



Clinical trial results:

A Phase 1/2 Open-Label, Multicenter Study Evaluating the Safety and Pharmacokinetics of Escalating Doses of IGM-2323 in Subjects with Relapsed/Refractory Non-Hodgkin Lymphomas

Summary

EudraCT number	2021-002339-44
Trial protocol	CZ ES IT DK
Global end of trial date	22 February 2024

Results information

Result version number	v1 (current)
This version publication date	07 March 2025
First version publication date	07 March 2025

Trial information

Trial identification

Sponsor protocol code	IGM-2323-001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04082936
WHO universal trial number (UTN)	-
Other trial identifiers	US IND Number: 140504

Notes:

Sponsors

Sponsor organisation name	IGM Biosciences, Inc.
Sponsor organisation address	325 East Middlefield Road, Mountain View, United States, CA 94043
Public contact	IGM Clinical Trials, IGM Biosciences, Inc., clinicaltrials@IGMbio.com
Scientific contact	IGM Clinical Trials, IGM Biosciences, Inc., clinicaltrials@IGMbio.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	22 February 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 February 2024
Global end of trial reached?	Yes
Global end of trial date	22 February 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Phase 1

- To evaluate the safety and tolerability of IGM-2323 in subjects with R/R NHL
- To determine a maximum tolerated dose (MTD) and/or a recommended Phase 2 dose (RP2D) and schedule of IGM-2323 as a single agent in subjects with R/R NHL

Phase 2 Expansion

- To select the optimally efficacious dose of IGM-2323 in subjects with R/R diffuse large B-cell lymphoma (DLBCL) and R/R follicular lymphoma (FL)

Protection of trial subjects:

Measures were taken to ensure the safety of subjects participating in this study, including the use of stringent inclusion and exclusion criteria, premedication, and close monitoring and management, as described below. Enrollment of subjects during the Dose-Escalation Phase was staggered such that the second subject in each cohort would not receive their Cycle 1 Day 1 dose of imvotamab until ≥ 72 hours after the first subject in each cohort. Subsequent subjects (e.g., between the second and third subject) enrolled in each cohort were staggered by at least 24 hours.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 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: 8
Country: Number of subjects enrolled	Czechia: 1
Country: Number of subjects enrolled	France: 5
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Australia: 17
Country: Number of subjects enrolled	United States: 48
Country: Number of subjects enrolled	Korea, Republic of: 17
Worldwide total number of subjects	97
EEA total number of subjects	15

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	44
From 65 to 84 years	51
85 years and over	2

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Adult subjects with relapsed/refractory Non-Hodgkin lymphoma were enrolled in this study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase 1 Fixed Dose QW: 0.5/2.5 mg

Arm description:

Fixed dose imvotamab 0.5/2.5 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Imvotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Imvotamab was diluted in normal saline for low-dose infusions. Imvotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Imvotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 1 Fixed Dose QW: 10 mg
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Arm description:

Fixed dose imvotamab 10 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Imvotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Imvotamab was diluted in normal saline for low-dose infusions. Imvotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Imvotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 1 Fixed Dose QW: 30 mg
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Arm description:

Fixed dose imvotamab 30 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Imvotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Imvotamab was diluted in normal saline for low-dose infusions. Imvotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Imvotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 1 Fixed Dose QW: 100 mg
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Arm description:

Fixed dose imvotamab 100 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Imvotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Imvotamab was diluted in normal saline for low-dose infusions. Imvotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Imvotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 1 Titration Dose QW: 100 mg
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Arm description:

Titration dose imvotamab 100 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Arm type	Experimental
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Investigational medicinal product name	Invotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Invotamab was diluted in normal saline for low-dose infusions. Invotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Invotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 1 Titration Dose QW: 200 mg
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Arm description:

Titration dose invotamab 200 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Invotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Invotamab was diluted in normal saline for low-dose infusions. Invotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Invotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 1 Titration Dose QW: 300 mg
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Arm description:

Titration dose invotamab 300 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks. QW = once weekly

Arm type	Experimental
Investigational medicinal product name	Invotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Invotamab was diluted in normal saline for low-dose infusions. Invotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Invotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 1 Titration Dose QW: 600 mg
Arm description: Titration dose imvotamab 600 mg once weekly (QW).	
Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.	
Arm type	Experimental
Investigational medicinal product name	Imvotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Imvotamab was diluted in normal saline for low-dose infusions. Imvotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Imvotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 1 Titration Dose QW: 1000 mg
Arm description: Titration dose imvotamab 1000 mg once weekly (QW).	
Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks. QW = once weekly	
Arm type	Experimental
Investigational medicinal product name	Imvotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Imvotamab was diluted in normal saline for low-dose infusions. Imvotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Imvotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 1 Titration Dose Q3W: 100 mg
Arm description: Titration dose imvotamab 100 mg once every 3 weeks (Q3W).	
Administered intravenously (IV) as weekly dosing for the first cycle, then moved to an every 3-week dosing schedule after.	
Arm type	Experimental
Investigational medicinal product name	Imvotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Imvotamab was diluted in normal saline for low-dose infusions. Imvotamab was administered to

participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Imvotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 1 Titration Dose Q3W: 300 mg
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Arm description:

Titration dose imvotamab 300 mg once every 3 weeks (Q3W).

Administered intravenously (IV) as weekly dosing for the first cycle, then moved to an every 3-week dosing schedule after.

Arm type	Experimental
Investigational medicinal product name	Imvotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Imvotamab was diluted in normal saline for low-dose infusions. Imvotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Imvotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Prior BiTE Titration Dose QW: 100 mg
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Arm description:

Participants with bispecific T-cell engager (BiTE).

Titration dose of 100 mg imvotamab once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Imvotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Imvotamab was diluted in normal saline for low-dose infusions. Imvotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Imvotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 2 Titration Dose QW: 100 mg
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Arm description:

Phase 2 Expansion Phase: Titration dose.

100 mg imvotamab administered once weekly (QW) intravenously (IV) on Days 1, 8, and 15 of 21-day

cycles.

Arm type	Experimental
Investigational medicinal product name	Invotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Invotamab was diluted in normal saline for low-dose infusions. Invotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Invotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Arm title	Phase 2 Titration Dose QW: 300 mg
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Arm description:

Phase 2 Expansion Phase: Titration dose.

300 mg invotamab administered once weekly (QW) intravenously (IV) on Days 1, 8, and 15 of 21-day cycles.

Arm type	Experimental
Investigational medicinal product name	Invotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Invotamab was diluted in normal saline for low-dose infusions. Invotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Invotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Investigational medicinal product name	Invotamab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Invotamab was diluted in normal saline for low-dose infusions. Invotamab was administered to participants by IV infusion using standard medical syringes and syringe pumps for lower doses, or IV bags and IV infusion pumps for larger doses.

Invotamab was infused over 1 hour \pm 15 minutes for the first 2 Dose Levels (0.5 mg and 2.5 mg doses). Subsequent Dose Levels (10 mg and higher doses) will be infused over 2 hours \pm 15 minutes. The infusion may have been slowed or interrupted for participants experiencing infusion-associated symptoms. For the first infusion (Cycle 1 Day 1), subjects in the Dose-Escalation Phase was observed for at least 24 hours.

