Clinical trial results:
A Phase 1/2, First-in-Human, Open-Label, Dose-Escalation and Expansion Study of IMGC936-0901 (Anti-ADAM9 Antibody Drug Conjugate) in Patients with Advanced Solid Tumors

Summary

EudraCT number	2021-002264-41
Trial protocol	ES
Global end of trial date	28 December 2023

Results information

Result version number	v1 (current)
This version publication date	05 January 2025
First version publication date	05 January 2025

Trial information

Trial identification

Sponsor protocol code	IMGC936-0901

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04622774
WHO universal trial number (UTN)	-
Other trial identifiers	IND Number: 141340

Notes:

Sponsors

Sponsor organisation name	ImmunoGen, Inc.
Sponsor organisation address	830 Winter Street, Waltham, United States, 02451
Public contact	Kenneth Dhimitri, ImmunoGen, Inc., 001 781207-5341, regulatory.affairs@immunogen.com
Scientific contact	Kenneth Dhimitri, ImmunoGen, Inc., 001 781207-5341, regulatory.affairs@immunogen.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	28 December 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 December 2023
Global end of trial reached?	Yes
Global end of trial date	28 December 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Dose Expansion Phase:
To describe objective response rate (ORR) for IMGC936 using Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1).

Protection of trial subjects:

The investigational study was conducted according to the Protection of Human Patients (21 CFR [Code of Federal Regulations] 50), Institutional Review Boards (21 CFR 56), Obligations of Clinical Investigators (21 CFR 312.60–312.69), current ICH guideline for GCP (ICH E6), and all other applicable regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2022
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 States: 44
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Spain: 6
Worldwide total number of subjects	56
EEA total number of subjects	12

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)	35
From 65 to 84 years	21

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study included a Dose Escalation Phase and Dose Expansion Phase.

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?	Yes
Arm title	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg

Arm description:

Participants received IMGC936 0.5 milligrams (mg)/kilogram (kg) via intravenous (IV) infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Arm type	Experimental
Investigational medicinal product name	IMGC936
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IMGC936 as described in arm descriptions.

Arm title	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg

Arm description:

Participants received IMGC936 1.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter

Arm type	Experimental
Investigational medicinal product name	IMGC936
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IMGC936 as described in arm descriptions.

Arm title	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg

Arm description:

Participants received IMGC936 2.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Arm type	Experimental
Investigational medicinal product name	IMGC936
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IMGC936 as described in arm descriptions.

Arm title	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg

Arm description:

Participants received IMGC936 4.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Arm type	Experimental
Investigational medicinal product name	IMGC936
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IMGC936 as described in arm descriptions.

Arm title	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg

Arm description:

Participants received IMGC936 5.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Arm type	Experimental
Investigational medicinal product name	IMGC936
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IMGC936 as described in arm descriptions.

Arm title	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg

Arm description:

Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Arm type	Experimental
Investigational medicinal product name	IMGC936
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IMGC936 as described in arm descriptions.

Arm title	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg

Arm description:

Participants received IMGC936 7.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Arm type	Experimental
Investigational medicinal product name	IMGC936
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IMGC936 as described in arm descriptions.

Arm title	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg

Arm description:

Participants received IMGC936 2.0 mg/kg on Days 1, 8, and 15 of a 28-day cycle for the first 2 cycles. On all subsequent cycles (Cycle 3 and beyond), participants received IMGC936 3.0 mg/kg on Days 1 and 8 of a 28-day cycle.

Arm type	Experimental
Investigational medicinal product name	IMGC936
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IMGC936 as described in arm descriptions.

Arm title	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg

Arm description:

Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Arm type	Experimental
Investigational medicinal product name	IMGC936
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IMGC936 as described in arm descriptions.

Arm title	Dose Expansion - TNBC: IMGC936 6.0 mg/kg

Arm description:

Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Arm type	Experimental
Investigational medicinal product name	IMGC936
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IMGC936 as described in arm descriptions.

Number of subjects in period 1	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg
Started	3	3	3
Received at least 1 dose of study drug	3	3	3
Completed	3	3	3

Number of subjects in period 1	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg
Started	3	3	10
Received at least 1 dose of study drug	3	3	10
Completed	3	3	10

Number of subjects in period 1	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg
Started	9	3	13
Received at least 1 dose of study drug	9	3	13
Completed	9	3	13

Number of subjects in period 1	Dose Expansion - TNBC: IMGC936 6.0 mg/kg
Started	6
Received at least 1 dose of study drug	6
Completed	6

Baseline characteristics

Reporting groups	
Reporting group title	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg
Reporting group description:	
Participants received IMGC936 0.5 milligrams (mg)/kilogram (kg) via intravenous (IV) infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg
Reporting group description:	
Participants received IMGC936 1.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter	
Reporting group title	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg
Reporting group description:	
Participants received IMGC936 2.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg
Reporting group description:	
Participants received IMGC936 4.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg
Reporting group description:	
Participants received IMGC936 5.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg
Reporting group description:	
Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg
Reporting group description:	
Participants received IMGC936 7.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg
Reporting group description:	
Participants received IMGC936 2.0 mg/kg on Days 1, 8, and 15 of a 28-day cycle for the first 2 cycles. On all subsequent cycles (Cycle 3 and beyond), participants received IMGC936 3.0 mg/kg on Days 1 and 8 of a 28-day cycle.	
Reporting group title	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg
Reporting group description:	
Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Expansion - TNBC: IMGC936 6.0 mg/kg
Reporting group description:	
Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	

Reporting group values	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg
Number of subjects	3	3	3
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			

Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous			
Safety population included all participants who received at least 1 dose of study drug.			
Units: years			
arithmetic mean	54.7	53.3	59.3
standard deviation	± 5.51	± 8.39	± 4.93
Gender categorical Units: Subjects			
Female	2	2	3
Male	1	1	0
Race Units: Subjects			
Asian	0	1	0
Black of African American	0	0	0
White	3	2	2
Unknown or Not Reported	0	0	1

Reporting group values	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg
Number of subjects	3	3	10
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous			
Safety population included all participants who received at least 1 dose of study drug.			
Units: years			
arithmetic mean	67.7	61.3	60.4
standard deviation	± 5.69	± 9.81	± 7.63
Gender categorical Units: Subjects			
Female	2	3	3
Male	1	0	7
Race Units: Subjects			
Asian	0	0	0

Black of African American	1	0	0
White	2	3	9
Unknown or Not Reported	0	0	1

Reporting group values	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg
Number of subjects	9	3	13
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Safety population included all participants who received at least 1 dose of study drug.			
Units: years			
arithmetic mean	63.4	61.0	64.8
standard deviation	± 8.46	± 5.57	± 8.80
Gender categorical Units: Subjects			
Female	3	2	6
Male	6	1	7
Race Units: Subjects			
Asian	0	0	0
Black of African American	0	0	1
White	9	3	11
Unknown or Not Reported	0	0	1

Reporting group values	Dose Expansion - TNBC: IMGC936 6.0 mg/kg	Total	
Number of subjects	6	56	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	

Age continuous			
Safety population included all participants who received at least 1 dose of study drug.			
Units: years			
arithmetic mean	55.8		
standard deviation	± 10.96	-	
Gender categorical			
Units: Subjects			
Female	6	32	
Male	0	24	
Race			
Units: Subjects			
Asian	1	2	
Black of African American	0	2	
White	5	49	
Unknown or Not Reported	0	3	

End points

End points reporting groups

Reporting group title	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg
Reporting group description:	
Participants received IMGC936 0.5 milligrams (mg)/kilogram (kg) via intravenous (IV) infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg
Reporting group description:	
Participants received IMGC936 1.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter	
Reporting group title	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg
Reporting group description:	
Participants received IMGC936 2.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg
Reporting group description:	
Participants received IMGC936 4.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg
Reporting group description:	
Participants received IMGC936 5.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg
Reporting group description:	
Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg
Reporting group description:	
Participants received IMGC936 7.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg
Reporting group description:	
Participants received IMGC936 2.0 mg/kg on Days 1, 8, and 15 of a 28-day cycle for the first 2 cycles. On all subsequent cycles (Cycle 3 and beyond), participants received IMGC936 3.0 mg/kg on Days 1 and 8 of a 28-day cycle.	
Reporting group title	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg
Reporting group description:	
Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Reporting group title	Dose Expansion - TNBC: IMGC936 6.0 mg/kg
Reporting group description:	
Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	
Subject analysis set title	Dose Escalation and Dose Expansion: IMGC936 6.0 mg/kg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.	

Primary: Dose Escalation Phase: Number of Participants With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Dose Escalation Phase: Number of Participants With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)[1][2]

End point description:

An adverse event (AE) was defined as any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. Serious AEs (SAEs) were defined as death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, a congenital anomaly or birth defect, or an important medical event that jeopardized participant and required medical intervention to prevent 1 of the outcomes listed in this definition. TEAEs were defined as any AEs with onset date between the first dose of IMGC936 and date of the last dose of IMGC936 + 30 days (inclusive) or date of the first anti-cancer therapy, whichever was earlier. A summary of other non-serious AEs and all serious AEs, regardless of causality is located in Reported AE section.

Safety population included all participants who received at least 1 dose of study drug.

End point type	Primary

End point timeframe:

Up to approximately 3 years

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only summary statistics were planned for this endpoint

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only summary statistics were planned for this endpoint

End point values	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: participants				
Any TEAEs	3	3	3	3
SAEs	1	0	1	0

End point values	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	9	3
Units: participants				
Any TEAEs	3	10	9	3
SAEs	1	1	4	2

Statistical analyses

No statistical analyses for this end point

Primary: Dose Escalation Phase: Number of Participants With Dose-limiting Toxicities (DLTs) Based on National Cancer Institute (NCI) Common Terminology Criteria for AEs Version 5.0 (CTCAE v5.0)

End point title	Dose Escalation Phase: Number of Participants With Dose-limiting Toxicities (DLTs) Based on National Cancer Institute (NCI) Common Terminology Criteria for AEs Version 5.0 (CTCAE v5.0)[3][4]

End point description:

DLTs were defined based on TEAEs or abnormal laboratory values that met DLT criteria. Hematologic DLT: Grade 4 neutropenia lasting >7 days; ≥Grade 3 febrile neutropenia Grade 4 thrombocytopenia; Grade 3 thrombocytopenia associated with bleeding; ≥Grade 3 hemolysis. Non-hematologic DLT: Any ≥Grade 3 non-hematologic event, including Grade 3 ocular symptoms and signs; Grade 2 AEs that were prolonged inordinately; • Hepatic laboratory abnormalities meeting Hy's law criteria; Eye pain or reduction in visual acuity that did not respond to topical ophthalmic therapy. Hepatic DLT: Any elevation of ≥1 transaminases >8 * upper limit of normal (ULN); Any Grade 3 elevation of ≥1 transaminases >5.0–8.0 * ULN that did not resolve to Grade 2 within 7 days and Grade 1 within 14 days; Grade 3 elevation of total bilirubin >5 * ULN; Any Grade 3 elevation of total bilirubin >3.0–5.0 * ULN that did not resolve to Grade 2 within 7 days and Grade 1 within 14 days; Any event meeting criteria for Hy's law.

End point type	Primary

End point timeframe:

Cycle 1 (21 days for Schedule A and 28 days for Schedule B)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only summary statistics were planned for this endpoint

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only summary statistics were planned for this endpoint

End point values	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: participants	0	0	0	0

End point values	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	9	3
Units: participants	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Dose Expansion Phase: Objective Response Rate (ORR) - Percentage of Participants With Objective Response as Assessed by the Investigator Using Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1)

End point title	Dose Expansion Phase: Objective Response Rate (ORR) - Percentage of Participants With Objective Response as Assessed by the Investigator Using Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1)[5][6]

End point description:

ORR was defined as percentage of participants with a confirmed best overall response (BOR) of complete response (CR) or partial response (PR). CR: Disappearance of all target or non-target lesions. All pathological or non-pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 millimeters (mm). PR: At least 30% decrease in the sum of the longest diameters (SoD) of target lesions, taking as reference the baseline SoD.

Response evaluable population included all participants who received at least 1 dose of study drug, had baseline measurable or non-measurable disease, and had at least 1 post-baseline radiographic tumor assessment or discontinued study drug due to clinical progression or death if no post-baseline tumor assessment.

End point type	Primary

End point timeframe:

Up to approximately 3 years

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only summary statistics were planned for this endpoint

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only summary statistics were planned for this endpoint

End point values	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg	Dose Expansion - TNBC: IMGC936 6.0 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	6		
Units: Percentage of Participants				
number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Dose Escalation and Dose Expansion Phase: Maximum Study Drug Concentration (Cmax)

End point title	Dose Escalation and Dose Expansion Phase: Maximum Study Drug Concentration (Cmax)[7]

End point description:

The Pharmacokinetics Analysis Set (PAS) included all participants who received at least one dose of IMGC936 and from whom results of plasma or serum concentrations were obtained for at least one sampling point. "99999" = Not calculable due to insufficient number of valid PK parameters.

End point type	Secondary

End point timeframe:

Schedule A: Cycle 1 Day 1 (C1D1), C3D1; Schedule B: C1D1, C1D15

Notes:

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

End point values	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: micrograms/milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
C1D1	14.17 (± 22)	22.21 (± 5.6)	56.69 (± 14.2)	107.2 (± 9.6)
C1D15	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg	Dose Escalation and Dose Expansion: IMGC936 6.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	3	9	3	29
Units: micrograms/milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
C1D1	114.8 (± 30.7)	162.4 (± 23.7)	51.74 (± 9.8)	149.5 (± 21.6)
C1D15	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C3D1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	168.4 (± 16.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Dose Escalation and Dose Expansion Phase: Number of Participants With Antidrug Antibodies (ADA)

End point title	Dose Escalation and Dose Expansion Phase: Number of Participants With Antidrug Antibodies (ADA)

End point description:

Safety population included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Up to approximately 3 years

End point values	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: participants	3	1	1	0

End point values	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	9	3
Units: participants	1	2	0	1

End point values	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg	Dose Expansion - TNBC: IMGC936 6.0 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	6		
Units: participants	3	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Dose Escalation Phase: ORR - Percentage of Participants With Objective Response as Assessed by the Investigator Using RECIST v1.1

End point title	Dose Escalation Phase: ORR - Percentage of Participants With Objective Response as Assessed by the Investigator Using RECIST v1.1[8]

End point description:

ORR was defined as percentage of participants with a confirmed BOR of CR or PR. CR: Disappearance of all target or non-target lesions. All pathological or non-pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm. PR: At least 30% decrease in the SoD of target lesions, taking as reference the baseline SoD.

Response evaluable population included all participants who received at least 1 dose of study drug, had baseline measurable or non-measurable disease, and had at least 1 post-baseline radiographic tumor

assessment or discontinued study drug due to clinical progression or death if no post-baseline tumor assessment.

End point type	Secondary

End point timeframe:

Up to approximately 3 years

Notes:

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

End point values	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	9	3
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Dose Escalation and Dose Expansion Phase: Duration of Response (DOR) as Assessed by the Investigator Using RECIST v1.1

End point title	Dose Escalation and Dose Expansion Phase: Duration of Response (DOR) as Assessed by the Investigator Using RECIST v1.1

End point description:

DOR was defined as the time from the date of the first response (CR or PR), until the date of progressive disease (PD) or death from any cause, whichever occurred first. DOR for participants who had not progressed or died at the time of analysis was censored at the date of their last tumor assessment. PD: At least a 20% increase in the SoD of target lesion, taken as reference the smallest (nadir) SoD since and including baseline. In addition to the relative increase of 20%, the SoD must also demonstrate an absolute increase of at least 5 mm. Unequivocal progression of non-target lesions. Unequivocal progression should not normally trump target lesion status. It must be representative of overall disease status change, not a single lesion increase. DOR was estimated using the Kaplan-Meier method.

"99999" = No participant had response; hence, data could not be calculated.

End point type	Secondary

End point timeframe:

Up to approximately 3 years

End point values	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: months				
median (full range (min-max))	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	9	3
Units: months				
median (full range (min-max))	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg	Dose Expansion - TNBC: IMGC936 6.0 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	6		
Units: months				
median (full range (min-max))	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Dose Expansion Phase: Number of Participants With TEAEs, SAEs, and IMGC936 Related TEAEs That Led to Discontinuation

End point title	Dose Expansion Phase: Number of Participants With TEAEs, SAEs, and IMGC936 Related TEAEs That Led to Discontinuation[9]

End point description:

An AE was defined as any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. SAEs were defined as death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity,

a congenital anomaly or birth defect, or an important medical event that jeopardized participant and required medical intervention to prevent 1 of the outcomes listed in this definition. TEAEs were defined as any AEs with onset date between the first dose of IMGC936 and date of the last dose of IMGC936 + 30 days (inclusive) or date of the first anti-cancer therapy, whichever was earlier. A summary of other non-serious AEs and all serious AEs, regardless of causality is located in Reported AE section.

Safety population included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Up to approximately 3 years

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only summary statistics were planned for this endpoint

End point values	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg	Dose Expansion - TNBC: IMGC936 6.0 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	6		
Units: participants				
Any TEAEs	13	6		
SAEs	4	2		
IMGC936 related TEAEs That Led to Discontinuation	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Dose Expansion Phase: Progression-Free Survival (PFS) as Assessed by the Investigator Using RECIST v1.1

End point title	Dose Expansion Phase: Progression-Free Survival (PFS) as Assessed by the Investigator Using RECIST v1.1[10]

End point description:

PFS was defined as the time from initiation of study drug until the date of PD or death whichever occurred first, estimated using the Kaplan-Meier method. PD: At least a 20% increase in the SoD of target lesion, taken as reference the smallest (nadir) SoD since and including baseline. In addition to the relative increase of 20%, the SoD must also demonstrate an absolute increase of at least 5 mm. Unequivocal progression of non-target lesions and appearance of new lesions. Unequivocal progression should not normally trump target lesion status. It must be representative of overall disease status change, not a single lesion increase.

Response evaluable population included all participants who received at least 1 dose of study drug, had baseline measurable or non-measurable disease, and had at least 1 post-baseline radiographic tumor assessment or discontinued study drug due to clinical progression or death if no post-baseline tumor assessment.

End point type	Secondary

End point timeframe:

Up to approximately 3 years

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only summary statistics were planned for this endpoint

End point values	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg	Dose Expansion - TNBC: IMGC936 6.0 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	6		
Units: months				
median (full range (min-max))	2.7 (0.7 to 6.7)	1.2 (0.0 to 2.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 3 years

Adverse event reporting additional description:

Safety population included all participants who received at least 1 dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg

Reporting group description:

Participants received IMGC936 4.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Reporting group title	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg

Reporting group description:

Participants received IMGC936 2.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Reporting group title	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg

Reporting group description:

Participants received IMGC936 1.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter

Reporting group title	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg

Reporting group description:

Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Reporting group title	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg

Reporting group description:

Participants received IMGC936 5.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Reporting group title	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg

Reporting group description:

Participants received IMGC936 0.5 milligrams (mg)/kilogram (kg) via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Reporting group title	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg

Reporting group description:

Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Reporting group title	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg

Reporting group description:

Participants received IMGC936 2.0 mg/kg on Days 1, 8, and 15 of a 28-day cycle for the first 2 cycles. On all subsequent cycles (Cycle 3 and beyond), participants received IMGC936 3.0 mg/kg on Days 1 and 8 of a 28-day cycle.

Reporting group title	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg

Reporting group description:

Participants received IMGC936 7.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Reporting group title	Dose Expansion - TNBC: IMGC936 6.0 mg/kg

Reporting group description:

Participants received IMGC936 6.0 mg/kg via IV infusion on Day 1 of Cycle 1 and every subsequent 21-day cycle thereafter.

Serious adverse events	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
number of deaths (all causes)	0	1	1
number of deaths resulting from adverse events			
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycotic endophthalmitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
number of deaths (all causes)	1	1	0
number of deaths resulting from adverse events			
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Pericardial effusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycotic endophthalmitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 13 (30.77%)	2 / 3 (66.67%)	4 / 9 (44.44%)

number of deaths (all causes) number of deaths resulting from adverse events	3	1	2
Investigations Blood alkaline phosphatase increased subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications Hip fracture subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders Pericardial effusion subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders Headache subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders Abdominal pain subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycotic endophthalmitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 13 (15.38%)	0 / 3 (0.00%)	0 / 9 (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

Serious adverse events	Dose Expansion - TNBC: IMGC936 6.0 mg/kg		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events			
Investigations			
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Pericardial effusion			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			

subjects affected / exposed	1 / 6 (16.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary obstruction			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal colic			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mycotic endophthalmitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 6 (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: 0 %

Non-serious adverse events	Dose Escalation - Schedule A: IMGC936 4.0 mg/kg	Dose Escalation - Schedule A: IMGC936 2.0 mg/kg	Dose Escalation - Schedule A: IMGC936 1.0 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	0	1	2
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sensation of blood flow			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Emphysema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural thickening			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract congestion			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Affective disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	3
Alanine aminotransferase increased			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	1
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	5
Blood potassium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural			

complications			
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Myoclonus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anaemia of malignant disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Splenic vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	2	1	1
Keratitis			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Keratopathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Punctate keratitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Asthenopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Corneal epithelial microcysts			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cornea verticillata			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night blindness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastric haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Large intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastric stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Steatorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Portal vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperkeratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Milia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mixed connective tissue disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose Escalation - Schedule A: IMGC936 6.0 mg/kg	Dose Escalation - Schedule A: IMGC936 5.0 mg/kg	Dose Escalation - Schedule A: IMGC936 0.5 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Hypertension			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	3 / 10 (30.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Oedema peripheral			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Asthenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			

subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sensation of blood flow			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	1	1	2
Pneumonitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Pulmonary embolism			

subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Emphysema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural thickening			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Mental status changes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Affective disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Sleep disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Lipase increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood sodium decreased			

subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Procedural pain			

subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	3
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	1	1	3
Restless legs syndrome			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Anaemia of malignant disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Splenic vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	2 / 10 (20.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	4	3	0
Vision blurred			
subjects affected / exposed	6 / 10 (60.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	9	4	0
Keratitis			

subjects affected / exposed	2 / 10 (20.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Keratopathy			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Punctate keratitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenopia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Corneal epithelial microcysts			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Cornea verticillata			

subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night blindness			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	2 / 10 (20.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	2	1	1
Nausea			
subjects affected / exposed	3 / 10 (30.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	3	2	1
Diarrhoea			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Dry mouth			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1

Abdominal pain upper			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Abdominal pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	2	3
Dysphagia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastric haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Large intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastric stenosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Stomatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Steatorrhoea			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Portal vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cholangitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperkeratosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Milia			

subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hydronephrosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Pain in extremity			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Joint swelling			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mixed connective tissue disease			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Tendonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
COVID-19			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hordeolum			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	2
Hyponatraemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Hypokalaemia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	1
Decreased appetite			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hypomagnesaemia			

subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Dose Expansion - NSCLC: IMGC936 6.0 mg/kg	Dose Escalation - Schedule B: IMGC936 2.0 mg/kg	Dose Escalation - Schedule A: IMGC936 7.0 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)	3 / 3 (100.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			

Hypertension			
subjects affected / exposed	1 / 13 (7.69%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	1	2	1
Hypotension			
subjects affected / exposed	1 / 13 (7.69%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Embolism			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 13 (15.38%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	2	1	1
Pyrexia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Asthenia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Chest discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Infusion site extravasation			

subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Sensation of blood flow			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Breast pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	2 / 13 (15.38%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Cough			
subjects affected / exposed	4 / 13 (30.77%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	5	1	0
Pneumonitis			
subjects affected / exposed	2 / 13 (15.38%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Hypoxia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Dyspnoea			
subjects affected / exposed	4 / 13 (30.77%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	5	1	0
Pulmonary embolism			

subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	2 / 13 (15.38%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Atelectasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Emphysema			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pleural thickening			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pneumothorax			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract congestion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Mental status changes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Affective disorder			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Delirium			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Investigations			
Lipase increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	0	1	3
Alanine aminotransferase increased			
subjects affected / exposed	1 / 13 (7.69%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	1	1	2
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 13 (7.69%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	1	1	2
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 13 (7.69%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	1	2	4
Weight decreased			

subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Amylase increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Blood potassium increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Blood chloride decreased			
subjects affected / exposed	2 / 13 (15.38%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Blood albumin decreased			
subjects affected / exposed	3 / 13 (23.08%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	6	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
International normalised ratio increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			

subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blood magnesium decreased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blood creatine increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Blood calcium increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Blood urea increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Heart rate increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Neutrophil count increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Troponin T increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Procedural pain			

subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	2 / 13 (15.38%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Infusion related reaction			
subjects affected / exposed	3 / 13 (23.08%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Taste disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	1 / 13 (7.69%)	1 / 3 (33.33%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Brain oedema			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	0 / 13 (0.00%)	2 / 3 (66.67%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Restless legs syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	3 / 13 (23.08%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	5	0	2
Thrombocytopenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	4
Anaemia of malignant disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	5 / 13 (38.46%)	0 / 3 (0.00%)	3 / 9 (33.33%)
occurrences (all)	11	0	4
Splenic vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	5 / 13 (38.46%)	2 / 3 (66.67%)	3 / 9 (33.33%)
occurrences (all)	11	4	4
Vision blurred			
subjects affected / exposed	8 / 13 (61.54%)	2 / 3 (66.67%)	7 / 9 (77.78%)
occurrences (all)	18	4	10
Keratitis			

subjects affected / exposed	2 / 13 (15.38%)	1 / 3 (33.33%)	4 / 9 (44.44%)
occurrences (all)	17	2	8
Keratopathy			
subjects affected / exposed	2 / 13 (15.38%)	0 / 3 (0.00%)	4 / 9 (44.44%)
occurrences (all)	3	0	4
Punctate keratitis			
subjects affected / exposed	3 / 13 (23.08%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	5	1	0
Photophobia			
subjects affected / exposed	4 / 13 (30.77%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	5	0	1
Cataract			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Visual impairment			
subjects affected / exposed	3 / 13 (23.08%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	4	1	0
Eye pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	1	1	2
Vitreous floaters			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Asthenopia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Eye irritation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Foreign body sensation in eyes			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Corneal epithelial microcysts			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cornea verticillata			

subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Diplopia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Eye pruritus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Lacrimation increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Night blindness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	2 / 13 (15.38%)	1 / 3 (33.33%)	4 / 9 (44.44%)
occurrences (all)	2	1	5
Nausea			
subjects affected / exposed	3 / 13 (23.08%)	1 / 3 (33.33%)	2 / 9 (22.22%)
occurrences (all)	4	1	2
Diarrhoea			
subjects affected / exposed	2 / 13 (15.38%)	1 / 3 (33.33%)	3 / 9 (33.33%)
occurrences (all)	2	1	3
Dry mouth			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0

Abdominal pain upper			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Abdominal pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Dysphagia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Gastric haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Large intestinal obstruction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastric stenosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Stomatitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Oesophagitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Steatorrhoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Portal vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cholangitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Hyperkeratosis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	2 / 13 (15.38%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Milia			

subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pain of skin			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Micturition urgency			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Urinary tract pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 13 (0.00%)	1 / 3 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Arthralgia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Mixed connective tissue disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			

Pneumonia			
subjects affected / exposed	2 / 13 (15.38%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	3 / 13 (23.08%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	6	0	0
Hyponatraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Decreased appetite			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypomagnesaemia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 13 (15.38%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	2
Dehydration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hypernatraemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Vitamin D deficiency			
subjects affected / exposed	1 / 13 (7.69%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 3 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose Expansion - TNBC: IMGC936 6.0 mg/kg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vascular disorders			

Hypertension			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Embolism			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	2		
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Infusion site extravasation			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Sensation of blood flow			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Breast pain			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pulmonary embolism			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Wheezing subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Atelectasis subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Dysphonia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Dyspnoea exertional subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Emphysema subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Pleural thickening subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Pneumothorax subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Productive cough subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Lower respiratory tract congestion subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Psychiatric disorders			

Mental status changes			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Affective disorder			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Delirium			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Investigations			
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	2		
Weight decreased			

subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Blood bilirubin increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Amylase increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Blood potassium increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Blood creatinine increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Blood chloride decreased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Blood albumin decreased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Activated partial thromboplastin time prolonged				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Platelet count decreased				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
International normalised ratio increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Blood thyroid stimulating hormone increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Blood sodium decreased				

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood magnesium decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood creatine increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood calcium increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Bilirubin conjugated increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood urea increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Heart rate increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
C-reactive protein increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Neutrophil count increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Troponin T increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Procedural pain			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Infusion related reaction			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Myoclonus			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Taste disorder			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Dizziness			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Restless legs syndrome			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Anaemia of malignant disease			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	4		
Splenic vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Eye disorders			
Dry eye			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Vision blurred			
subjects affected / exposed	4 / 6 (66.67%)		
occurrences (all)	4		
Keratitis			

subjects affected / exposed	2 / 6 (33.33%)			
occurrences (all)	3			
Keratopathy				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Punctate keratitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Photophobia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Cataract				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Visual impairment				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Eye pain				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Vitreous floaters				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Asthenopia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Eye irritation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Foreign body sensation in eyes				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Corneal epithelial microcysts				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Cornea verticillata				

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Diplopia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Eye pruritus			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Lacrimation increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Night blindness			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Periorbital oedema			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Ocular hyperaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Nausea			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Dry mouth			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0			
Constipation subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1			
Dyspepsia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0			
Ascites subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0			
Abdominal pain subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 3			
Dysphagia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1			
Gastric haemorrhage subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1			
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0			
Large intestinal obstruction subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1			
Gastric stenosis subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1			
Oesophageal pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0			
Mesenteric vein thrombosis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0			

Stomatitis subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Oesophagitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Steatorrhoea subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Salivary hypersecretion subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Proctalgia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Hepatobiliary disorders Portal vein thrombosis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Cholangitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Skin and subcutaneous tissue disorders Hyperkeratosis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Dry skin subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Pruritus subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Rash subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Milia			

subjects affected / exposed occurrences (all) Dermatitis contact subjects affected / exposed occurrences (all) Pain of skin subjects affected / exposed occurrences (all) Hyperhidrosis subjects affected / exposed occurrences (all) Skin hyperpigmentation subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0		
Renal and urinary disorders Renal colic subjects affected / exposed occurrences (all) Micturition urgency subjects affected / exposed occurrences (all) Urinary tract pain subjects affected / exposed occurrences (all) Hydronephrosis subjects affected / exposed occurrences (all) Nephrolithiasis subjects affected / exposed occurrences (all) Haematuria subjects affected / exposed occurrences (all)	 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0		
Endocrine disorders Hypothyroidism			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Joint range of motion decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Mixed connective tissue disease			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Tendonitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Infections and infestations			

Pneumonia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
COVID-19 subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Hordeolum subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Skin infection subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Hyponatraemia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 2		
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Decreased appetite subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Hypomagnesaemia			

subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	3		
Hypoalbuminaemia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hypernatraemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 August 2020	Amendment 1
22 April 2021	Amendment 2
29 March 2022	Amendment 3

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported