7 (0.42 to 64.12)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Duration of Response (DOR) Based on RECIST v1.1

End point title	Phase 1 and 2: Duration of Response (DOR) Based on RECIST v1.1
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End point description:

The efficacy population will consist of all subjects who had at least one assessment of tumor size after exposure to ALKS 4230. This endpoint was planned but due to lack of responses (CR or PR), data are not available, and no analyses were performed.

End point type	Secondary
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End point timeframe:

From the first documentation of response (CR or PR) to the first documentation of objective tumor progression or death due to any cause (up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2)

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[63]	0 ^[64]	0 ^[65]	0 ^[66]
Units: days				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[63] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[64] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[65] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[66] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[67]	0 ^[68]	0 ^[69]	0 ^[70]
Units: days				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[67] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[68] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[69] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[70] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[71]	0 ^[72]	0 ^[73]	0 ^[74]
Units: days				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[71] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[72] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[73] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[74] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[75]	0 ^[76]		
Units: days				
median (full range (min-max))	(to)	(to)		

Notes:

[75] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[76] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Time to Response (TTR) Based on RECIST v1.1

End point title	Phase 1 and 2: Time to Response (TTR) Based on RECIST v1.1
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End point description:

The efficacy population will consist of all subjects who had at least one assessment of tumor size after exposure to ALKS 4230. This endpoint was planned but due to lack of responses (CR or PR), data are not available, and no analyses were performed.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[77]	0 ^[78]	0 ^[79]	0 ^[80]
Units: days				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[77] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[78] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[79] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[80] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[81]	0 ^[82]	0 ^[83]	0 ^[84]
Units: days				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[81] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[82] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[83] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[84] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[85]	0 ^[86]	0 ^[87]	0 ^[88]
Units: days				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[85] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[86] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[87] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[88] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[89]	0 ^[90]		
Units: days				
median (full range (min-max))	(to)	(to)		

Notes:

[89] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[90] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Progression Free Survival (PFS) Based on RECIST v1.1

End point title	Phase 1 and 2: Progression Free Survival (PFS) Based on RECIST v1.1
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End point description:

Progression-free survival was defined as the time from the first dose of nemvaleukin to the first documentation of objective tumor progression or death due to any cause. PD: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this included the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to the first documentation of objective tumor progression or death due to any cause (up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2)

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[91]	0 ^[92]	0 ^[93]	0 ^[94]
Units: weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[91] - no data

[92] - no data

[93] - no data

[94] - no data

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[95]	0 ^[96]	0 ^[97]	0 ^[98]
Units: weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[95] - no data

[96] - no data

[97] - no data

[98] - no data

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[99]	10	7	13
Units: weeks				
median (confidence interval 95%)	(to)	11.71 (4.57 to 99999)	14.14 (5.29 to 45.43)	6.14 (5.29 to 22.57)

Notes:

[99] - no data

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	6		
Units: weeks				
median (confidence interval 95%)	8.71 (6.00 to 19.43)	14.29 (4.29 to 16.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Immune ORR (iORR) Based on Immune Response Evaluation Criteria in Solid Tumors (iRECIST)

End point title	Phase 1 and 2: Immune ORR (iORR) Based on Immune Response Evaluation Criteria in Solid Tumors (iRECIST)
End point description: The efficacy population will consist of all subjects who had at least one assessment of tumor size after exposure to ALKS 4230. This endpoint was planned but due to a decision to prioritize less frequent IV dosing, data are not available, and no analyses were performed.	
End point type	Secondary
End point timeframe: From first dose of study drug up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2	

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[100]	0 ^[101]	0 ^[102]	0 ^[103]
Units: percentage of subjects				

Notes:

[100] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[101] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[102] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[103] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[104]	0 ^[105]	0 ^[106]	0 ^[107]
Units: percentage of subjects				

Notes:

[104] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[105] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[106] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[107] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose	Phase 2, Dose	Phase 2, Dose	Phase 2, Dose
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	Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Expansion Phase, NSCLC	Expansion Phase, SCCHN	Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[108]	0 ^[109]	0 ^[110]	0 ^[111]
Units: percentage of subjects				

Notes:

[108] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[109] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[110] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[111] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[112]	0 ^[113]		
Units: percentage of subjects				

Notes:

[112] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[113] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Immune DCR (iDCR) Based on iRECIST

End point title	Phase 1 and 2: Immune DCR (iDCR) Based on iRECIST
End point description:	
The efficacy population will consist of all subjects who had at least one assessment of tumor size after exposure to ALKS 4230. This endpoint was planned but due to a decision to prioritize less frequent IV dosing, data are not available, and no analyses were performed.	
End point type	Secondary
End point timeframe:	
From first dose of study drug up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2	

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[114]	0 ^[115]	0 ^[116]	0 ^[117]
Units: percentage of subjects				

Notes:

[114] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[115] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[116] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[117] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[118]	0 ^[119]	0 ^[120]	0 ^[121]
Units: percentage of subjects				

Notes:

[118] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[119] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[120] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[121] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[122]	0 ^[123]	0 ^[124]	0 ^[125]
Units: percentage of subjects				

Notes:

[122] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[123] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[124] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[125] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[126]	0 ^[127]		
Units: percentage of subjects				

Notes:

[126] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[127] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Immune DOR (iDOR) Based on iRECIST

End point title	Phase 1 and 2: Immune DOR (iDOR) Based on iRECIST
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End point description:

The efficacy population will consist of all subjects who had at least one assessment of tumor size after exposure to ALKS 4230. This endpoint was planned but due to a decision to prioritize less frequent IV dosing, data are not available, and no analyses were performed.