Number of subjects in period 1	Phase 1 Fixed Dose QW: 0.5/2.5 mg	Phase 1 Fixed Dose QW: 10 mg	Phase 1 Fixed Dose QW: 30 mg
Started	2	3	6
Completed	0	0	0
Not completed	2	3	6
Adverse event, serious fatal	1	1	1
Consent withdrawn by subject	-	-	-
Protocol Defined Disease Progression	-	-	-
Physician decision	-	-	-
Study terminated by sponsor	1	2	5

Number of subjects in period 1	Phase 1 Fixed Dose QW: 100 mg	Phase 1 Titration Dose QW: 100 mg	Phase 1 Titration Dose QW: 200 mg
Started	1	13	1
Completed	0	0	0
Not completed	1	13	1
Adverse event, serious fatal	1	3	1
Consent withdrawn by subject	-	4	-
Protocol Defined Disease Progression	-	-	-
Physician decision	-	-	-
Study terminated by sponsor	-	6	-

Number of subjects in period 1	Phase 1 Titration Dose QW: 300 mg	Phase 1 Titration Dose QW: 600 mg	Phase 1 Titration Dose QW: 1000 mg
Started	13	8	5
Completed	0	0	0
Not completed	13	8	5
Adverse event, serious fatal	4	4	2
Consent withdrawn by subject	3	1	-
Protocol Defined Disease Progression	-	-	-
Physician decision	-	-	-
Study terminated by sponsor	6	3	3

Number of subjects in period 1	Phase 1 Titration Dose Q3W: 100 mg	Phase 1 Titration Dose Q3W: 300 mg	Prior BiTE Titration Dose QW: 100 mg
Started	2	2	1
Completed	0	0	0
Not completed	2	2	1
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	-	-
Protocol Defined Disease Progression	1	1	-
Physician decision	-	1	-
Study terminated by sponsor	-	-	1

Number of subjects in period 1	Phase 2 Titration Dose QW: 100 mg	Phase 2 Titration Dose QW: 300 mg
Started	19	21
Completed	0	0
Not completed	19	21
Adverse event, serious fatal	5	4
Consent withdrawn by subject	2	2
Protocol Defined Disease Progression	-	-
Physician decision	-	-
Study terminated by sponsor	12	15

Baseline characteristics

Reporting groups

Reporting group title	Phase 1 Fixed Dose QW: 0.5/2.5 mg
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Reporting group description:

Fixed dose imvotamab 0.5/2.5 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Fixed Dose QW: 10 mg
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Reporting group description:

Fixed dose imvotamab 10 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Fixed Dose QW: 30 mg
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Reporting group description:

Fixed dose imvotamab 30 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Fixed Dose QW: 100 mg
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Reporting group description:

Fixed dose imvotamab 100 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 100 mg
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Reporting group description:

Titration dose imvotamab 100 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 200 mg
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Reporting group description:

Titration dose imvotamab 200 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 300 mg
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Reporting group description:

Titration dose imvotamab 300 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks. QW = once weekly

Reporting group title	Phase 1 Titration Dose QW: 600 mg
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Reporting group description:

Titration dose imvotamab 600 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 1000 mg
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Reporting group description:

Titration dose imvotamab 1000 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks. QW = once weekly

Reporting group title	Phase 1 Titration Dose Q3W: 100 mg
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Reporting group description:

Titration dose imvotamab 100 mg once every 3 weeks (Q3W).

Administered intravenously (IV) as weekly dosing for the first cycle, then moved to an every 3-week dosing schedule after.

Reporting group title	Phase 1 Titration Dose Q3W: 300 mg
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Reporting group description:

Titration dose imvotamab 300 mg once every 3 weeks (Q3W).

Administered intravenously (IV) as weekly dosing for the first cycle, then moved to an every 3-week dosing schedule after.

Reporting group title	Prior BiTE Titration Dose QW: 100 mg
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Reporting group description:

Participants with bispecific T-cell engager (BiTE).

Titration dose of 100 mg imvotamab once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 2 Titration Dose QW: 100 mg
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Reporting group description:

Phase 2 Expansion Phase: Titration dose.

100 mg imvotamab administered once weekly (QW) intravenously (IV) on Days 1, 8, and 15 of 21-day cycles.

Reporting group title	Phase 2 Titration Dose QW: 300 mg
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Reporting group description:

Phase 2 Expansion Phase: Titration dose.

300 mg imvotamab administered once weekly (QW) intravenously (IV) on Days 1, 8, and 15 of 21-day cycles.

Reporting group values	Phase 1 Fixed Dose QW: 0.5/2.5 mg	Phase 1 Fixed Dose QW: 10 mg	Phase 1 Fixed Dose QW: 30 mg
Number of subjects	2	3	6
Age categorical			
Units: Subjects			
≤ 65 years	1	1	4
66 - 75 years	0	2	2
> 75 years	1	0	0
Age continuous			
0000 = not calculated			
Units: years			
arithmetic mean	64.0	69.7	60.3
standard deviation	± 24.04	± 8.39	± 8.39
Gender categorical			
Units: Subjects			
Female	2	0	1
Male	0	3	5
Race			
Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0

Native Hawaiian or Other Pacific Islander	0	0	0
White	2	3	6
Not Reported	0	0	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	3	6
Not Reported	0	0	0
Country			
Units: Subjects			
Australia	0	0	0
Czech Republic	0	0	0
France	0	0	0
Italy	0	0	0
South Korea	0	0	0
Spain	0	0	0
United States of America	2	3	6
Eastern Cooperative Oncology Group Performance Status			
ECOG PS = Eastern Cooperative Oncology Group Performance Status			
Units: Subjects			
ECOG PS 0	1	1	5
ECOG PS 1	1	2	1
ECOG PS 2	0	0	0

Reporting group values	Phase 1 Fixed Dose QW: 100 mg	Phase 1 Titration Dose QW: 100 mg	Phase 1 Titration Dose QW: 200 mg
Number of subjects	1	13	1
Age categorical			
Units: Subjects			
≤ 65 years	1	6	0
66 - 75 years	0	4	0
> 75 years	0	3	1
Age continuous			
0000 = not calculated			
Units: years			
arithmetic mean	64.0	64.1	82.0
standard deviation	± 0000	± 14.30	± 0000
Gender categorical			
Units: Subjects			
Female	0	5	0
Male	1	8	1
Race			
Units: Subjects			
Asian	0	4	0
Black or African American	0	2	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	1	7	1
Not Reported	0	0	0
Ethnicity			
Units: Subjects			

Hispanic or Latino	0	1	0
Not Hispanic or Latino	1	11	1
Not Reported	0	1	0
Country			
Units: Subjects			
Australia	0	4	0
Czech Republic	0	0	0
France	0	0	0
Italy	0	0	0
South Korea	0	4	0
Spain	0	0	0
United States of America	1	5	1
Eastern Cooperative Oncology Group Performance Status			
ECOG PS = Eastern Cooperative Oncology Group Performance Status			
Units: Subjects			
ECOG PS 0	1	4	0
ECOG PS 1	0	9	1
ECOG PS 2	0	0	0

Reporting group values	Phase 1 Titration Dose QW: 300 mg	Phase 1 Titration Dose QW: 600 mg	Phase 1 Titration Dose QW: 1000 mg
Number of subjects	13	8	5
Age categorical			
Units: Subjects			
≤ 65 years	7	1	3
66 - 75 years	3	4	1
> 75 years	3	3	1
Age continuous			
0000 = not calculated			
Units: years			
arithmetic mean	62.4	72.9	60.6
standard deviation	± 15.32	± 7.49	± 15.49
Gender categorical			
Units: Subjects			
Female	4	2	1
Male	9	6	4
Race			
Units: Subjects			
Asian	5	2	1
Black or African American	0	0	0
Native Hawaiian or Other Pacific Islander	1	0	0
White	7	6	3
Not Reported	0	0	1
Ethnicity			
Units: Subjects			
Hispanic or Latino	1	1	1
Not Hispanic or Latino	12	7	4
Not Reported	0	0	0
Country			
Units: Subjects			

Australia	2	2	2
Czech Republic	0	0	0
France	0	0	0
Italy	0	0	0
South Korea	4	2	0
Spain	0	0	0
United States of America	7	4	3
Eastern Cooperative Oncology Group Performance Status			
ECOG PS = Eastern Cooperative Oncology Group Performance Status			
Units: Subjects			
ECOG PS 0	4	1	3
ECOG PS 1	9	7	2
ECOG PS 2	0	0	0

Reporting group values	Phase 1 Titration Dose Q3W: 100 mg	Phase 1 Titration Dose Q3W: 300 mg	Prior BiTE Titration Dose QW: 100 mg
Number of subjects	2	2	1
Age categorical			
Units: Subjects			
≤ 65 years	0	1	1
66 - 75 years	2	1	0
> 75 years	0	0	0
Age continuous			
0000 = not calculated			
Units: years			
arithmetic mean	69.0	60.5	56.0
standard deviation	± 4.24	± 7.78	± 0000
Gender categorical			
Units: Subjects			
Female	1	1	0
Male	1	1	1
Race			
Units: Subjects			
Asian	1	1	0
Black or African American	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	1	1	1
Not Reported	0	0	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	2	1	1
Not Reported	0	0	0
Country			
Units: Subjects			
Australia	0	0	1
Czech Republic	0	0	0
France	0	0	0
Italy	0	0	0
South Korea	1	1	0
Spain	0	0	0

United States of America	1	1	0
Eastern Cooperative Oncology Group Performance Status			
ECOG PS = Eastern Cooperative Oncology Group Performance Status			
Units: Subjects			
ECOG PS 0	0	1	0
ECOG PS 1	2	1	1
ECOG PS 2	0	0	0

Reporting group values	Phase 2 Titration Dose QW: 100 mg	Phase 2 Titration Dose QW: 300 mg	Total
Number of subjects	19	21	97
Age categorical			
Units: Subjects			
≤ 65 years	6	12	44
66 - 75 years	7	7	33
> 75 years	6	2	20
Age continuous			
0000 = not calculated			
Units: years			
arithmetic mean	68.6	60.0	
standard deviation	± 11.69	± 13.95	-
Gender categorical			
Units: Subjects			
Female	4	5	26
Male	15	16	71
Race			
Units: Subjects			
Asian	3	3	20
Black or African American	0	1	3
Native Hawaiian or Other Pacific Islander	0	0	1
White	14	14	67
Not Reported	2	3	6
Ethnicity			
Units: Subjects			
Hispanic or Latino	3	2	10
Not Hispanic or Latino	14	16	81
Not Reported	2	3	6
Country			
Units: Subjects			
Australia	3	3	17
Czech Republic	1	0	1
France	2	3	5
Italy	0	1	1
South Korea	2	3	17
Spain	6	2	8
United States of America	5	9	48
Eastern Cooperative Oncology Group Performance Status			
ECOG PS = Eastern Cooperative Oncology Group Performance Status			
Units: Subjects			
ECOG PS 0	6	9	36

ECOG PS 1	12	11	59
ECOG PS 2	1	1	2

End points

End points reporting groups

Reporting group title	Phase 1 Fixed Dose QW: 0.5/2.5 mg
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Reporting group description:

Fixed dose imvotamab 0.5/2.5 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Fixed Dose QW: 10 mg
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Reporting group description:

Fixed dose imvotamab 10 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Fixed Dose QW: 30 mg
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Reporting group description:

Fixed dose imvotamab 30 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Fixed Dose QW: 100 mg
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Reporting group description:

Fixed dose imvotamab 100 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 100 mg
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Reporting group description:

Titration dose imvotamab 100 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 200 mg
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Reporting group description:

Titration dose imvotamab 200 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 300 mg
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Reporting group description:

Titration dose imvotamab 300 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks. QW = once weekly

Reporting group title	Phase 1 Titration Dose QW: 600 mg
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Reporting group description:

Titration dose imvotamab 600 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 1000 mg
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Reporting group description:

Titration dose imvotamab 1000 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks. QW = once weekly

Reporting group title	Phase 1 Titration Dose Q3W: 100 mg
Reporting group description:	
Titration dose imvotamab 100 mg once every 3 weeks (Q3W).	
Administered intravenously (IV) as weekly dosing for the first cycle, then moved to an every 3-week dosing schedule after.	
Reporting group title	Phase 1 Titration Dose Q3W: 300 mg
Reporting group description:	
Titration dose imvotamab 300 mg once every 3 weeks (Q3W).	
Administered intravenously (IV) as weekly dosing for the first cycle, then moved to an every 3-week dosing schedule after.	
Reporting group title	Prior BiTE Titration Dose QW: 100 mg
Reporting group description:	
Participants with bispecific T-cell engager (BiTE).	
Titration dose of 100 mg imvotamab once weekly (QW).	
Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.	
Reporting group title	Phase 2 Titration Dose QW: 100 mg
Reporting group description:	
Phase 2 Expansion Phase: Titration dose.	
100 mg imvotamab administered once weekly (QW) intravenously (IV) on Days 1, 8, and 15 of 21-day cycles.	
Reporting group title	Phase 2 Titration Dose QW: 300 mg
Reporting group description:	
Phase 2 Expansion Phase: Titration dose.	
300 mg imvotamab administered once weekly (QW) intravenously (IV) on Days 1, 8, and 15 of 21-day cycles.	
Subject analysis set title	Phase 2 Titration Dose QW: 100 mg: DLBCL
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants in the 100 mg Cohort of the Phase 2 expansion group with diffuse large B-cell lymphoma (DLBCL)	
Subject analysis set title	Phase 2 Titration Dose QW: 100 mg: FL
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants in the 100 mg Cohort of the Phase 2 expansion group with follicular lymphoma (FL)	
Subject analysis set title	Phase 2 Titration Dose QW: 300 mg: DLBCL
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants in the 300 mg Cohort of the Phase 2 expansion group with diffuse large B-cell lymphoma (DLBCL)	
Subject analysis set title	Phase 2 Titration Dose QW: 300 mg: FL
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants in the 300 mg Cohort of the Phase 2 expansion group with follicular lymphoma (FL)	
Primary: Overall response rate (ORR) as determined by study investigators according to the Lugano Classification in Lymphoma (Phase 2 expansion)	
End point title	Overall response rate (ORR) as determined by study investigators according to the Lugano Classification in Lymphoma (Phase 2 expansion) ^[1]

End point description:

The overall response rate (ORR) as determined by study investigators according to the Lugano Classification in Lymphoma (Phase 2 expansion) is presented.

End point type	Primary
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End point timeframe:

Approximately 4.4 years (i.e., first subject enrolled through last end-of-study visit)

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: Not applicable.

End point values	Phase 2 Titration Dose QW: 100 mg: DLBCL	Phase 2 Titration Dose QW: 100 mg: FL	Phase 2 Titration Dose QW: 300 mg: DLBCL	Phase 2 Titration Dose QW: 300 mg: FL
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	12	12	7	9
Units: participants				
Complete Response	1	1	2	3
Partial Response	2	0	1	0
Stable Disease	2	3	3	3
Progressive Disease	6	8	1	3
Not Evaluable	0	0	0	0
Discontinued before first tumor assessment	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Objective Response Rate (Phase 2 expansion)

End point title	Objective Response Rate (Phase 2 expansion)
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End point description:

The Objective Response Rate in the Phase 2 expansion cohorts are presented, split into subgroups of diffuse large B-cell lymphoma or follicular lymphoma.

End point type	Primary
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End point timeframe:

Approximately 4.4 years (i.e., first subject enrolled through last end-of-study visit)

End point values	Phase 2 Titration Dose QW: 100 mg: DLBCL	Phase 2 Titration Dose QW: 100 mg: FL	Phase 2 Titration Dose QW: 300 mg: DLBCL	Phase 2 Titration Dose QW: 300 mg: FL
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	12	12	7	9
Units: participants	3	1	3	3

Statistical analyses

Statistical analysis title	Objective Response Rate 95% CI (100 mg DLBCL)
Statistical analysis description: The 95% confidence interval (CI) for the objective response rate in the 100 mg DLBCL sub-group is presented.	
Comparison groups	Phase 2 Titration Dose QW: 100 mg: DLBCL v Phase 2 Titration Dose QW: 100 mg: FL v Phase 2 Titration Dose QW: 300 mg: DLBCL v Phase 2 Titration Dose QW: 300 mg: FL
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	CI
Point estimate	25
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.5
upper limit	57.2

Statistical analysis title	Objective Response Rate 95% CI (300 mg DLBCL)
Statistical analysis description: The 95% confidence interval (CI) for the objective response rate in the 300 mg DLBCL sub-group is presented.	
Comparison groups	Phase 2 Titration Dose QW: 100 mg: DLBCL v Phase 2 Titration Dose QW: 100 mg: FL v Phase 2 Titration Dose QW: 300 mg: DLBCL v Phase 2 Titration Dose QW: 300 mg: FL
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	CI
Point estimate	8.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	38.5

Statistical analysis title	Objective Response Rate 95% CI (100 mg FL)
Statistical analysis description: The 95% confidence interval (CI) for the objective response rate in the 100 mg FL sub-group is presented.	

Comparison groups	Phase 2 Titration Dose QW: 100 mg: DLBCL v Phase 2 Titration Dose QW: 100 mg: FL v Phase 2 Titration Dose QW: 300 mg: DLBCL v Phase 2 Titration Dose QW: 300 mg: FL
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	CI
Point estimate	42.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.9
upper limit	81.6

Statistical analysis title	Objective Response Rate 95% CI (300 mg FL)
Statistical analysis description: The 95% confidence interval (CI) for the objective response rate in the 300 mg FL sub-group is presented.	
Comparison groups	Phase 2 Titration Dose QW: 100 mg: DLBCL v Phase 2 Titration Dose QW: 100 mg: FL v Phase 2 Titration Dose QW: 300 mg: DLBCL v Phase 2 Titration Dose QW: 300 mg: FL
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	CI
Point estimate	33.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.5
upper limit	70.1

Primary: Treatment related Grade 3 or higher treatment-emergent adverse events	
End point title	Treatment related Grade 3 or higher treatment-emergent adverse events ^[2]
End point description: Participants who experienced a treatment related Grade 3 (severe) or higher treatment-emergent adverse events (TEAEs) are presented.	
End point type	Primary
End point timeframe: Approximately 4.4 years (i.e., first subject enrolled through last end-of-study visit)	
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: Not applicable.	

End point values	Phase 1 Fixed Dose QW: 0.5/2.5 mg	Phase 1 Fixed Dose QW: 10 mg	Phase 1 Fixed Dose QW: 30 mg	Phase 1 Fixed Dose QW: 100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	6	1
Units: participants				
Grade 3 or higher treatment-related TEAE	1	0	2	0

End point values	Phase 1 Titration Dose QW: 100 mg	Phase 1 Titration Dose QW: 200 mg	Phase 1 Titration Dose QW: 300 mg	Phase 1 Titration Dose QW: 600 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	1	13	8
Units: participants				
Grade 3 or higher treatment-related TEAE	2	0	4	2

End point values	Phase 1 Titration Dose QW: 1000 mg	Phase 1 Titration Dose Q3W: 100 mg	Phase 1 Titration Dose Q3W: 300 mg	Prior BiTE Titration Dose QW: 100 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	2	2	1
Units: participants				
Grade 3 or higher treatment-related TEAE	2	0	0	1

End point values	Phase 2 Titration Dose QW: 100 mg	Phase 2 Titration Dose QW: 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	21		
Units: participants				
Grade 3 or higher treatment-related TEAE	5	4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Approximately 4.4 years (i.e., first subject enrolled through last end-of-study visit)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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Reporting groups

Reporting group title	Phase 1 Fixed Dose QW: 0.5/2.5 mg
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Reporting group description:

Fixed dose imvotamab 0.5/2.5 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Fixed Dose QW: 10 mg
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Reporting group description:

Fixed dose imvotamab 10 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Fixed Dose QW: 30 mg
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Reporting group description:

Fixed dose imvotamab 30 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Fixed Dose QW: 100 mg
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Reporting group description:

Fixed dose imvotamab 100 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 100 mg
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Reporting group description:

Titration dose imvotamab 100 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 200 mg
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Reporting group description:

Titration dose imvotamab 200 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 300 mg
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Reporting group description:

Titration dose imvotamab 300 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks. QW = once weekly

Reporting group title	Phase 1 Titration Dose QW: 600 mg
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Reporting group description:

Titration dose imvotamab 600 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4

cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 1 Titration Dose QW: 1000 mg
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Reporting group description:

Titration dose imvotamab 1000 mg once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks. QW = once weekly

Reporting group title	Phase 1 Titration Dose Q3W: 100 mg
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Reporting group description:

Titration dose imvotamab 100 mg once every 3 weeks (Q3W).

Administered intravenously (IV) as weekly dosing for the first cycle, then moved to an every 3-week dosing schedule after.

Reporting group title	Phase 1 Titration Dose Q3W: 300 mg
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Reporting group description:

Titration dose imvotamab 300 mg once every 3 weeks (Q3W).

Administered intravenously (IV) as weekly dosing for the first cycle, then moved to an every 3-week dosing schedule after.

Reporting group title	Prior BiTE Titration Dose QW: 100 mg
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Reporting group description:

Participants with bispecific T-cell engager (BiTE).

Titration dose of 100 mg imvotamab once weekly (QW).

Administered intravenously (IV) on Days 1, 8, and 15 of 21-day cycles. Subjects were treated with 4 cycles (3 weeks each), for a total of 12 planned infusions over 12 weeks.

Reporting group title	Phase 2 Titration Dose QW: 100 mg
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Reporting group description:

Phase 2 Expansion Phase: Titration dose.

100 mg imvotamab administered once weekly (QW) intravenously (IV) on Days 1, 8, and 15 of 21-day cycles.

Reporting group title	Phase 2 Titration Dose QW: 300 mg
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Reporting group description:

Phase 2 Expansion Phase: Titration dose.

300 mg imvotamab administered once weekly (QW) intravenously (IV) on Days 1, 8, and 15 of 21-day cycles.

Serious adverse events	Phase 1 Fixed Dose QW: 0.5/2.5 mg	Phase 1 Fixed Dose QW: 10 mg	Phase 1 Fixed Dose QW: 30 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	2 / 6 (33.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Haemoglobin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Tumour lysis syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 1 Fixed Dose QW: 100 mg	Phase 1 Titration Dose QW: 100 mg	Phase 1 Titration Dose QW: 200 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	4 / 13 (30.77%)	1 / 1 (100.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (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
Sudden death			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 1 (100.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (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
Investigations			
Haemoglobin decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (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

Tooth fracture subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 13 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Blood and lymphatic system disorders Febrile neutropenia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 13 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Lymphadenopathy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 13 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Pancytopenia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 13 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Gastrointestinal disorders Gastrointestinal obstruction subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 13 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 13 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Musculoskeletal and connective tissue disorders Flank pain subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0	0 / 13 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Infections and infestations Pneumonia			

subjects affected / exposed	0 / 1 (0.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (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
Device related infection			

subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Tumour lysis syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 1 Titration	Phase 1 Titration	Phase 1 Titration
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	Dose QW: 300 mg	Dose QW: 600 mg	Dose QW: 1000 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 13 (15.38%)	3 / 8 (37.50%)	2 / 5 (40.00%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 13 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	1 / 13 (7.69%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 13 (0.00%)	2 / 8 (25.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Pulmonary embolism			
subjects affected / exposed	1 / 13 (7.69%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Haemoglobin decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			

subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal obstruction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	1 / 13 (7.69%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			

Tumour lysis syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 1 Titration Dose Q3W: 100 mg	Phase 1 Titration Dose Q3W: 300 mg	Prior BiTE Titration Dose QW: 100 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	1 / 1 (100.00%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			

Cytokine release syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Haemoglobin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 1 (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
Road traffic accident			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 1 (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
Infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 1 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Tumour lysis syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2 Titration Dose QW: 100 mg	Phase 2 Titration Dose QW: 300 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 19 (31.58%)	7 / 21 (33.33%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 19 (5.26%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (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	0 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 19 (5.26%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			

subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Haemoglobin decreased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (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 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pancytopenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrointestinal obstruction			
subjects affected / exposed	1 / 19 (5.26%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (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			
Pneumonia			
subjects affected / exposed	2 / 19 (10.53%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 19 (5.26%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arthritis infective			

subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	1 / 19 (5.26%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site cellulitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			

subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Tumour lysis syndrome			
subjects affected / exposed	1 / 19 (5.26%)	0 / 21 (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 Fixed Dose QW: 0.5/2.5 mg	Phase 1 Fixed Dose QW: 10 mg	Phase 1 Fixed Dose QW: 30 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	3 / 3 (100.00%)	6 / 6 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	4 / 6 (66.67%)
occurrences (all)	8	7	6
Pyrexia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	3 / 6 (50.00%)
occurrences (all)	4	0	11
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	4 / 6 (66.67%)
occurrences (all)	0	0	10
Non-cardiac chest pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	3 / 6 (50.00%)
occurrences (all)	0	0	8
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	2 / 6 (33.33%)
occurrences (all)	1	1	3
Investigations			
Neutrophil count decreased			

subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	3
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	4
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	2 / 6 (33.33%)
occurrences (all)	0	5	3
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	4 / 6 (66.67%)
occurrences (all)	0	0	10
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	2
Dizziness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 2 (50.00%)	2 / 3 (66.67%)	2 / 6 (33.33%)
occurrences (all)	1	2	5
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	4 / 6 (66.67%)
occurrences (all)	0	0	4
Diarrhoea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	2
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Constipation			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	2 / 6 (33.33%)
occurrences (all)	0	1	3
Rash			

subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	4
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	3
Arthralgia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	1 / 2 (50.00%)	2 / 3 (66.67%)	2 / 6 (33.33%)
occurrences (all)	1	2	3
Decreased appetite			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Non-serious adverse events	Phase 1 Fixed Dose QW: 100 mg	Phase 1 Titration Dose QW: 100 mg	Phase 1 Titration Dose QW: 200 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	12 / 13 (92.31%)	1 / 1 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 1 (100.00%)	1 / 13 (7.69%)	1 / 1 (100.00%)
occurrences (all)	1	1	1
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 1 (100.00%)	5 / 13 (38.46%)	0 / 1 (0.00%)
occurrences (all)	1	6	0
Pyrexia			
subjects affected / exposed	1 / 1 (100.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	1	3	0
Chills			
subjects affected / exposed	1 / 1 (100.00%)	2 / 13 (15.38%)	1 / 1 (100.00%)
occurrences (all)	1	2	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 13 (7.69%) 1	0 / 1 (0.00%) 0
Immune system disorders Cytokine release syndrome subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 13 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	1 / 13 (7.69%) 1 1 / 13 (7.69%) 2 1 / 13 (7.69%) 1	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 13 (0.00%) 0	0 / 1 (0.00%) 0
Investigations Neutrophil count decreased subjects affected / exposed occurrences (all) Platelet count decreased subjects affected / exposed occurrences (all) Blood creatinine increased subjects affected / exposed occurrences (all) Aspartate aminotransferase increased subjects affected / exposed occurrences (all) Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 1 / 1 (100.00%) 1 1 / 1 (100.00%) 1 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	2 / 13 (15.38%) 5 1 / 13 (7.69%) 1 0 / 13 (0.00%) 0 1 / 13 (7.69%) 1 0 / 13 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0

Weight decreased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 13 (7.69%) 1	0 / 1 (0.00%) 0
Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all)	1 / 1 (100.00%) 1	3 / 13 (23.08%) 4	0 / 1 (0.00%) 0
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 13 (0.00%) 0	0 / 1 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	3 / 13 (23.08%) 3	0 / 1 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	2 / 13 (15.38%) 2	0 / 1 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 13 (7.69%) 1	0 / 1 (0.00%) 0
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	1 / 1 (100.00%) 2	3 / 13 (23.08%) 6	0 / 1 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 13 (0.00%) 0	0 / 1 (0.00%) 0
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	1 / 1 (100.00%) 2	2 / 13 (15.38%) 3	0 / 1 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	2 / 13 (15.38%) 2	0 / 1 (0.00%) 0
Abdominal pain			

subjects affected / exposed	0 / 1 (0.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	3 / 13 (23.08%)	1 / 1 (100.00%)
occurrences (all)	0	4	1
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 1 (100.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	2	2	0
Arthralgia			

subjects affected / exposed	0 / 1 (0.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 13 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	1 / 1 (100.00%)	4 / 13 (30.77%)	0 / 1 (0.00%)
occurrences (all)	1	4	0
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	3 / 13 (23.08%)	0 / 1 (0.00%)
occurrences (all)	0	5	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Hypomagnesaemia			
subjects affected / exposed	1 / 1 (100.00%)	2 / 13 (15.38%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Hyperuricaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 13 (7.69%)	0 / 1 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Phase 1 Titration Dose QW: 300 mg	Phase 1 Titration Dose QW: 600 mg	Phase 1 Titration Dose QW: 1000 mg
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Total subjects affected by non-serious adverse events subjects affected / exposed	13 / 13 (100.00%)	8 / 8 (100.00%)	5 / 5 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 13 (7.69%)	2 / 8 (25.00%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Hypertension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	4 / 13 (30.77%)	2 / 8 (25.00%)	2 / 5 (40.00%)
occurrences (all)	4	2	2
Pyrexia			
subjects affected / exposed	3 / 13 (23.08%)	2 / 8 (25.00%)	1 / 5 (20.00%)
occurrences (all)	10	4	1
Chills			
subjects affected / exposed	3 / 13 (23.08%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	7	2	0
Non-cardiac chest pain			
subjects affected / exposed	3 / 13 (23.08%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	3	1	0
Oedema peripheral			
subjects affected / exposed	2 / 13 (15.38%)	1 / 8 (12.50%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 13 (7.69%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	8	1	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 13 (7.69%)	4 / 8 (50.00%)	0 / 5 (0.00%)
occurrences (all)	1	4	0
Cough			
subjects affected / exposed	1 / 13 (7.69%)	1 / 8 (12.50%)	1 / 5 (20.00%)
occurrences (all)	1	2	1

Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 8 (0.00%) 0	0 / 5 (0.00%) 0
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	3 / 13 (23.08%) 3	2 / 8 (25.00%) 2	1 / 5 (20.00%) 1
Investigations Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 8 (0.00%) 0	0 / 5 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 8 (12.50%) 1	1 / 5 (20.00%) 1
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 8 (0.00%) 0	3 / 5 (60.00%) 7
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 8 (0.00%) 0	3 / 5 (60.00%) 10
Weight decreased subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 8 (0.00%) 0	0 / 5 (0.00%) 0
Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 3	3 / 8 (37.50%) 3	2 / 5 (40.00%) 3
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	3 / 8 (37.50%) 3	0 / 5 (0.00%) 0
Nervous system disorders			

Headache			
subjects affected / exposed	1 / 13 (7.69%)	2 / 8 (25.00%)	1 / 5 (20.00%)
occurrences (all)	1	2	1
Dizziness			
subjects affected / exposed	3 / 13 (23.08%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	4	0	0
Paraesthesia			
subjects affected / exposed	3 / 13 (23.08%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 13 (30.77%)	4 / 8 (50.00%)	1 / 5 (20.00%)
occurrences (all)	7	7	1
Neutropenia			
subjects affected / exposed	2 / 13 (15.38%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	5	1	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	4 / 13 (30.77%)	2 / 8 (25.00%)	1 / 5 (20.00%)
occurrences (all)	4	2	1
Diarrhoea			
subjects affected / exposed	3 / 13 (23.08%)	3 / 8 (37.50%)	2 / 5 (40.00%)
occurrences (all)	6	3	2
Abdominal pain			
subjects affected / exposed	2 / 13 (15.38%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Vomiting			
subjects affected / exposed	2 / 13 (15.38%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	3	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 13 (7.69%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	3
Dyspepsia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Constipation			

subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 13 (7.69%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	4	0	1
Urticaria			
subjects affected / exposed	1 / 13 (7.69%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Rash			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	2 / 13 (15.38%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	1
Hyperhidrosis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 13 (23.08%)	2 / 8 (25.00%)	1 / 5 (20.00%)
occurrences (all)	4	3	1
Arthralgia			
subjects affected / exposed	2 / 13 (15.38%)	1 / 8 (12.50%)	1 / 5 (20.00%)
occurrences (all)	2	2	1
Muscle spasms			
subjects affected / exposed	2 / 13 (15.38%)	0 / 8 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Pain in extremity			
subjects affected / exposed	0 / 13 (0.00%)	1 / 8 (12.50%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	0 / 8 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pneumonia			

subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	0 / 8 (0.00%) 0	0 / 5 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Metabolism and nutrition disorders			
Hypophosphataemia subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	3 / 8 (37.50%) 5	1 / 5 (20.00%) 1
Decreased appetite subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0
Hyperuricaemia subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	1 / 8 (12.50%) 1	0 / 5 (0.00%) 0

Non-serious adverse events	Phase 1 Titration Dose Q3W: 100 mg	Phase 1 Titration Dose Q3W: 300 mg	Prior BiTE Titration Dose QW: 100 mg
Total subjects affected by non-serious adverse events subjects affected / exposed	2 / 2 (100.00%)	2 / 2 (100.00%)	1 / 1 (100.00%)
Vascular disorders			
Hypotension subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
General disorders and administration site conditions			
Fatigue subjects affected / exposed occurrences (all)	2 / 2 (100.00%) 2	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0

Pyrexia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Chills			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Platelet count decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Neutropenia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Gastrointestinal disorders			
Nausea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 4	0 / 1 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 1	0 / 1 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 1	0 / 1 (0.00%) 0
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Skin and subcutaneous tissue disorders			
Pruritus subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Urticaria subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 4	0 / 1 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0
Dry skin			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 2 Titration Dose QW: 100 mg	Phase 2 Titration Dose QW: 300 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 19 (94.74%)	20 / 21 (95.24%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 19 (5.26%)	0 / 21 (0.00%)	
occurrences (all)	1	0	
Hypertension			
subjects affected / exposed	1 / 19 (5.26%)	1 / 21 (4.76%)	
occurrences (all)	3	2	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 19 (10.53%)	5 / 21 (23.81%)	
occurrences (all)	2	5	
Pyrexia			
subjects affected / exposed	4 / 19 (21.05%)	5 / 21 (23.81%)	
occurrences (all)	8	9	
Chills			
subjects affected / exposed	1 / 19 (5.26%)	2 / 21 (9.52%)	
occurrences (all)	2	2	
Non-cardiac chest pain			
subjects affected / exposed	1 / 19 (5.26%)	1 / 21 (4.76%)	
occurrences (all)	1	1	
Oedema peripheral			
subjects affected / exposed	0 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Immune system disorders			

Cytokine release syndrome subjects affected / exposed occurrences (all)	2 / 19 (10.53%) 4	1 / 21 (4.76%) 3	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	4 / 21 (19.05%) 8	
Cough subjects affected / exposed occurrences (all)	3 / 19 (15.79%) 3	1 / 21 (4.76%) 1	
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 21 (4.76%) 1	
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	3 / 21 (14.29%) 4	
Investigations			
Neutrophil count decreased subjects affected / exposed occurrences (all)	4 / 19 (21.05%) 9	4 / 21 (19.05%) 13	
Platelet count decreased subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 2	1 / 21 (4.76%) 1	
Blood creatinine increased subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	2 / 21 (9.52%) 2	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	1 / 21 (4.76%) 2	
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	0 / 21 (0.00%) 0	
Weight decreased subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	2 / 21 (9.52%) 2	

Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all)	2 / 19 (10.53%) 6	2 / 21 (9.52%) 9	
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 21 (4.76%) 1	
Nervous system disorders Headache subjects affected / exposed occurrences (all) Dizziness subjects affected / exposed occurrences (all) Paraesthesia subjects affected / exposed occurrences (all)	2 / 19 (10.53%) 2 0 / 19 (0.00%) 0 0 / 19 (0.00%) 0	2 / 21 (9.52%) 3 0 / 21 (0.00%) 0 1 / 21 (4.76%) 1	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) Neutropenia subjects affected / exposed occurrences (all)	6 / 19 (31.58%) 17 2 / 19 (10.53%) 4	3 / 21 (14.29%) 6 3 / 21 (14.29%) 3	
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Abdominal pain subjects affected / exposed occurrences (all) Vomiting	3 / 19 (15.79%) 3 2 / 19 (10.53%) 3 2 / 19 (10.53%) 2	4 / 21 (19.05%) 5 2 / 21 (9.52%) 3 1 / 21 (4.76%) 1	

subjects affected / exposed	0 / 19 (0.00%)	3 / 21 (14.29%)	
occurrences (all)	0	3	
Gastroesophageal reflux disease			
subjects affected / exposed	3 / 19 (15.79%)	0 / 21 (0.00%)	
occurrences (all)	3	0	
Dyspepsia			
subjects affected / exposed	1 / 19 (5.26%)	1 / 21 (4.76%)	
occurrences (all)	1	1	
Constipation			
subjects affected / exposed	1 / 19 (5.26%)	1 / 21 (4.76%)	
occurrences (all)	1	1	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	2 / 19 (10.53%)	2 / 21 (9.52%)	
occurrences (all)	2	3	
Urticaria			
subjects affected / exposed	0 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Rash			
subjects affected / exposed	2 / 19 (10.53%)	0 / 21 (0.00%)	
occurrences (all)	2	0	
Dry skin			
subjects affected / exposed	0 / 19 (0.00%)	2 / 21 (9.52%)	
occurrences (all)	0	2	
Hyperhidrosis			
subjects affected / exposed	1 / 19 (5.26%)	1 / 21 (4.76%)	
occurrences (all)	1	1	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 21 (4.76%)	
occurrences (all)	0	1	
Arthralgia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			

subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 21 (4.76%) 1	
Pain in extremity subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 21 (4.76%) 1	
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	4 / 21 (19.05%) 4	
Pneumonia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	1 / 21 (4.76%) 1	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	3 / 19 (15.79%) 3	0 / 21 (0.00%) 0	
Metabolism and nutrition disorders Hypophosphataemia subjects affected / exposed occurrences (all)	4 / 19 (21.05%) 7	0 / 21 (0.00%) 0	
Decreased appetite subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0	1 / 21 (4.76%) 1	
Hypokalaemia subjects affected / exposed occurrences (all)	3 / 19 (15.79%) 3	0 / 21 (0.00%) 0	
Hypomagnesaemia subjects affected / exposed occurrences (all)	3 / 19 (15.79%) 3	1 / 21 (4.76%) 1	
Hyperuricaemia subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 21 (4.76%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 June 2019	The main purpose of this amendment is to update the line of treatment for Phase 1b from 2L+ to 3L+ and modify the starting dose of imvotamab when given in combination with loncastuximab tesirine. Other changes include administrative edits, table of contents, and minor copy edits or clarifications and can be seen in the full redline version of the protocol amendment.
07 May 2020	<ul style="list-style-type: none">- Moved pharmacodynamics (PD) evaluation to extrapolatory objectives (Synopsis Secondary Objectives, Synopsis Secondary Endpoints, Synopsis Exploratory Endpoints, Synopsis Key Exploratory Objectives, Section 2).- Provided clarification (Synopsis, Study Design, Section 3.1 Overall study design).- Updated numbers of study sites (Synopsis, Sites, Section 3.8).- Updated on DLT assessment (Section 3.2.2.1, 3.2.3.1).- Authorized all other regulatory authorities to resume study after suspension (Section 3.12).- Updated inclusion and exclusion criteria (Section 5.1, 5.2).- Added new section for adverse event evaluation and management (Section 6.4.1).- Provided guidance for dose reduction which are not included under dose reduction guidance table (Section 6.8).- Provided clarifications (Section 8.4.1.1, 8.5.1, 8.6.2, 8.8.2).- Added new laboratory parameters for clinical analysis (Section 8.7.1).- Updated section to include information on extrapolatory biomarkers (Section 8.8).- Updates on pharmacodynamic assessments (Section 8.8.3, 8.8.4).- Update on timing for serum exploratory complement assessments (Section 8.8.5).- Update section to include additional biopsy requirement (Section 8.9).- Added new section on archival tumor tissue (Section 8.9.1.1).- Updated section to include information on optional pre-treatments biopsy requirements).- Update on on-treatment biopsy evaluation timing (Section 8.9.2).- Added new section for patients at participating sites regarding whole genome sequencing (Section 8.10).- Addition in reason for removing patient from study (Section 9.2).- Updated section as estimated loss-to-follow-up rate (Section 11.).- Added new section for data not collected due to COVID-19 or other reasons (Section 12.3).- Updated as per change in PK sample collection (Appendix A, Schedule of Assessments).

10 July 2020	<p>Substantial changes relation to the revision from Protocol Amendment 2 to Protocol Amendment 3 are presented below:</p> <ul style="list-style-type: none"> - Provided clarification regarding continue extended dosing (Section 3.1 Overall study design). - Provided clarification on intermediate dose and intermediate dose cohorts (Section 3.2.2.4 Intermediate Dose Levels). - Update on stage II dose escalation (Section 3.2.2.5 Dose escalation Decisions). - Added new section for step dose escalation approach (Section 3.3 Step Dose Escalation Approach). - Provided clarification regarding continuation of extended dosing (Section 3.5.3 Dosing Duration). - Provided duration of set-up dose infusion (Section 6.1.2 Dosage, Administration, and Compliance). - Provided information on hospitalization for patients on alternative dosing regimen (Section 6.3 Hospitalization). - Deleted "dose reduction" guidance from this section and added new section to include Dose Reduction information (Section 6.8 Dose and Schedule Modifications, Section 6.9). - Added new hematology test to laboratory analysis (Section 8.7.1 Clinical Laboratory Analysis). - Updated adverse event reporting (Section 10.2, 10.6.2, 10.6.4, 10.7, 11.5.1). - Added new reference for added information (Section 14, References). - The schedule of assessments has been adjusted (Appendix A, Schedule of Assessments).
07 September 2021	<ul style="list-style-type: none"> - An additional secondary objective was added to the study to evaluate efficacy of IGM-2323 in subjects who have previously received bispecific T-cell engager treatment, which is being added as an additional cohort. - The study design text was updated to include more information, and in particular to add text regarding Part 1, Stage II and III dose titration - The number of subjects enrolled was adjusted to account for additional cohorts - A new section (1.2.3.2.4) was added to provide new information on Epcoritamab (Section 1.2.3, Bispecific Antibodies). - Clarification of dexamethasone dosing and the duration of IGM-2323 infusion in subjects with certain previous medical histories was added (Section 6.1.2, Dosage, Administration, and Compliance). - Hospitalization details were updated to clarify removal of hospitalization requirement after treatment with IGM-2323 (Section 6.3, Hospitalization). - A section was added to define recommendations for enrollment and COVID-19 vaccines (Section 6.10.2, COVID-19 Vaccination). - The screening procedure was updated to include a statement that a subject is considered enrolled once they receive their first dose of study drug (Section 7.1, Screening). - This section was updated to clarify the DNA sample collection process (Section 8.10, Whole Genome Sequencing or Whole Exome Sequencing). - The Adverse Events of Special Interest section was updated to include detail regarding infusion[1] related reactions and cytokine release syndrome (Section 10.6, Adverse Events of Special Interests). - The efficacy endpoints were updated with additional language regarding the duration of CR calculation (Section 11.0, Efficacy Analysis). - The schedule of assessments has been adjusted (Appendix A, Schedule of Assessments). - Updated figure to clarify that a positive HBV surface antigen test is only exclusionary if HBV DNA PCR is also positive (Appendix B, Criteria for HBV DNA PCR Qualitative Testing).

08 October 2021	<ul style="list-style-type: none"> - The primary objectives were changed to include a new Phase 2 primary objective to reflect the updated study design (Synopsis, Primary Objectives). - The study design text was updated to include the new Phase 1 and Phase 2 language, and to adjust the planned number of subjects enrolled to account for updated study design (Synopsis, Study Design). - The number of subjects enrolled was adjusted (Synopsis, Subject Number). - The dose expansion section was adjusted to include additional arms to account for the updated study design (Synopsis, Dose Expansion). - An additional Phase 2 primary endpoint was added to the study to account for the updated study design (Synopsis, Primary Endpoints). - SRC language was updated to include an additional sentence regarding the Phase 2 data (Synopsis, Scientific Review Committee). - The primary objectives and endpoints were modified to include a new Phase 2 endpoint to account for the updated study design (Section 2, Objectives and Endpoints, Primary Endpoints). - The study design text in Section 3.7 was updated to include more information to clarify the addition of the Phase 2 Dose Expansion (Section 3.7, Phase 2 Expansion). - The RP2D section was updated to define the RP2D selection parameters (Section 3.8, Recommended Phase 2 Dose). - SRC language was updated to include an additional sentence regarding the Phase 2 data (Section 3.11 (Study Oversight – Scientific Review Committee)). - Inclusion criteria number 14 was added to define that each enrolled patient must have a mandatory biopsy performed (Section 5.1, Inclusion Criteria). - Treatment administration information was updated to address treatment of Cohorts G1 and G2 at a reduced dosing frequency after Cycle 1 (Section 6.2, Study Treatment Administration). - Updates made according to the new Phase 1/2 study design (Section 11.1, 11.4, 11.10.1, 11.10.2). - Schedule of Assessments has been adjusted (Appendix 1, Schedule of Assessments).
17 November 2021	There is no summary of changes available from PA 5.0 to 5.1.
08 February 2022	<p>The main changes from Amendment 5.1 to Amendment 5.3 are listed below. Other changes include administrative updates to the Cover Page and Table of Contents, and can be seen in the full redline version of the protocol amendment.</p> <ul style="list-style-type: none"> - Added new section to include safety stopping rules for Phase 1, Stage IV, Section 3.5.1 (Safety Stopping Rules). - Updated patient numbers in paragraph 3 to be consistent with study design, Section 3.7 (Phase 2 Expansion). - Added guidance for interrupting, stopping, and re-starting IMG-2323 in the case of cytokine release syndrome, Section 6.6 (Cytokine Release Syndrome). - Added section to define end of study, Section 7.9 (End of Study). - Added language indicating that safety data will be reviewed by the SRC, Section 11.4 (Interim Analysis). - Added section to include safety stopping rules for Phase 2, Section 11.4.1 (Safety Stopping Rules for Phase 2).
08 February 2022	<p>The main changes from Amendment 5.0 to Amendment 5.2 are listed below. Other changes include administrative updates to the Cover Page and Table of Contents and can be seen in the full redline version of the protocol amendment.</p> <ul style="list-style-type: none"> - Removed reference to dose levels higher than 1000mg, Section 3.2.2.5 (Dose Escalation Decisions). - Removed reference to dose levels higher than 1000mg, Section 3.3 (Titration Dose Escalation Approach). - Added exclusion criterion 37, which clarifies eligibility based on vaccination status, Section 5.2 (Exclusion Criteria).

30 June 2022	<p>The main changes from Amendment 5.3 to Amendment 5.4 are listed below. Other changes include administrative updates to the Cover Page and Investigator's Agreement Page and can be seen in the full redline version of the protocol amendment.</p> <ul style="list-style-type: none"> - Additional language to Section 6.10.1 (Concomitant Medications): . Vaccination information (including COVID-19) must be collected 30 days before treatment, during treatment, and 90 days after the last dose. - Added footnote to Section 8.7.1, Table 5, to indicate pregnancy testing is for women of child-bearing potential. Also, screening pregnancy must be via serum test, but all others may be either serum or urine, based on site preference. - Pre-infusion pregnancy tests were updated in Schedule of Assessments (Appendix A: Tables 13, 14, and 15).
21 November 2022	<p>The main changes from Amendment 5 to Amendment 6 are listed below. Other changes include administrative edits, figures, table of contents, and minor copy edits or clarifications and can be seen in the full redline version of the protocol amendment.</p> <ul style="list-style-type: none"> - The drug name "IGM-2323" was updated to "imvotamab" throughout the protocol. - A new Phase 1b combination cohort was added to the protocol. - "Phase 1" was changed to "Phase 1a" to distinguish parts of the study due to the addition of Phase 1b
16 February 2023	<p>The main purpose of this amendment is to update the line of treatment for Phase 1b from 2L+ to 3L+ and modify the starting dose of imvotamab when given in combination with loncastuximab tesirine. Other changes include administrative edits, table of contents, and minor copy edits or clarifications and can be seen in the full redline version of the protocol amendment.</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to an increasingly competitive landscape in Non-Hodgkin lymphoma (NHL), the study was terminated by the Sponsor. This was based on the availability of internal resources and the rapidly evolving competitive landscape of relapsed/refractory NHL.

Notes: