



Clinical trial results:

A Phase I/II Open-Label, Multi-center Study of the Safety and Efficacy of IMCnyeso, an HLA-A* 0201-Restricted, NY-ESO-1 and LAGE-1A-specific soluble T Cell Receptor and Anti-CD3 Bi-specific Molecule, as a Single Agent in HLA-A* 0201 Positive Patients With Advanced NY-ESO-1 and/or LAGE-1A Positive Cancer

Summary

EudraCT number	2017-002243-15
Trial protocol	GB
Global end of trial date	10 June 2021

Results information

Result version number	v1 (current)
This version publication date	10 March 2022
First version publication date	10 March 2022

Trial information

Trial identification

Sponsor protocol code	IMCnyeso-101
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03515551
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Immunocore, Ltd.
Sponsor organisation address	92 Park Drive, Milton Park, Abingdon, United Kingdom, Oxon, OX14 4RY
Public contact	Study Director, Immunocore Ltd., 001 844IMMUNO1, clinicaltrials@immunocore.com
Scientific contact	Study Director, Immunocore Ltd., 001 844IMMUNO1, clinicaltrials@immunocore.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	10 June 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	10 June 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

This was planned to be a multi-center, open label, dose finding Phase 1/2 study of single agent IMCnyeso administered in subjects with NY-ESO-1 and/or LAGE-A1 positive tumors. The primary objective of the dose escalation phase (Phase 1) was to determine the maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D) of IMCnyeso in subjects with advanced solid tumors. Preliminary efficacy was to be evaluated in Phase 2. The study was terminated early (prior to initiation of Phase 2) by the Sponsor as a strategic decision (not based on any safety signal).

Protection of trial subjects:

This clinical study was designed and was implemented and reported in accordance with the ICH Harmonised Tripartite Guidelines for Good Clinical Practice E6 (R1), with applicable local regulations (including European Directive 2001/20/EC and United States Code of Federal Regulations, CFR Title 21), and with the ethical principles laid down in the Declaration of Helsinki (2013).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 June 2018
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	United Kingdom: 10
Country: Number of subjects enrolled	Canada: 3
Country: Number of subjects enrolled	United States: 15
Worldwide total number of subjects	28
EEA total number of subjects	0

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)	23
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The sponsor elected to not proceed with the efficacy determining expansion phase (Phase 2) of IMCnyeso-101 for strategic reasons. Phase 2 data were not collected. As of 25 Mar 2021, further enrollment into the Phase 1 dose escalation phase was discontinued and last patient visit was 10 June 2021.

Pre-assignment

Screening details:

There were a total of 28 unique subjects; one subject from the 10 mcg cohort was sequentially enrolled in the 30-100 mcg cohort. Participants who were receiving study drug were allowed to continue treatment until unacceptable toxicity, disease progression, or other reason to discontinue occurred.

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Phase 1: IMCnyeso 3 mcg

Arm description:

Single-agent IMCnyeso at 3 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen

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

Dosage and administration details:

Subjects enrolled in this study received treatment with single-agent IMCnyeso dosed weekly on Days 1, 8, 15, and 22 of each 4-week cycle. There were 4 fixed-dose, dose escalation cohorts: 3, 10, 30, and 100 mcg. There were 3 inpatient dose escalation cohorts: 30-100 mcg, 30-100-180 mcg, and 30-100-300 mcg.

Arm title	Phase 1: IMCnyeso 10 mcg
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Arm description:

Single-agent IMCnyeso at 10 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen

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

Dosage and administration details:

Subjects enrolled in this study received treatment with single-agent IMCnyeso dosed weekly on Days 1, 8, 15, and 22 of each 4-week cycle. There were 4 fixed-dose, dose escalation cohorts: 3, 10, 30, and 100 mcg. There were 3 inpatient dose escalation cohorts: 30-100 mcg, 30-100-180 mcg, and 30-100-300 mcg.

Arm title	Phase 1: IMCnyeso 30 mcg
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Arm description:

Single-agent IMCnyeso at 30 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen

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

Dosage and administration details:

Subjects enrolled in this study received treatment with single-agent IMCnyeso dosed weekly on Days 1, 8, 15, and 22 of each 4-week cycle. There were 4 fixed-dose, dose escalation cohorts: 3, 10, 30, and 100 mcg. There were 3 inpatient dose escalation cohorts: 30-100 mcg, 30-100-180 mcg, and 30-100-300 mcg.

Arm title	Phase 1: IMCnyeso 100 mcg
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Arm description:

Single-agent IMCnyeso at 100 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen

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

Dosage and administration details:

Subjects enrolled in this study received treatment with single-agent IMCnyeso dosed weekly on Days 1, 8, 15, and 22 of each 4-week cycle. There were 4 fixed-dose, dose escalation cohorts: 3, 10, 30, and 100 mcg. There were 3 inpatient dose escalation cohorts: 30-100 mcg, 30-100-180 mcg, and 30-100-300 mcg.

Arm title	Phase 1: IMCnyeso 30-100 mcg
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Arm description:

IMCnyeso administered intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using an inpatient escalation regimen (30 mcg on Cycle 1 Day 1, then 100 mcg starting on Cycle 1 Day 8)

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

Dosage and administration details:

Subjects enrolled in this study received treatment with single-agent IMCnyeso dosed weekly on Days 1, 8, 15, and 22 of each 4-week cycle. There were 4 fixed-dose, dose escalation cohorts: 3, 10, 30, and 100 mcg. There were 3 inpatient dose escalation cohorts: 30-100 mcg, 30-100-180 mcg, and 30-100-300 mcg.

Arm title	Phase 1: IMCnyeso 30-100-180 mcg
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Arm description:

IMCnyeso administered intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using an inpatient escalation regimen (30 mcg on Cycle 1 Day 1, then 100 mcg on Cycle 1 Day 8, then 180 mcg starting on Cycle 1 Day 15)

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

Dosage and administration details:

Subjects enrolled in this study received treatment with single-agent IMCnyeso dosed weekly on Days 1, 8, 15, and 22 of each 4-week cycle. There were 4 fixed-dose, dose escalation cohorts: 3, 10, 30, and 100 mcg. There were 3 inpatient dose escalation cohorts: 30-100 mcg, 30-100-180 mcg, and 30-100-300 mcg.

Arm title	Phase 1: IMCnyeso 30-100-300 mcg
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Arm description:

IMCnyeso administered intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using an inpatient escalation regimen (30 mcg on Cycle 1 Day 1, then 100 mcg on Cycle 1 Day 8, then 300 mcg starting on Cycle 1 Day 15)

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

Dosage and administration details:

Subjects enrolled in this study received treatment with single-agent IMCnyeso dosed weekly on Days 1, 8, 15, and 22 of each 4-week cycle. There were 4 fixed-dose, dose escalation cohorts: 3, 10, 30, and 100 mcg. There were 3 inpatient dose escalation cohorts: 30-100 mcg, 30-100-180 mcg, and 30-100-300 mcg.

Number of subjects in period 1	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg
Started	4	3	5
Completed	0	0	0
Not completed	4	3	5
Consent withdrawn by subject	-	1	-
Death	4	1	2
Study ended by sponsor	-	-	2
Transferred to other arm/group	-	1	-
Lost to follow-up	-	-	1
Joined	0	0	0
Transferred in from other group/arm	-	-	-

Number of subjects in period 1	Phase 1: IMCnyeso 100 mcg	Phase 1: IMCnyeso 30-100 mcg	Phase 1: IMCnyeso 30-100-180 mcg
Started	3	4	4
Completed	0	0	0
Not completed	3	5	4
Consent withdrawn by subject	-	-	-
Death	2	2	4

Study ended by sponsor	1	3	-
Transferred to other arm/group	-	-	-
Lost to follow-up	-	-	-
Joined	0	1	0
Transferred in from other group/arm	-	1	-

Number of subjects in period 1	Phase 1: IMCnyeso 30-100-300 mcg
Started	5
Completed	0
Not completed	5
Consent withdrawn by subject	1
Death	1
Study ended by sponsor	3
Transferred to other arm/group	-
Lost to follow-up	-
Joined	0
Transferred in from other group/arm	-

Baseline characteristics

Reporting groups^[1]

Reporting group title	Overall study
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Reporting group description: -

Notes:

[1] - The number of subjects reported to be in the baseline period is not equal to the worldwide number of subjects enrolled in the trial. It is expected that these numbers will be the same.

Justification: One subject from the 10 mcg cohort was sequentially enrolled in the 30-100 mcg cohort; there were a total of 28 unique subjects

Reporting group values	Overall study	Total	
Number of subjects	28	28	
Age categorical			
Units: Subjects			
Adults (18-64 years)	23	23	
From 65-84 years	5	5	
Gender categorical			
Units: Subjects			
Female	12	12	
Male	16	16	
Original cancer diagnosis			
Units: Subjects			
Melanoma	7	7	
Synovial sarcoma	20	20	
Urothelial carcinoma	1	1	
Non-small cell lung cancer	0	0	

End points

End points reporting groups

Reporting group title	Phase 1: IMCnyeso 3 mcg
Reporting group description: Single-agent IMCnyeso at 3 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen	
Reporting group title	Phase 1: IMCnyeso 10 mcg
Reporting group description: Single-agent IMCnyeso at 10 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen	
Reporting group title	Phase 1: IMCnyeso 30 mcg
Reporting group description: Single-agent IMCnyeso at 30 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen	
Reporting group title	Phase 1: IMCnyeso 100 mcg
Reporting group description: Single-agent IMCnyeso at 100 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen	
Reporting group title	Phase 1: IMCnyeso 30-100 mcg
Reporting group description: IMCnyeso administered intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using an inpatient escalation regimen (30 mcg on Cycle 1 Day 1, then 100 mcg starting on Cycle 1 Day 8)	
Reporting group title	Phase 1: IMCnyeso 30-100-180 mcg
Reporting group description: IMCnyeso administered intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using an inpatient escalation regimen (30 mcg on Cycle 1 Day 1, then 100 mcg on Cycle 1 Day 8, then 180 mcg starting on Cycle 1 Day 15)	
Reporting group title	Phase 1: IMCnyeso 30-100-300 mcg
Reporting group description: IMCnyeso administered intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using an inpatient escalation regimen (30 mcg on Cycle 1 Day 1, then 100 mcg on Cycle 1 Day 8, then 300 mcg starting on Cycle 1 Day 15)	

Primary: Number of subjects with dose-limiting toxicities

End point title	Number of subjects with dose-limiting toxicities ^[1]
End point description: Dose-limiting toxicities were defined as an adverse event or abnormal laboratory value assessed as having a suspected relationship to study drug that occurs within the evaluation period, from the first dose up until Day 28 after the first dose	
End point type	Primary
End point timeframe: Up to 35 months	
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: There are no statistical analyses for descriptive data.	

End point values	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg	Phase 1: IMCnyeso 100 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3 ^[2]	5	3
Units: Subjects	0	0	0	0

Notes:

[2] - 1 subject from the 10 mcg cohort was sequentially enrolled in the 30-100 mcg cohort

End point values	Phase 1: IMCnyeso 30- 100 mcg	Phase 1: IMCnyeso 30- 100-180 mcg	Phase 1: IMCnyeso 30- 100-300 mcg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	5	
Units: Subjects	0	0	2	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with adverse events

End point title	Number of subjects with adverse events ^[3]
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End point description:

Treatment-emergent adverse events are defined as any adverse event (AE) that started after the first dose of study drug up to 30 days after last dose of study drug, including abnormal laboratory values, vital signs, or electrocardiogram results. AE severity is graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03

End point type	Primary
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End point timeframe:

Up to 35 months

Notes:

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

Justification: There are no statistical analyses for descriptive data.

End point values	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg	Phase 1: IMCnyeso 100 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	3
Units: Subjects				
Any treatment-emergent adverse event (TEAE)	4	3	5	3
Any TEAE Grade ≥ 3	3	1	1	3
Any TEAE leading to death	0	0	0	0

End point values	Phase 1: IMCnyeso 30- 100 mcg	Phase 1: IMCnyeso 30- 100-180 mcg	Phase 1: IMCnyeso 30- 100-300 mcg	
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Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	5	
Units: Subjects				
Any treatment-emergent adverse event (TEAE)	5	4	5	
Any TEAE Grade ≥ 3	3	4	4	
Any TEAE leading to death	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with no dose interruptions or reductions

End point title	Number of subjects with no dose interruptions or reductions ^[4]
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End point description:

Tolerability of study treatment was assessed by summarizing the number of subjects with no treatment dose interruptions and dose reductions

End point type	Primary
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End point timeframe:

Up to 35 months

Notes:

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

Justification: There are no statistical analyses for descriptive data.

End point values	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg	Phase 1: IMCnyeso 100 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	3
Units: Subjects				
No dose interruption at any time	2	0	0	2
No dose reduction at any time	4	3	5	3

End point values	Phase 1: IMCnyeso 30- 100 mcg	Phase 1: IMCnyeso 30- 100-180 mcg	Phase 1: IMCnyeso 30- 100-300 mcg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	5	
Units: Subjects				
No dose interruption at any time	2	0	0	
No dose reduction at any time	4	4	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with best overall response

End point title	Number of subjects with best overall response
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End point description:

Number of subjects with best overall response, including complete response, partial response, stable disease, and progressive disease, based on local Investigator assessment as defined in RECIST v.1.1. Data were pooled for this analysis due to small sample size per cohort with evaluable data. CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease

End point type	Secondary
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End point timeframe:

Up to 35 months

End point values	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg	Phase 1: IMCnyeso 100 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	3
Units: Subjects				
Complete Response	0	0	0	0
Partial Response	0	0	0	0
Stable Disease	0	0	2	0
Progressive Disease	3	3	3	3

End point values	Phase 1: IMCnyeso 30- 100 mcg	Phase 1: IMCnyeso 30- 100-180 mcg	Phase 1: IMCnyeso 30- 100-300 mcg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	5	
Units: Subjects				
Complete Response	0	0	0	
Partial Response	0	0	0	
Stable Disease	2	0	1	
Progressive Disease	3	3	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival

End point title	Progression-free survival
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End point description:

Progression-free survival is defined as the time from first dose until the date of objective progression, or death from any cause, whichever occurs first.

End point type	Secondary
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End point timeframe:

Up to 35 months

End point values	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg	Phase 1: IMCnyeso 100 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	3
Units: Months				
median (confidence interval 95%)	1.8 (0.7 to 2.4)	1.6 (1.2 to 2.1)	2.1 (1.9 to 7.8)	1.9 (1.3 to 1.9)

End point values	Phase 1: IMCnyeso 30- 100 mcg	Phase 1: IMCnyeso 30- 100-180 mcg	Phase 1: IMCnyeso 30- 100-300 mcg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	5 ^[5]	
Units: Months				
median (confidence interval 95%)	2.1 (0.8 to 3.8)	1.8 (0.9 to 2.1)	1.4 (1.0 to 9999)	

Notes:

[5] - 9999 = not estimable due to insufficient number of events

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival

End point title	Overall survival
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End point description:

Overall survival is defined as the time (in months) from the date of randomization to the date of death due to any cause.

End point type	Secondary
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End point timeframe:

Up to 35 months

End point values	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg	Phase 1: IMCnyeso 100 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3 ^[6]	5 ^[7]	3 ^[8]
Units: Months				
median (confidence interval 95%)	3.3 (2.1 to 5.9)	9999 (2.2 to 9999)	9999 (3.7 to 9999)	9.7 (2.3 to 9999)

Notes:

[6] - 9999 = not estimable due to insufficient number of events

[7] - 9999 = not estimable due to insufficient number of events

[8] - 9999 = not estimable due to insufficient number of events

End point values	Phase 1: IMCnyeso 30- 100 mcg	Phase 1: IMCnyeso 30- 100-180 mcg	Phase 1: IMCnyeso 30- 100-300 mcg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5 ^[9]	4	5 ^[10]	
Units: Months				
median (confidence interval 95%)	9999 (5.2 to 9999)	7.5 (0.9 to 11.7)	9999 (3.7 to 9999)	

Notes:

[9] - 9999 = not estimable due to insufficient number of events

[10] - 9999 = not estimable due to insufficient number of events

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-time Curve From Time Zero to the Time of Last Measurable Concentration (AUC0-last)

End point title	Area Under the Plasma Concentration-time Curve From Time Zero to the Time of Last Measurable Concentration (AUC0-last)
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End point description:

End point type	Secondary
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End point timeframe:

Predose and 1, 2, 4, 6, 8, and 12 hours post dose on Cycle 1 Day 1 and Cycle 1 Day 15

End point values	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg	Phase 1: IMCnyeso 100 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: hr*pg/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	12500 (± 6910)	17700 (± 14400)	132000 (± 44600)	295000 (± 72400)
Cycle 1 Day 15	7270 (± 4530)	29500 (± 35900)	149000 (± 70500)	301000 (± 223000)

End point values	Phase 1: IMCnyeso 30- 100 mcg	Phase 1: IMCnyeso 30- 100-180 mcg	Phase 1: IMCnyeso 30- 100-300 mcg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	4 ^[11]	
Units: hr*pg/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	182000 (± 180000)	78800 (± 32500)	127000 (± 53700)	
Cycle 1 Day 15	497000 (± 260000)	611000 (± 330000)	142000 (± 9999)	

Notes:

[11] - 9999 = not estimable due to insufficient number of subjects

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Drug Concentration After Single Dose Administration (C_{max})

End point title	Maximum Observed Plasma Drug Concentration After Single Dose Administration (C _{max})
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End point description:

End point type	Secondary
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End point timeframe:

Predose and 1, 2, 4, 6, 8, and 12 hours post dose on Cycle 1 Day 1 and Cycle 1 Day 15

End point values	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg	Phase 1: IMCnyeso 100 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: pg/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	1130 (± 674)	1530 (± 1160)	6850 (± 1110)	16100 (± 961)
Cycle 1 Day 15	1090 (± 634)	1800 (± 1290)	6220 (± 1450)	17900 (± 1910)

End point values	Phase 1: IMCnyeso 30- 100 mcg	Phase 1: IMCnyeso 30- 100-180 mcg	Phase 1: IMCnyeso 30- 100-300 mcg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	4 ^[12]	
Units: pg/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	6810 (± 5290)	3890 (± 932)	6710 (± 1380)	
Cycle 1 Day 15	19900 (± 3570)	26900 (± 3930)	65800 (± 000)	

Notes:

[12] - 9999 = not estimable due to insufficient number of subjects

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reach Maximum Plasma Concentration (Tmax)

End point title	Time to Reach Maximum Plasma Concentration (Tmax)
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End point description:

End point type	Secondary
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End point timeframe:

Predose and 1, 2, 4, 6, 8, and 12 hours post dose on Cycle 1 Day 1 and Cycle 1 Day 15

End point values	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg	Phase 1: IMCnyeso 100 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: Hours				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	1.00 (± 0.00)	1.00 (± 0.00)	1.00 (± 0.00)	1.67 (± 1.15)
Cycle 1 Day 15	1.00 (± 0.00)	1.00 (± 0.00)	1.00 (± 0.00)	1.00 (± 0.00)

End point values	Phase 1: IMCnyeso 30- 100 mcg	Phase 1: IMCnyeso 30- 100-180 mcg	Phase 1: IMCnyeso 30- 100-300 mcg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	4 ^[13]	
Units: Hours				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	1.00 (± 0.00)	1.25 (± 0.50)	1.00 (± 0.00)	
Cycle 1 Day 15	1.00 (± 0.00)	1.00 (± 0.00)	2.00 (± 0.00)	

Notes:

[13] - 000 = not estimable due to insufficient number of subjects

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Anti-IMCnyeso Antibody Formation

End point title	Number of Subjects With Anti-IMCnyeso Antibody Formation
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End point description:

Number of subjects with positive treatment-boosted or treatment-induced anti-IMCnyeso antibody titers

End point type	Secondary
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End point timeframe:

Up to 35 months

End point values	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg	Phase 1: IMCnyeso 100 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	3
Units: Subjects	0	0	0	1

End point values	Phase 1: IMCnyeso 30- 100 mcg	Phase 1: IMCnyeso 30- 100-180 mcg	Phase 1: IMCnyeso 30- 100-300 mcg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	5	
Units: Subjects	0	0	1	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 35 months

Adverse event reporting additional description:

The Safety Analysis Set includes all subjects who received at least 1 full or partial dose of study drug in Phase 1; the Phase 2 arm was not started and no data were collected. One subject was sequentially enrolled in two cohorts (10 mcg and 30-100 mcg). Events in either cohort are counted once in the total cohort.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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Reporting groups

Reporting group title	Phase 1: IMCnyeso 3 mcg
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Reporting group description:

Single-agent IMCnyeso at 3 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen

Reporting group title	Phase 1: IMCnyeso 10 mcg
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Reporting group description:

Single-agent IMCnyeso at 10 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen

Reporting group title	Phase 1: IMCnyeso 30 mcg
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Reporting group description:

Single-agent IMCnyeso at 30 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen

Reporting group title	Phase 1: IMCnyeso 100 mcg
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Reporting group description:

Single-agent IMCnyeso at 100 mcg dosed weekly intravenously on Days 1, 8, 15, and 22 of each 4-week cycle using a fixed-dose regimen

Reporting group title	Phase 1: IMCnyeso 30-100 mcg
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Reporting group description:

Single-agent IMCnyeso at 30 mcg intravenously on Cycle 1 Day 1, then 100 mcg weekly intravenously starting on Cycle 1 Day 8 of each 4-week cycle

Reporting group title	Phase 1: IMCnyeso 30-100-180 mcg
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Reporting group description:

Single-agent IMCnyeso at 30 mcg intravenously on Cycle 1 Day 1, 100 mcg on Cycle 1 Day 8, then 180 mcg weekly intravenously starting on Cycle 1 Day 15 of each 4-week cycle

Reporting group title	Phase 1: IMCnyeso 30-100-300 mcg
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Reporting group description:

Single-agent IMCnyeso at 30 mcg intravenously on Cycle 1 Day 1, 100 mcg on Cycle 1 Day 8, then 300 mcg weekly intravenously starting on Cycle 1 Day 15 of each 4-week cycle

Serious adverse events	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
number of deaths (all causes)	4	1	2
number of deaths resulting from	0	0	0

adverse events			
Investigations			
Aspartate aminotransferase increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
Overdose			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal obstruction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Cardiac disorders			
Sinus tachycardia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release storm			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	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
Intra-abdominal haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Dyspnoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Hypoxia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (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
Pleural effusion			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (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
Musculoskeletal and connective tissue disorders			
Muscular haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
Lung infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 1: IMCnyeso 100 mcg	Phase 1: IMCnyeso 30-100 mcg	Phase 1: IMCnyeso 30-100-180 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	2 / 5 (40.00%)	3 / 4 (75.00%)
number of deaths (all causes)	2	2	4
number of deaths resulting from adverse events	0	0	0
Investigations			
Aspartate aminotransferase increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Overdose			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal obstruction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Sinus tachycardia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders Febrile neutropenia alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 3 (0.00%) 0 / 0 0 / 0	 0 / 5 (0.00%) 0 / 0 0 / 0	 0 / 4 (0.00%) 0 / 0 0 / 0
General disorders and administration site conditions Fatigue alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 3 (0.00%) 0 / 0 0 / 0	 0 / 5 (0.00%) 0 / 0 0 / 0	 0 / 4 (0.00%) 0 / 0 0 / 0
Immune system disorders Cytokine release storm alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 1 / 3 (33.33%) 1 / 1 0 / 0	 0 / 5 (0.00%) 0 / 0 0 / 0	 1 / 4 (25.00%) 1 / 1 0 / 0
Gastrointestinal disorders Abdominal pain alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 3 (0.00%) 0 / 0 0 / 0	 0 / 5 (0.00%) 0 / 0 0 / 0	 0 / 4 (0.00%) 0 / 0 0 / 0
Intra-abdominal haemorrhage alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 3 (0.00%) 0 / 0 0 / 0	 0 / 5 (0.00%) 0 / 0 0 / 0	 0 / 4 (0.00%) 0 / 0 0 / 0
Hepatobiliary disorders Hepatic failure alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscular haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Lung infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 1: IMCnyeso 30-100-300 mcg		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Investigations			
Aspartate aminotransferase increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Overdose			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tracheal obstruction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypotension			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Sinus tachycardia			

alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Febrile neutropenia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Cytokine release storm			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intra-abdominal haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			

Hepatic failure alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 5 (20.00%) 0 / 2 0 / 0		
Respiratory, thoracic and mediastinal disorders Dyspnoea alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 5 (0.00%) 0 / 0 0 / 0		
Epistaxis alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 5 (0.00%) 0 / 0 0 / 0		
Hypoxia alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 5 (0.00%) 0 / 0 0 / 0		
Pleural effusion alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 5 (0.00%) 0 / 0 0 / 0		
Musculoskeletal and connective tissue disorders Muscular haemorrhage alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 5 (0.00%) 0 / 0 0 / 0		
Infections and infestations			

Lung infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Phase 1: IMCnyeso 3 mcg	Phase 1: IMCnyeso 10 mcg	Phase 1: IMCnyeso 30 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	3 / 3 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypotension			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypertension			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hot flush			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Superior vena cava syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Axillary pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Chest discomfort			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Chills			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	3 / 5 (60.00%)
occurrences (all)	0	1	5
Face oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Facial pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 4 (50.00%)	2 / 3 (66.67%)	2 / 5 (40.00%)
occurrences (all)	4	3	2
Feeling cold			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Influenza like illness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Local swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malaise			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	1
Oedema peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 4 (50.00%)	2 / 3 (66.67%)	4 / 5 (80.00%)
occurrences (all)	5	3	11
Immune system disorders			
Cytokine release syndrome			
alternative assessment type: Non-systematic			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Reproductive system and breast disorders			
Amenorrhoea alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pelvic pain alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Oropharyngeal pain alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Dyspnoea alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	1 / 5 (20.00%)
occurrences (all)	2	2	1
Cough alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 4 (50.00%)	1 / 3 (33.33%)	2 / 5 (40.00%)
occurrences (all)	2	1	2
Hypoxia alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	3
Nasal congestion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pleural effusion			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dry throat			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dysphonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pulmonary haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract irritation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
alternative assessment type: Non-systematic			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Confusional state</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Insomnia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>1 / 5 (20.00%)</p> <p>1</p>
<p>Product issues</p> <p>Thrombosis in device</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p>
<p>Investigations</p> <p>Alanine aminotransferase increased</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Amylase increased</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Aspartate aminotransferase increased</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Blood bilirubin increased</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Blood creatinine increased</p> <p>alternative assessment type: Non-systematic</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p> <p>1 / 3 (33.33%)</p> <p>1</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>1 / 5 (20.00%)</p> <p>1</p> <p>1 / 5 (20.00%)</p> <p>1</p>

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Breath sounds abnormal			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Heart rate increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	3	0

Weight increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
White blood cell count decreased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0
Injury, poisoning and procedural complications Contusion alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Hand fracture alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Infusion related reaction alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	0 / 3 (0.00%) 0 1 / 3 (33.33%) 2 0 / 3 (0.00%) 0	1 / 5 (20.00%) 1 0 / 5 (0.00%) 0 1 / 5 (20.00%) 1
Cardiac disorders Sinus tachycardia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Tachycardia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0 1 / 4 (25.00%) 1	1 / 3 (33.33%) 1 0 / 3 (0.00%) 0	0 / 5 (0.00%) 0 0 / 5 (0.00%) 0
Nervous system disorders Headache alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 3	3 / 3 (100.00%) 6	4 / 5 (80.00%) 8

Dysgeusia alternative assessment type: Non-systematic	subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
	occurrences (all)	0	1	1
Tremor alternative assessment type: Non-systematic	subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
	occurrences (all)	0	1	0
Dizziness alternative assessment type: Non-systematic	subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
	occurrences (all)	0	0	0
Neuralgia alternative assessment type: Non-systematic	subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
	occurrences (all)	1	0	0
Paraesthesia alternative assessment type: Non-systematic	subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
	occurrences (all)	0	0	1
Phantom pain alternative assessment type: Non-systematic	subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
	occurrences (all)	0	0	1
Somnolence alternative assessment type: Non-systematic	subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
	occurrences (all)	0	0	0
Blood and lymphatic system disorders				
Anaemia alternative assessment type: Non-systematic	subjects affected / exposed	4 / 4 (100.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
	occurrences (all)	7	6	8
Neutropenia alternative assessment type: Non-systematic				

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1
Ear and labyrinth disorders Ear discomfort alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Vertigo alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	 0 / 3 (0.00%) 0 1 / 3 (33.33%) 1	 1 / 5 (20.00%) 1 0 / 5 (0.00%) 0
Eye disorders Dry eye alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Eye pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Eyelid oedema alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 1 / 4 (25.00%) 1	 1 / 3 (33.33%) 1 1 / 3 (33.33%) 1 0 / 3 (0.00%) 0	 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0
Gastrointestinal disorders Abdominal pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Constipation alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Diarrhoea alternative assessment type: Non-systematic	 1 / 4 (25.00%) 1 1 / 4 (25.00%) 1	 0 / 3 (0.00%) 0 1 / 3 (33.33%) 2	 1 / 5 (20.00%) 1 2 / 5 (40.00%) 2

subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Duodenal ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gastritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Mouth haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 4 (50.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	2	2	0
Stomatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	2 / 3 (66.67%)	2 / 5 (40.00%)
occurrences (all)	0	6	4
Hepatobiliary disorders			
Hepatic failure			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Alopecia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Erythema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Night sweats			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Purpura			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
alternative assessment type: Non-systematic			

subjects affected / exposed occurrences (all) Skin mass alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 5 (0.00%) 0 0 / 5 (0.00%) 0
Endocrine disorders Adrenal insufficiency alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Hypothyroidism alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	1 / 3 (33.33%) 10 1 / 3 (33.33%) 1	0 / 5 (0.00%) 0 0 / 5 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Back pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Bone pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Flank pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Muscle rigidity alternative assessment type: Non-systematic	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	1 / 3 (33.33%) 1 1 / 3 (33.33%) 4 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 5 (0.00%) 0 2 / 5 (40.00%) 2 1 / 5 (20.00%) 1 0 / 5 (0.00%) 0

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Myalgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	0	2	1
Infections and infestations			
Coronavirus infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Localised infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Oral candidiasis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sinusitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Skin infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Viral respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Urinary tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Dehydration			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 4 (50.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	5	0	0
Hypophosphataemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0

Non-serious adverse events	Phase 1: IMCnyeso 100 mcg	Phase 1: IMCnyeso 30-100 mcg	Phase 1: IMCnyeso 30-100-180 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	5 / 5 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Vascular disorders			
Hypotension			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	5	1
Hypertension			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hot flush			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	2 / 5 (40.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Phlebitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Superior vena cava syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Axillary pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 3 (66.67%)	2 / 5 (40.00%)	3 / 4 (75.00%)
occurrences (all)	7	9	10
Face oedema			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Facial pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 3 (66.67%)	0 / 5 (0.00%)	2 / 4 (50.00%)
occurrences (all)	4	0	4
Feeling cold			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Local swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Malaise			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Pyrexia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	3 / 3 (100.00%) 7	5 / 5 (100.00%) 10	3 / 4 (75.00%) 8
Immune system disorders Cytokine release syndrome alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	2 / 5 (40.00%) 4	3 / 4 (75.00%) 6
Reproductive system and breast disorders Amenorrhoea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Menstruation irregular alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Pelvic pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Vaginal haemorrhage alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Oropharyngeal pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 1 / 3 (33.33%) 1	1 / 5 (20.00%) 1 1 / 5 (20.00%) 1 1 / 5 (20.00%) 1 0 / 5 (0.00%) 0 1 / 5 (20.00%) 1	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Dyspnoea alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 3 (33.33%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 3 (66.67%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Hypoxia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	2
Epistaxis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry throat			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Upper respiratory tract irritation alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Psychiatric disorders Anxiety alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Confusional state alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Insomnia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 1 / 3 (33.33%) 3 0 / 3 (0.00%) 0	2 / 5 (40.00%) 2 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0
Product issues Thrombosis in device alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1	0 / 4 (0.00%) 0
Investigations Alanine aminotransferase increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Amylase increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Aspartate aminotransferase increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	1 / 5 (20.00%) 2 0 / 5 (0.00%) 0 1 / 5 (20.00%) 2	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0

Blood bilirubin increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Blood creatinine increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Blood lactate dehydrogenase increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Body temperature increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Breath sounds abnormal alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Heart rate increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Lymphocyte count decreased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	0 / 5 (0.00%) 0	1 / 4 (25.00%) 1
Neutrophil count decreased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	2 / 4 (50.00%) 5
Oxygen saturation decreased alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Weight increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
Contusion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 3 (100.00%)	2 / 5 (40.00%)	1 / 4 (25.00%)
occurrences (all)	7	4	1
Dysgeusia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Neuralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Phantom pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
alternative assessment type: Non-systematic			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 5 (0.00%) 0	0 / 4 (0.00%) 0
Blood and lymphatic system disorders Anaemia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Neutropenia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 5 (0.00%) 0 1 / 5 (20.00%) 1	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0
Ear and labyrinth disorders Ear discomfort alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Vertigo alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 5 (0.00%) 0 1 / 5 (20.00%) 1	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0
Eye disorders Dry eye alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Eye pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Eyelid oedema alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0
Gastrointestinal disorders			

Abdominal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Duodenal ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	3 / 5 (60.00%)	2 / 4 (50.00%)
occurrences (all)	1	4	2
Stomatitis			
alternative assessment type: Non-systematic			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vomiting</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p> <p>2 / 3 (66.67%)</p> <p>2</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>1 / 5 (20.00%)</p> <p>2</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>2 / 4 (50.00%)</p> <p>2</p>
<p>Hepatobiliary disorders</p> <p>Hepatic failure</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	<p>1 / 4 (25.00%)</p> <p>1</p>
<p>Skin and subcutaneous tissue disorders</p> <p>Dry skin</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pruritus generalised</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Alopecia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Erythema</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Night sweats</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Purpura</p> <p>alternative assessment type: Non-systematic</p>	<p>1 / 3 (33.33%)</p> <p>1</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>1 / 3 (33.33%)</p> <p>1</p> <p>0 / 3 (0.00%)</p> <p>0</p>	<p>1 / 5 (20.00%)</p> <p>1</p> <p>1 / 5 (20.00%)</p> <p>1</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>1 / 5 (20.00%)</p> <p>1</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>

subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rash erythematous			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin mass			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Adrenal insufficiency			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Back pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bone pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle rigidity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Muscle tightness			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 3 (66.67%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Pain in extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Infections and infestations			
Coronavirus infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Viral respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Metabolism and nutrition disorders			
Decreased appetite			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dehydration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypercalcaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	2

Non-serious adverse events	Phase 1: IMCnyeso 30-100-300 mcg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Tumour pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Vascular disorders			

<p>Hypotension</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>3 / 5 (60.00%)</p> <p>9</p>		
<p>Hypertension</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 5 (20.00%)</p> <p>2</p>		
<p>Hot flush</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p>		
<p>Phlebitis</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p>		
<p>Superior vena cava syndrome</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 5 (0.00%)</p> <p>0</p>		
<p>General disorders and administration site conditions</p> <p>Axillary pain</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Chest discomfort</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Chills</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Face oedema</p> <p>alternative assessment type: Non-</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>3 / 5 (60.00%)</p> <p>14</p>		

systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Facial pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 5 (60.00%)		
occurrences (all)	4		
Feeling cold			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Influenza like illness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Local swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Malaise			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Non-cardiac chest pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
alternative assessment type: Non-systematic			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pain</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pyrexia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 5 (20.00%)</p> <p>1</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>5 / 5 (100.00%)</p> <p>16</p>		
<p>Immune system disorders</p> <p>Cytokine release syndrome</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>5 / 5 (100.00%)</p> <p>14</p>		
<p>Reproductive system and breast disorders</p> <p>Amenorrhoea</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Menstruation irregular</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pelvic pain</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vaginal haemorrhage</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Oropharyngeal pain</p> <p>alternative assessment type: Non-systematic</p>	<p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p> <p>0 / 5 (0.00%)</p> <p>0</p>		

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 5 (60.00%)		
occurrences (all)	5		
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Hypoxia			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 5 (40.00%)		
occurrences (all)	4		
Epistaxis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Nasal congestion			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Pleural effusion			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Dry throat			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Dysphonia			
alternative assessment type: Non-systematic			

<p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Pulmonary haemorrhage</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Upper respiratory tract irritation</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Psychiatric disorders</p> <p>Anxiety</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Confusional state</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Insomnia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Product issues</p> <p>Thrombosis in device</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Investigations</p> <p>Alanine aminotransferase increased</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Amylase increased</p> <p>alternative assessment type: Non-systematic</p>			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	6		
Blood bilirubin increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Body temperature increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Breath sounds abnormal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Heart rate increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Neutrophil count decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Oxygen saturation decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Weight decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Weight increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Contusion			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Hand fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Infusion related reaction			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Sinus tachycardia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	4		
Tachycardia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 5 (80.00%)		
occurrences (all)	5		
Dysgeusia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Tremor			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Dizziness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Neuralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Paraesthesia			
alternative assessment type: Non-systematic			

<p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Phantom pain</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Somnolence</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Blood and lymphatic system disorders</p> <p>Anaemia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>2 / 5 (40.00%)</p> <p>occurrences (all)</p> <p>8</p> <p>Neutropenia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>1 / 5 (20.00%)</p> <p>occurrences (all)</p> <p>1</p>			
<p>Ear and labyrinth disorders</p> <p>Ear discomfort</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Vertigo</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Eye disorders</p> <p>Dry eye</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Eye pain</p> <p>alternative assessment type: Non-systematic</p>			

<p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Eyelid oedema</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Gastrointestinal disorders</p> <p>Abdominal pain</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Constipation</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>1 / 5 (20.00%)</p> <p>occurrences (all)</p> <p>2</p> <p>Diarrhoea</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Duodenal ulcer</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Gastritis</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Mouth haemorrhage</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>1 / 5 (20.00%)</p> <p>occurrences (all)</p> <p>1</p> <p>Mouth ulceration</p> <p>alternative assessment type: Non-systematic</p>			

<p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Nausea</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>1 / 5 (20.00%)</p> <p>occurrences (all)</p> <p>4</p> <p>Stomatitis</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Vomiting</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>2 / 5 (40.00%)</p> <p>occurrences (all)</p> <p>4</p>			
<p>Hepatobiliary disorders</p> <p>Hepatic failure</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Skin and subcutaneous tissue disorders</p> <p>Dry skin</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Pruritus generalised</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Alopecia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Erythema</p> <p>alternative assessment type: Non-systematic</p>			

<p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Night sweats</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Purpura</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Rash erythematous</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Rash maculo-papular</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Skin mass</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Endocrine disorders</p> <p>Adrenal insufficiency</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Hypothyroidism</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>0 / 5 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Musculoskeletal and connective tissue disorders</p> <p>Arthralgia</p> <p>alternative assessment type: Non-systematic</p>			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Back pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Bone pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Flank pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Muscle rigidity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Muscle tightness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Muscular weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Myalgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		

Pain in extremity alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Infections and infestations Coronavirus infection alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		
Localised infection alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Oral candidiasis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Pharyngitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Rhinitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Sinusitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Skin infection alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Viral respiratory tract infection alternative assessment type: Non-systematic			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Urinary tract infection alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 5 (40.00%) 3		
Dehydration alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Hypercalcaemia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Hypokalaemia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Hypophosphataemia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 January 2018	--Additional DLT criterion added --Updated inclusion criteria #10 to require that during Phase II patients with NSCLC harboring anaplastic lymphoma kinase rearrangements or EGFR mutations have had prior treatment with Health --Authority-approved targeted therapies --Duration of sample storage was added --Additional emergency contact added on cover page --Corrected typographical errors and inconsistencies and inserted minor clarifications throughout to improve the readability and content presentation
12 June 2019	--Description of potential risks was revised to incorporate emerging data from related molecules including the ImmTAC IMCgp100. The CRS section was updated to include frequencies of relevant AEs. -----Potential risks of hepatic and pulmonary events were added. --Added provision to allow enrollment in expansion cohorts to be increased from n=9 to n=24 (previously fixed at n=10) --Response was no longer to be evaluated per modified irRECIST. Treatment discontinuation was required when unequivocal disease progression was confirmed, aligned with current standards. Inpatient dose-escalation approaches were modified based on beneficial data in other CD3 bispecifics to allow the SST to initiate a 1-step or 2-step IPE regimen and/or allow pre-medication. A longer DLT evaluation period and adjusted Cycle 1 schedule were added for patients who were receiving IPE. --The first 3 patients at each dose level were to be hospitalized for 2 nights after the first dose of IMCnyeso. --DLT criteria were revised --Allowed/prohibited concomitant medications were edited --Toxicity management guidelines were updated to align with protocols for other ImmTAC molecules. --The schedule of assessment tables were reformatted for ease of use with a few clarifications --Safety follow-up was changed to 30 days, based on the <24-hour half-life of ImmTAC.

24 February 2020	<p>--To reduce the risk to patients from acute mechanism-related toxicities by moving to IPE regimens, the dose-escalation rules were updated, so that at any escalation step, a new permitted dose level based on the BLRM could be assessed using the same regimen as the prior cohort or using a regimen with additional steps. Furthermore, because ImmTAC-associated toxicities are generally acute, a 28-day DLT period was be used for all schedules.</p> <p>--Based on the observation that all signs/symptoms of CRS, to date, had occurred rapidly (within a few hours) following administration of IMCnyeso, the SST could decide to reduce the minimum required post-end of infusion monitoring time to no less than 8 hours on C1D1, C1D8, and/or C1D15 during the Phase II portion of the study. Consistent with prior versions of the protocol, hospitalization would be extended if clinically indicated for any given patient.</p> <p>--Eligibility criteria were updated based on investigator feedback as follows:</p> <ol style="list-style-type: none"> Patients with a clinically stable, asymptomatic Grade 2 endocrine disorder due to prior anti-cancer therapy (previously restricted to hypothyroidism) were permitted to be enrolled in the study. The minimum allowed creatinine clearance (calculated using Cockcroft-Gault formula or measured) was reduced from 50 mL/min to 40 mL/min. The washout period for oral antibiotics was reduced from 14 days to 7 days prior to the first dose of study drug (note: no change was made to the washout period for IV antibiotics). <p>4. Instructions for allowed and prohibited concomitant medications were edited to include guidance regarding vaccine use.</p> <p>--If dose escalation proceeded to a dose of >150 mcg according to BLRM output and treatment at this dose level is well tolerated, additional BLRM simulations were to be performed to predict rates of toxicity for higher dose levels.</p>
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Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
10 May 2021	Following portfolio review, the study was terminated early (prior to initiation of Phase 2) by the Sponsor as a strategic decision (not based on any safety signal).	-

Notes:

Limitations and caveats

None reported