End point type	Secondary
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End point timeframe:

From the first documentation of response (CR or PR) to the first documentation of objective tumor progression or death due to any cause (up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2)

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[128]	0 ^[129]	0 ^[130]	0 ^[131]
Units: days				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[128] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[129] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[130] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[131] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[132]	0 ^[133]	0 ^[134]	0 ^[135]
Units: days				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[132] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[133] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[134] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[135] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[136]	0 ^[137]	0 ^[138]	0 ^[139]
Units: days				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[136] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[137] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[138] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[139] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 2, Dose Expansion	Phase 2, Dose Expansion		
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	Phase, Ovarian Cancer Cohort 1	Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[140]	0 ^[141]		
Units: days				
median (full range (min-max))	(to)	(to)		

Notes:

[140] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[141] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Immune PFS (iPFS) Based on iRECIST

End point title	Phase 1 and 2: Immune PFS (iPFS) Based on iRECIST
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End point description:

The efficacy population will consist of all subjects who had at least one assessment of tumor size after exposure to ALKS 4230. This endpoint was planned but due to a decision to prioritize less frequent IV dosing, data are not available, and no analyses were performed.

End point type	Secondary
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End point timeframe:

From first dose of study drug up to the first documentation of objective tumor progression or death due to any cause (up to 22.3 months for Phase 1 and up to 20.2 months for Phase 2)

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[142]	0 ^[143]	0 ^[144]	0 ^[145]
Units: percentage of subjects				

Notes:

[142] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[143] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[144] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[145] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[146]	0 ^[147]	0 ^[148]	0 ^[149]
Units: percentage of subjects				

Notes:

[146] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[147] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[148] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[149] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[150]	0 ^[151]	0 ^[152]	0 ^[153]
Units: percentage of subjects				

Notes:

[150] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[151] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[152] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[153] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

End point values	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[154]	0 ^[155]		
Units: percentage of subjects				

Notes:

[154] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

[155] - Due to a decision to prioritize less frequent IV dosing, no analyses were performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Overall Survival (OS)

End point title	Phase 2: Overall Survival (OS) ^[156]
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End point description:

Overall survival was defined as the time from the first dose to the date of death due to any cause. For participants without documentation of death, overall survival was censored on the last date the participants were known to be alive. Antitumor evaluable population included of all subjects who had at least one assessment of tumor size after exposure to ALKS 4230.

End point type	Secondary
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End point timeframe:

From first dose of study drug until 30 days after last dose (up to 21.2 months for Phase 2)

Notes:

[156] - 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: OS was assessed in Part 1 arms only.

End point values	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	13	14
Units: weeks				
median (confidence interval 95%)	99999 (5.14 to 99999)	99999 (5.86 to 99999)	24.43 (8.43 to 40.57)	19.43 (8.86 to 99999)

End point values	Phase 2, Dose Expansion Phase, OC Cohort 2			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: weeks				
median (confidence interval 95%)	99999 (7.00 to 99999)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug until 30 days after last dose (up to 23.3 months for Phase 1 and up to 21.2 months for Phase 2)

Adverse event reporting additional description:

Safety population included all subjects who received any exposure to study drug (SC ALKS 4230 in Phase 1 and SC ALKS 4230 or pembrolizumab in Phase 2).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25
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Reporting groups

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.3 milligram (mg) monotherapy, subcutaneous (SC) injection, every 7 days (Q7D). After 6 weeks of monotherapy, if tolerated, then pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation or study discontinuation or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 0.6 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 1 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 6 mg monotherapy, SC injection, Q7D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a

dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 1 mg monotherapy, SC injection, every 21 days (Q21D). After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 3 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 6 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion over 30 minutes in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D
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Reporting group description:

Subjects with advanced solid tumors received nemvaleukin alfa 10 mg monotherapy, SC injection, Q21D. After 6 weeks of monotherapy, if tolerated, pembrolizumab was added as an intravenous infusion in a dose of 200 mg every 3 weeks with the ALKS 4230 regimen. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, NSCLC
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Reporting group description:

Subjects with non-small-cell lung cancer (NSCLC) received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, SCCHN
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Reporting group description:

Subjects with squamous cell carcinoma of the head and neck (SCCHN) received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.

Reporting group title	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Reporting group description:	
Subjects with gastric/gastroesophageal junction (GEJ) adenocarcinoma received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.	
Reporting group title	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1
Reporting group description:	
Subjects with ovarian cancer (OC) in cohort 1 received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.	
Reporting group title	Phase 2, Dose Expansion Phase, OC Cohort 2
Reporting group description:	
Subjects with ovarian cancer (OC) in cohort 2 received nemvaleukin alfa 3 mg monotherapy, SC injection, Q7D with pembrolizumab 200 mg, intravenous infusion, Q21D. Subjects who received combination treatment with SC ALKS 4230 and pembrolizumab continued to receive treatment with the study regimen for up to 2 years following initiation of combination treatment, as long as the subject derives clinical benefit or until the occurrence of any of the other criteria for treatment discontinuation, study discontinuation, or withdrawal. Subjects might continue ALKS 4230 as monotherapy after confirmation with the Sponsor if they appeared to be deriving clinical benefit.	

Serious adverse events	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 7 (14.29%)	2 / 3 (66.67%)	3 / 7 (42.86%)
number of deaths (all causes)	4	1	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 / 7 (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
Tumour flare			
subjects affected / exposed	0 / 7 (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
Vascular disorders			
Capillary leak syndrome			

subjects affected / exposed	0 / 7 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 7 (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
Chest pain			
subjects affected / exposed	0 / 7 (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
Injection site reaction			
subjects affected / exposed	0 / 7 (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
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 7 (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
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 7 (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
Pulmonary embolism			
subjects affected / exposed	0 / 7 (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
Atelectasis			

subjects affected / exposed	0 / 7 (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
Immune-mediated lung disease			
subjects affected / exposed	0 / 7 (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
Pneumonitis			
subjects affected / exposed	0 / 7 (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
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 7 (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
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 7 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 7 (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
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 7 (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			
Small intestinal obstruction			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	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
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	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
Swollen tongue			
subjects affected / exposed	0 / 7 (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	1 / 7 (14.29%)	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
Ascites			
subjects affected / exposed	0 / 7 (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
Constipation			
subjects affected / exposed	0 / 7 (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
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 7 (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
Large intestine perforation			

subjects affected / exposed	0 / 7 (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
Pancreatitis acute			
subjects affected / exposed	0 / 7 (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
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 7 (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
Portal vein thrombosis			
subjects affected / exposed	0 / 7 (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
Bile duct stenosis			
subjects affected / exposed	0 / 7 (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 / 7 (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
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 7 (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			
Clostridium difficile colitis			

subjects affected / exposed	0 / 7 (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			
subjects affected / exposed	0 / 7 (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
COVID-19			
subjects affected / exposed	0 / 7 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 7 (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 aspiration			
subjects affected / exposed	0 / 7 (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
Septic shock			
subjects affected / exposed	0 / 7 (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
Urinary tract infection			
subjects affected / exposed	0 / 7 (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
Metabolism and nutrition disorders			
Failure to thrive			
subjects affected / exposed	0 / 7 (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
Hyponatraemia			

subjects affected / exposed	0 / 7 (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
Hyperkalaemia			
subjects affected / exposed	0 / 7 (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

Serious adverse events	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 7 (57.14%)	4 / 8 (50.00%)	0 / 4 (0.00%)
number of deaths (all causes)	7	5	2
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour flare			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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			
Capillary leak syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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			
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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 / 7 (14.29%)	0 / 8 (0.00%)	0 / 4 (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
Atelectasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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			
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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			
Depressed level of consciousness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 4 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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			
Small intestinal obstruction			
subjects affected / exposed	1 / 7 (14.29%)	1 / 8 (12.50%)	0 / 4 (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
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swollen tongue			

subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 4 (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
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 4 (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
Portal vein thrombosis			

subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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			
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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			
Clostridium difficile colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Failure to thrive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
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	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	2 / 9 (22.22%)
number of deaths (all causes)	2	3	5
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	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 9 (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
Tumour flare			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
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			
Capillary leak syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
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 / 8 (0.00%)	0 / 9 (0.00%)
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			
Pleural effusion			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
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			
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
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			
Depressed level of consciousness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
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			
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swollen tongue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
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 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
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 / 8 (0.00%)	0 / 9 (0.00%)
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			
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
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 Clostridium difficile colitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	1 / 9 (11.11%) 0 / 1 0 / 0
Pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	1 / 9 (11.11%) 0 / 1 0 / 0
COVID-19 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 9 (0.00%) 0 / 0 0 / 0
Escherichia urinary tract infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 9 (0.00%) 0 / 0 0 / 0
Pneumonia aspiration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 9 (0.00%) 0 / 0 0 / 0
Septic shock subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 9 (0.00%) 0 / 0 0 / 0
Urinary tract infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 9 (0.00%) 0 / 0 0 / 0
Metabolism and nutrition disorders Failure to thrive subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	1 / 9 (11.11%) 0 / 1 0 / 0

Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
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	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 11 (27.27%)	4 / 10 (40.00%)	3 / 13 (23.08%)
number of deaths (all causes)	5	4	10
number of deaths resulting from adverse events	1	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour flare			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
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			
Capillary leak syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			

subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
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			
Pleural effusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
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 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0

Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
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 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swollen tongue			

subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
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 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pancreatitis acute			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			

subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
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			
Muscular weakness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
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			
Clostridium difficile colitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	0 / 13 (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
Septic shock			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Failure to thrive			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
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	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2	
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 17 (52.94%)	4 / 8 (50.00%)	
number of deaths (all causes)	10	1	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour flare			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Capillary leak syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 17 (11.76%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection site reaction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 17 (5.88%)	1 / 8 (12.50%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			

subjects affected / exposed	1 / 17 (5.88%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 17 (5.88%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated lung disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			

Febrile neutropenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	2 / 17 (11.76%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swollen tongue			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)	1 / 8 (12.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 17 (0.00%)	1 / 8 (12.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 17 (0.00%)	1 / 8 (12.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			

subjects affected / exposed	1 / 17 (5.88%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	1 / 17 (5.88%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 17 (5.88%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations Clostridium difficile colitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 17 (0.00%) 0 / 0 0 / 0	 0 / 8 (0.00%) 0 / 0 0 / 0	
Pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 17 (0.00%) 0 / 0 0 / 0	 0 / 8 (0.00%) 0 / 0 0 / 0	
COVID-19 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 17 (0.00%) 0 / 0 0 / 0	 1 / 8 (12.50%) 0 / 1 0 / 0	
Escherichia urinary tract infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 17 (0.00%) 0 / 0 0 / 0	 1 / 8 (12.50%) 0 / 1 0 / 0	
Pneumonia aspiration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 17 (0.00%) 0 / 0 0 / 0	 0 / 8 (0.00%) 0 / 0 0 / 0	
Septic shock subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 17 (0.00%) 0 / 0 0 / 0	 0 / 8 (0.00%) 0 / 0 0 / 0	
Urinary tract infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 1 / 17 (5.88%) 0 / 1 0 / 0	 0 / 8 (0.00%) 0 / 0 0 / 0	
Metabolism and nutrition disorders Failure to thrive subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 17 (0.00%) 0 / 0 0 / 0	 0 / 8 (0.00%) 0 / 0 0 / 0	

Hyponatraemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 0.6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q7D
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	3 / 3 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	3
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	5 / 7 (71.43%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	12	0	2
Fatigue			
subjects affected / exposed	5 / 7 (71.43%)	1 / 3 (33.33%)	3 / 7 (42.86%)
occurrences (all)	15	2	4
Chills			

subjects affected / exposed	3 / 7 (42.86%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	13	0	2
Injection site erythema			
subjects affected / exposed	5 / 7 (71.43%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	10	0	2
Injection site reaction			
subjects affected / exposed	2 / 7 (28.57%)	1 / 3 (33.33%)	2 / 7 (28.57%)
occurrences (all)	3	1	2
Injection site pruritus			
subjects affected / exposed	4 / 7 (57.14%)	1 / 3 (33.33%)	2 / 7 (28.57%)
occurrences (all)	4	4	2
Injection site pain			
subjects affected / exposed	3 / 7 (42.86%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	4	0	1
Injection site swelling			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Oedema peripheral			
subjects affected / exposed	2 / 7 (28.57%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Pain			
subjects affected / exposed	4 / 7 (57.14%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	12	0	1
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site oedema			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nodule			

subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	1 / 7 (14.29%) 1
Physical deconditioning subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 7 (14.29%) 1
Discomfort subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Injection site rash subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 2	2 / 3 (66.67%) 3	1 / 7 (14.29%) 1
Dyspnoea subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	2 / 3 (66.67%) 2	0 / 7 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 3 (33.33%) 2	1 / 7 (14.29%) 1
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 3 (33.33%) 1	1 / 7 (14.29%) 1
Insomnia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 7 (14.29%) 1
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	2 / 7 (28.57%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oxygen saturation decreased			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Platelet count decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Flank pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 7 (14.29%) 2
Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all) Fall subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 0 1 / 7 (14.29%) 1	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	2 / 7 (28.57%) 0 0 / 7 (0.00%) 0
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all) Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0 1 / 7 (14.29%) 2	0 / 3 (0.00%) 0 1 / 3 (33.33%) 1	1 / 7 (14.29%) 1 0 / 7 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Neuropathy peripheral subjects affected / exposed occurrences (all) Dysgeusia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1 1 / 7 (14.29%) 1 2 / 7 (28.57%) 4 0 / 7 (0.00%) 0	0 / 3 (0.00%) 0 1 / 3 (33.33%) 1 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 7 (0.00%) 0 1 / 7 (14.29%) 1 1 / 7 (14.29%) 1 1 / 7 (14.29%) 1
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) Lymphopenia	4 / 7 (57.14%) 4	0 / 3 (0.00%) 0	2 / 7 (28.57%) 2

subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	4 / 7 (57.14%)
occurrences (all)	1	0	6
Neutropenia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	4 / 7 (57.14%)	0 / 3 (0.00%)	3 / 7 (42.86%)
occurrences (all)	11	0	4
Vomiting			
subjects affected / exposed	4 / 7 (57.14%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	7	0	2
Diarrhoea			
subjects affected / exposed	4 / 7 (57.14%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	9	1	2
Abdominal pain			
subjects affected / exposed	3 / 7 (42.86%)	1 / 3 (33.33%)	3 / 7 (42.86%)
occurrences (all)	4	2	3
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	2 / 3 (66.67%)	2 / 7 (28.57%)
occurrences (all)	1	2	2
Abdominal distension			
subjects affected / exposed	2 / 7 (28.57%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Gastritis			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	2 / 7 (28.57%)
occurrences (all)	2	1	2
Hyperhidrosis			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Rash maculo-papular			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Rash pruritic			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Acute kidney injury subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	1 / 3 (33.33%) 1	0 / 7 (0.00%) 0
Arthralgia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 2	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 3	1 / 3 (33.33%) 1	0 / 7 (0.00%) 0
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 4	1 / 3 (33.33%) 2	0 / 7 (0.00%) 0
Muscular weakness subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 4	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Dehydration			
subjects affected / exposed	2 / 7 (28.57%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Hypokalaemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	2	1	3
Hypercalcaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hypoalbuminaemia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	0	1	4
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q7D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 1mg Q21D
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	8 / 8 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Vascular disorders			

Hypotension subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1	0 / 4 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
General disorders and administration site conditions			
Pyrexia subjects affected / exposed occurrences (all)	5 / 7 (71.43%) 5	5 / 8 (62.50%) 5	0 / 4 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 5	6 / 8 (75.00%) 7	1 / 4 (25.00%) 1
Chills subjects affected / exposed occurrences (all)	5 / 7 (71.43%) 9	5 / 8 (62.50%) 8	0 / 4 (0.00%) 0
Injection site erythema subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	3 / 8 (37.50%) 3	2 / 4 (50.00%) 2
Injection site reaction subjects affected / exposed occurrences (all)	5 / 7 (71.43%) 14	4 / 8 (50.00%) 16	1 / 4 (25.00%) 1
Injection site pruritus subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	1 / 4 (25.00%) 1
Injection site pain subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	2 / 8 (25.00%) 4	1 / 4 (25.00%) 1
Injection site swelling subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1	1 / 4 (25.00%) 1
Oedema peripheral subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	2 / 8 (25.00%) 2	1 / 4 (25.00%) 1
Pain			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Asthenia			
subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	1 / 8 (12.50%) 1	0 / 4 (0.00%) 0
Chest pain			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1	0 / 4 (0.00%) 0
Influenza like illness			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1	0 / 4 (0.00%) 0
Injection site oedema			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 8 (12.50%) 1	0 / 4 (0.00%) 0
Nodule			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Physical deconditioning			
subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Discomfort			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Injection site rash			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 8 (12.50%) 1	0 / 4 (0.00%) 0
Dyspnoea			
subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 8 (0.00%) 0	1 / 4 (25.00%) 0
Oropharyngeal pain			

subjects affected / exposed	2 / 7 (28.57%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Nasal congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 7 (42.86%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 7 (57.14%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood urea increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			

subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Lymphocyte count decreased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Flank pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Injury, poisoning and procedural complications			
Infusion related reaction subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 8 (12.50%) 1	0 / 4 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	1 / 8 (12.50%) 1	0 / 4 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 2	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Nervous system disorders			

Dizziness subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 8 (25.00%) 3	0 / 4 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	4 / 8 (50.00%) 7	0 / 4 (0.00%) 0
Neuropathy peripheral subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 8 (25.00%) 2	0 / 4 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	4 / 7 (57.14%) 4	0 / 8 (0.00%) 0	1 / 4 (25.00%) 2
Lymphopenia subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 4	2 / 8 (25.00%) 2	2 / 4 (50.00%) 2
Neutropenia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 8 (12.50%) 2	0 / 4 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Gastrointestinal disorders			
Nausea subjects affected / exposed occurrences (all)	4 / 7 (57.14%) 4	2 / 8 (25.00%) 2	0 / 4 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	5 / 8 (62.50%) 7	0 / 4 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 8 (25.00%) 2	0 / 4 (0.00%) 0
Abdominal pain			

subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	3 / 7 (42.86%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Dysphagia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Rash pruritic subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Alopecia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	1 / 4 (25.00%) 1
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 8 (12.50%) 1	2 / 4 (50.00%) 2
Arthralgia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 8 (12.50%) 4	1 / 4 (25.00%) 1
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0

Myalgia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 7 (28.57%)	3 / 8 (37.50%)	2 / 4 (50.00%)
occurrences (all)	2	3	2
Dehydration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 8 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			

subjects affected / exposed	1 / 7 (14.29%)	1 / 8 (12.50%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 8 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 3mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 6mg Q21D	Phase 1, Dose Escalation Phase: Nemvaleukin Alfa 10mg Q21D
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	8 / 8 (100.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	3 / 8 (37.50%)	3 / 9 (33.33%)
occurrences (all)	0	3	3
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	4 / 4 (100.00%)	4 / 8 (50.00%)	7 / 9 (77.78%)
occurrences (all)	6	6	19
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)	2 / 8 (25.00%)	4 / 9 (44.44%)
occurrences (all)	2	3	7
Chills			
subjects affected / exposed	3 / 4 (75.00%)	1 / 8 (12.50%)	7 / 9 (77.78%)
occurrences (all)	3	1	14
Injection site erythema			
subjects affected / exposed	3 / 4 (75.00%)	4 / 8 (50.00%)	4 / 9 (44.44%)
occurrences (all)	5	4	5
Injection site reaction			

subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	3 / 9 (33.33%)
occurrences (all)	2	2	5
Injection site pruritus			
subjects affected / exposed	1 / 4 (25.00%)	4 / 8 (50.00%)	1 / 9 (11.11%)
occurrences (all)	1	5	1
Injection site pain			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	2 / 9 (22.22%)
occurrences (all)	0	3	2
Injection site swelling			
subjects affected / exposed	2 / 4 (50.00%)	2 / 8 (25.00%)	0 / 9 (0.00%)
occurrences (all)	2	2	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Injection site oedema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nodule			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Physical deconditioning			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Discomfort			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	3 / 8 (37.50%)	2 / 9 (22.22%)
occurrences (all)	0	4	2
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	2 / 9 (22.22%)
occurrences (all)	0	3	2
Blood creatinine increased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	3 / 9 (33.33%)
occurrences (all)	1	1	7
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Blood urea increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	2
Oxygen saturation decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			

Infusion related reaction subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	2 / 9 (22.22%) 2
Fall subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1	1 / 9 (11.11%) 1
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	3 / 9 (33.33%) 3
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	2 / 8 (25.00%) 2	2 / 9 (22.22%) 2
Headache subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	1 / 8 (12.50%) 1	2 / 9 (22.22%) 3
Neuropathy peripheral subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1	1 / 9 (11.11%) 1
Dysgeusia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	4 / 8 (50.00%) 6	1 / 9 (11.11%) 2
Lymphopenia subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 8 (0.00%) 0	2 / 9 (22.22%) 5
Neutropenia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 8 (12.50%) 4	2 / 9 (22.22%) 2
Thrombocytopenia			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 4 (50.00%)	3 / 8 (37.50%)	5 / 9 (55.56%)
occurrences (all)	2	4	9
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	5 / 9 (55.56%)
occurrences (all)	0	3	7
Diarrhoea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	2 / 9 (22.22%)
occurrences (all)	1	1	3
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	1 / 9 (11.11%)
occurrences (all)	1	3	2
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Night sweats			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			

Hypothyroidism subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Back pain subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 3	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Arthralgia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	2 / 8 (25.00%) 2	2 / 9 (22.22%) 2
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1	1 / 9 (11.11%) 1
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Muscular weakness subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 8 (12.50%) 1	1 / 9 (11.11%) 1
Infections and infestations			
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	2 / 8 (25.00%) 2	3 / 9 (33.33%) 5
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	0 / 9 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	2 / 8 (25.00%) 2	3 / 9 (33.33%) 5
Dehydration subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 8 (0.00%) 0	3 / 9 (33.33%) 8

Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 9 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Phase 2, Dose Expansion Phase, NSCLC	Phase 2, Dose Expansion Phase, SCCHN	Phase 2, Dose Expansion Phase, Gastric/GEJ Cancer
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 11 (100.00%)	10 / 10 (100.00%)	13 / 13 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Hypertension			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	2 / 13 (15.38%)
occurrences (all)	0	2	3
General disorders and administration site conditions			

Pyrexia			
subjects affected / exposed	8 / 11 (72.73%)	6 / 10 (60.00%)	6 / 13 (46.15%)
occurrences (all)	45	26	25
Fatigue			
subjects affected / exposed	1 / 11 (9.09%)	6 / 10 (60.00%)	4 / 13 (30.77%)
occurrences (all)	1	26	5
Chills			
subjects affected / exposed	4 / 11 (36.36%)	3 / 10 (30.00%)	3 / 13 (23.08%)
occurrences (all)	11	3	8
Injection site erythema			
subjects affected / exposed	4 / 11 (36.36%)	2 / 10 (20.00%)	3 / 13 (23.08%)
occurrences (all)	14	3	5
Injection site reaction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Injection site pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	3 / 13 (23.08%)
occurrences (all)	7	0	3
Injection site swelling			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	1 / 13 (7.69%)
occurrences (all)	2	3	1
Pain			
subjects affected / exposed	2 / 11 (18.18%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	3	0	1
Asthenia			
subjects affected / exposed	4 / 11 (36.36%)	1 / 10 (10.00%)	3 / 13 (23.08%)
occurrences (all)	11	1	5
Chest pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Influenza like illness subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Injection site oedema subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 10 (10.00%) 1	1 / 13 (7.69%) 1
Nodule subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Physical deconditioning subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Discomfort subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 4	0 / 10 (0.00%) 0	1 / 13 (7.69%) 1
Injection site rash subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	1 / 13 (7.69%) 2
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	3 / 10 (30.00%) 4	1 / 13 (7.69%) 1
Dyspnoea subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 3	1 / 10 (10.00%) 1	1 / 13 (7.69%) 1
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Insomnia			

subjects affected / exposed	3 / 11 (27.27%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	6 / 11 (54.55%)	3 / 10 (30.00%)	1 / 13 (7.69%)
occurrences (all)	8	4	1
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 11 (54.55%)	2 / 10 (20.00%)	2 / 13 (15.38%)
occurrences (all)	8	2	3
Blood creatinine increased			
subjects affected / exposed	2 / 11 (18.18%)	1 / 10 (10.00%)	1 / 13 (7.69%)
occurrences (all)	2	1	3
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 11 (27.27%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	5	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Blood urea increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Neutrophil count decreased			
subjects affected / exposed	1 / 11 (9.09%)	2 / 10 (20.00%)	2 / 13 (15.38%)
occurrences (all)	1	2	6
Lymphocyte count decreased			
subjects affected / exposed	2 / 11 (18.18%)	1 / 10 (10.00%)	2 / 13 (15.38%)
occurrences (all)	2	2	4
Weight decreased			

subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 2	1 / 10 (10.00%) 1	3 / 13 (23.08%) 4
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	2 / 13 (15.38%) 3
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 10 (10.00%) 1	2 / 13 (15.38%) 6
Flank pain subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Injury, poisoning and procedural complications			
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	1 / 13 (7.69%) 1
Fall subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 10 (10.00%) 1	2 / 13 (15.38%) 3
Headache subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 2	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Neuropathy peripheral subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Dysgeusia			

subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 11 (27.27%)	2 / 10 (20.00%)	3 / 13 (23.08%)
occurrences (all)	5	3	4
Lymphopenia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Neutropenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	4 / 11 (36.36%)	4 / 10 (40.00%)	5 / 13 (38.46%)
occurrences (all)	6	11	7
Vomiting			
subjects affected / exposed	3 / 11 (27.27%)	4 / 10 (40.00%)	2 / 13 (15.38%)
occurrences (all)	4	8	2
Diarrhoea			
subjects affected / exposed	2 / 11 (18.18%)	2 / 10 (20.00%)	2 / 13 (15.38%)
occurrences (all)	4	2	3
Abdominal pain			
subjects affected / exposed	0 / 11 (0.00%)	2 / 10 (20.00%)	2 / 13 (15.38%)
occurrences (all)	0	2	3
Constipation			
subjects affected / exposed	1 / 11 (9.09%)	2 / 10 (20.00%)	6 / 13 (46.15%)
occurrences (all)	2	2	6
Abdominal distension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			

subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	3 / 13 (23.08%)
occurrences (all)	1	1	3
Hyperhidrosis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	2 / 13 (15.38%)
occurrences (all)	1	3	5
Dry skin			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	2 / 11 (18.18%)	0 / 10 (0.00%)	2 / 13 (15.38%)
occurrences (all)	3	0	4

Rash			
subjects affected / exposed	1 / 11 (9.09%)	2 / 10 (20.00%)	0 / 13 (0.00%)
occurrences (all)	1	7	0
Alopecia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	3 / 13 (23.08%)
occurrences (all)	1	1	4
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 10 (10.00%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Arthralgia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 10 (0.00%)	2 / 13 (15.38%)
occurrences (all)	1	0	2
Musculoskeletal pain			
subjects affected / exposed	1 / 11 (9.09%)	1 / 10 (10.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
Myalgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 10 (10.00%) 1	0 / 13 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	8 / 11 (72.73%) 13	2 / 10 (20.00%) 2	4 / 13 (30.77%) 5
Dehydration subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 10 (20.00%) 2	0 / 13 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 10 (20.00%) 4	0 / 13 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 10 (10.00%) 1	1 / 13 (7.69%) 2
Hypomagnesaemia subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 2	1 / 10 (10.00%) 1	0 / 13 (0.00%) 0
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 10 (0.00%) 0	1 / 13 (7.69%) 3
Hypophosphataemia subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 2	0 / 10 (0.00%) 0	0 / 13 (0.00%) 0

Non-serious adverse events	Phase 2, Dose Expansion Phase, Ovarian Cancer Cohort 1	Phase 2, Dose Expansion Phase, OC Cohort 2	
Total subjects affected by non-serious adverse events subjects affected / exposed	17 / 17 (100.00%)	8 / 8 (100.00%)	

Neoplasms benign, malignant and unspecified (incl cysts and polyps) Tumour pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Vascular disorders Hypotension subjects affected / exposed occurrences (all) Hypertension subjects affected / exposed occurrences (all)	4 / 17 (23.53%) 6 1 / 17 (5.88%) 1	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Chills subjects affected / exposed occurrences (all) Injection site erythema subjects affected / exposed occurrences (all) Injection site reaction subjects affected / exposed occurrences (all) Injection site pruritus subjects affected / exposed occurrences (all) Injection site pain subjects affected / exposed occurrences (all) Injection site swelling subjects affected / exposed occurrences (all)	8 / 17 (47.06%) 12 9 / 17 (52.94%) 18 9 / 17 (52.94%) 18 3 / 17 (17.65%) 12 0 / 17 (0.00%) 0 2 / 17 (11.76%) 6 2 / 17 (11.76%) 2 0 / 17 (0.00%) 0	2 / 8 (25.00%) 2 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 1 / 8 (12.50%) 2 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	

Oedema peripheral subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 3	1 / 8 (12.50%) 1	
Pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Asthenia subjects affected / exposed occurrences (all)	4 / 17 (23.53%) 4	0 / 8 (0.00%) 0	
Chest pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Influenza like illness subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Injection site oedema subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 4	0 / 8 (0.00%) 0	
Nodule subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Physical deconditioning subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Discomfort subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Injection site rash subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 2	0 / 8 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	3 / 17 (17.65%) 4	0 / 8 (0.00%) 0	
Dyspnoea			

subjects affected / exposed occurrences (all)	4 / 17 (23.53%) 5	1 / 8 (12.50%) 1	
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Nasal congestion subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Insomnia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 2	2 / 8 (25.00%) 5	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	4 / 17 (23.53%) 5	4 / 8 (50.00%) 6	
Blood creatinine increased subjects affected / exposed occurrences (all)	6 / 17 (35.29%) 12	0 / 8 (0.00%) 0	
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 2	1 / 8 (12.50%) 1	
Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	1 / 8 (12.50%) 1	
Blood urea increased subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Oxygen saturation decreased			

subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Platelet count decreased subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 8 (0.00%) 0	
Neutrophil count decreased subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 3	0 / 8 (0.00%) 0	
Lymphocyte count decreased subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 8 (0.00%) 0	
Weight decreased subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Blood bilirubin increased subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 2	1 / 8 (12.50%) 1	
White blood cell count decreased subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 8 (0.00%) 0	
Flank pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Injury, poisoning and procedural complications			
Infusion related reaction subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	2 / 8 (25.00%) 3	
Fall subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Sinus tachycardia			

subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 17 (17.65%)	1 / 8 (12.50%)	
occurrences (all)	3	1	
Headache			
subjects affected / exposed	1 / 17 (5.88%)	1 / 8 (12.50%)	
occurrences (all)	1	2	
Neuropathy peripheral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 17 (17.65%)	1 / 8 (12.50%)	
occurrences (all)	10	1	
Lymphopenia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Neutropenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	9 / 17 (52.94%)	3 / 8 (37.50%)	
occurrences (all)	13	3	
Vomiting			
subjects affected / exposed	9 / 17 (52.94%)	1 / 8 (12.50%)	
occurrences (all)	16	1	
Diarrhoea			

subjects affected / exposed	6 / 17 (35.29%)	0 / 8 (0.00%)	
occurrences (all)	9	0	
Abdominal pain			
subjects affected / exposed	7 / 17 (41.18%)	1 / 8 (12.50%)	
occurrences (all)	8	1	
Constipation			
subjects affected / exposed	2 / 17 (11.76%)	1 / 8 (12.50%)	
occurrences (all)	2	1	
Abdominal distension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Dysphagia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Gastritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 17 (17.65%)	0 / 8 (0.00%)	
occurrences (all)	3	0	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Dry skin			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	

Night sweats subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Rash pruritic subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Erythema subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Rash subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 8 (0.00%) 0	
Alopecia subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 2	0 / 8 (0.00%) 0	
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Dysuria subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	1 / 8 (12.50%) 1	
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 2	0 / 8 (0.00%) 0	
Arthralgia subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 8 (0.00%) 0	

Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Myalgia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Muscular weakness subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Infections and infestations			
Urinary tract infection subjects affected / exposed occurrences (all)	5 / 17 (29.41%) 5	0 / 8 (0.00%) 0	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	5 / 17 (29.41%) 6	1 / 8 (12.50%) 1	
Dehydration subjects affected / exposed occurrences (all)	5 / 17 (29.41%) 7	0 / 8 (0.00%) 0	
Hypokalaemia subjects affected / exposed occurrences (all)	4 / 17 (23.53%) 4	2 / 8 (25.00%) 2	
Hypercalcaemia subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 8 (0.00%) 0	
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 8 (12.50%) 1	
Hypomagnesaemia			

subjects affected / exposed	4 / 17 (23.53%)	2 / 8 (25.00%)	
occurrences (all)	4	2	
Hyponatraemia			
subjects affected / exposed	1 / 17 (5.88%)	1 / 8 (12.50%)	
occurrences (all)	1	1	
Hypophosphataemia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 8 (25.00%)	
occurrences (all)	0	2	

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