Clinical trial results:
Safety and Efficacy of GEN3009 (DuoHexaBody®-CD37) in Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma - A First-in-Human, Open-label, Phase 1/2a Dose Escalation Trial With Dose Expansion Cohorts

Summary

EudraCT number	2019-002752-16
Trial protocol	DK ES NL FR BE
Global end of trial date	28 July 2023

Results information

Result version number	v1 (current)
This version publication date	02 June 2024
First version publication date	02 June 2024

Trial information

Trial identification

Sponsor protocol code	GCT3009-01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04358458
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Genmab A/S
Sponsor organisation address	Carl Jacobsens Vej 30, Valby, Denmark, 2500
Public contact	Medical Lead, Genmab, +45 7020 2728, regulatory@genmab.com
Scientific contact	Medical Lead, Genmab, +45 7020 2728, regulatory@genmab.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 July 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial is to determine the anti-tumor efficacy in subjects with Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma.

Protection of trial subjects:

All the participants will sign the informed consent form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 March 2020
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	Belgium: 2
Country: Number of subjects enrolled	Denmark: 7
Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	Spain: 10
Country: Number of subjects enrolled	United States: 21
Worldwide total number of subjects	46
EEA total number of subjects	25

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)	16
From 65 to 84 years	29

85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The study was conducted at investigative sites in Belgium, Denmark, Netherlands, Spain and the United States from 13 March 2020 to 28 July 2023.

Pre-assignment

Screening details:

This study was to be conducted in 2 parts; Part 1 was the dose-escalation phase and Part 2 was the expansion phase. However, due to early termination of the study, the sponsor decided not to conduct the expansion phase (Part 2).

Period 1

Period 1 title	Overall period (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	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)

Arm description:

Participants received GEN3009 Dose level A in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Arm type	Experimental
Investigational medicinal product name	GEN3009
Investigational medicinal product code	
Other name	DuoHexaBody®-CD37
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Arm title	Part 1: GEN3009 Dose Level B in S1

Arm description:

Participants received GEN3009 Dose level B in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Arm type	Experimental
Investigational medicinal product name	GEN3009
Investigational medicinal product code	
Other name	DuoHexaBody®-CD37
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Arm title	Part 1: GEN3009 Dose Level C in S1

Arm description:

Participants received GEN3009 Dose level C in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Arm type	Experimental

Investigational medicinal product name	GEN3009
Investigational medicinal product code	
Other name	DuoHexaBody®-CD37
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Arm title	Part 1: GEN3009 Dose Level D in S1

Arm description:

Participants received GEN3009 Dose level D in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at Cycle 1 Day 1 (C1D1) and the remaining amount at Day 2 (C1D2).

Arm type	Experimental
Investigational medicinal product name	GEN3009
Investigational medicinal product code	
Other name	DuoHexaBody®-CD37
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Arm title	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)

Arm description:

Participants received GEN3009 Dose level D in S2 (in US only) by IV infusion on Days 1, 4, 8, 11, 15, 18, 22 and 25 in cycles 1, Day 1, 8, 15 and 22 in Cycles 2-3, Day 1 and 15 in Cycles 4-9 and Day 1 starting Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. Participants received half of the full dose on Days 1, 4, 8, 11, 15, 18, 22, and 25 i.e. two half doses on Days 1 and 4 of each week for the first cycle.

Arm type	Experimental
Investigational medicinal product name	GEN3009
Investigational medicinal product code	
Other name	DuoHexaBody®-CD37
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Arm title	Part 1: GEN3009 Dose Level E in S1

Arm description:

Participants received GEN3009 Dose level E in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Arm type	Experimental
Investigational medicinal product name	GEN3009
Investigational medicinal product code	
Other name	DuoHexaBody®-CD37
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Arm title	Part 1: GEN3009 Dose Level F in S1

Arm description:

Participants received GEN3009 Dose level F in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Arm type	Experimental
Investigational medicinal product name	GEN3009
Investigational medicinal product code	
Other name	DuoHexaBody®-CD37
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Arm title	Part 1: GEN3009 Dose Level G in S1

Arm description:

Participants received GEN3009 Dose level G in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Arm type	Experimental
Investigational medicinal product name	GEN3009
Investigational medicinal product code	
Other name	DuoHexaBody®-CD37
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Number of subjects in period 1	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1
Started	3	4	7
Completed	0	0	0
Not completed	3	4	7
Consent withdrawn by subject	-	-	1
Death	1	1	3
Sponsor request	2	3	3
Site is closing study participation	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Part 1: GEN3009 Dose Level D in S1	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1
Started	10	3	10
Completed	0	0	0
Not completed	10	3	10

Consent withdrawn by subject	1	-	1
Death	8	1	6
Sponsor request	-	2	3
Site is closing study participation	1	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Started	3	6
Completed	0	0
Not completed	3	6
Consent withdrawn by subject	-	1
Death	2	3
Sponsor request	1	1
Site is closing study participation	-	-
Lost to follow-up	-	1

Baseline characteristics

Reporting groups

Reporting group title	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)

Reporting group description:

Participants received GEN3009 Dose level A in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Reporting group title	Part 1: GEN3009 Dose Level B in S1

Reporting group description:

Participants received GEN3009 Dose level B in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Reporting group title	Part 1: GEN3009 Dose Level C in S1

Reporting group description:

Participants received GEN3009 Dose level C in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Reporting group title	Part 1: GEN3009 Dose Level D in S1

Reporting group description:

Participants received GEN3009 Dose level D in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at Cycle 1 Day 1 (C1D1) and the remaining amount at Day 2 (C1D2).

Reporting group title	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)

Reporting group description:

Participants received GEN3009 Dose level D in S2 (in US only) by IV infusion on Days 1, 4, 8, 11, 15, 18, 22 and 25 in cycles 1, Day 1, 8, 15 and 22 in Cycles 2-3, Day 1 and 15 in Cycles 4-9 and Day 1 starting Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. Participants received half of the full dose on Days 1, 4, 8, 11, 15, 18, 22, and 25 i.e. two half doses on Days 1 and 4 of each week for the first cycle.

Reporting group title	Part 1: GEN3009 Dose Level E in S1

Reporting group description:

Participants received GEN3009 Dose level E in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Reporting group title	Part 1: GEN3009 Dose Level F in S1

Reporting group description:

Participants received GEN3009 Dose level F in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Reporting group title	Part 1: GEN3009 Dose Level G in S1

Reporting group description:

Participants received GEN3009 Dose level G in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Reporting group values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1
Number of subjects	3	4	7
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	65	54.5	74.6
standard deviation	± 3.46	± 8.81	± 8.68
Gender categorical Units: Subjects			
Female	2	1	2
Male	1	3	5
Ethnicity Units: Subjects			
Missing	0	2	5
Not Hispanic or Latino	2	2	2
Not Reported	1	0	0
Race Units: Subjects			
Black or African American	1	1	0
Missing	0	0	0
Not Reported	0	0	0
Other	0	0	0
White	2	3	7

Reporting group values	Part 1: GEN3009 Dose Level D in S1	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1
Number of subjects	10	3	10
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	67.1	63.3	69.4
standard deviation	± 9.89	± 16.86	± 10.23
Gender categorical Units: Subjects			
Female	2	0	2
Male	8	3	8
Ethnicity Units: Subjects			
Missing	4	0	8
Not Hispanic or Latino	6	3	0
Not Reported	0	0	2
Race Units: Subjects			
Black or African American	2	0	0
Missing	0	0	1

Not Reported	1	0	0
Other	0	0	1
White	7	3	8

Reporting group values	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1	Total
Number of subjects	3	6	46
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	70.3	60.8	
standard deviation	± 9.87	± 17.38	-
Gender categorical Units: Subjects			
Female	1	1	11
Male	2	5	35
Ethnicity Units: Subjects			
Missing	3	3	25
Not Hispanic or Latino	0	3	18
Not Reported	0	0	3
Race Units: Subjects			
Black or African American	0	1	5
Missing	0	0	1
Not Reported	0	0	1
Other	0	0	1
White	3	5	38

End points

End points reporting groups

Reporting group title	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)

Reporting group description:

Participants received GEN3009 Dose level A in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Reporting group title	Part 1: GEN3009 Dose Level B in S1

Reporting group description:

Participants received GEN3009 Dose level B in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Reporting group title	Part 1: GEN3009 Dose Level C in S1

Reporting group description:

Participants received GEN3009 Dose level C in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Reporting group title	Part 1: GEN3009 Dose Level D in S1

Reporting group description:

Participants received GEN3009 Dose level D in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at Cycle 1 Day 1 (C1D1) and the remaining amount at Day 2 (C1D2).

Reporting group title	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)

Reporting group description:

Participants received GEN3009 Dose level D in S2 (in US only) by IV infusion on Days 1, 4, 8, 11, 15, 18, 22 and 25 in cycles 1, Day 1, 8, 15 and 22 in Cycles 2-3, Day 1 and 15 in Cycles 4-9 and Day 1 starting Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. Participants received half of the full dose on Days 1, 4, 8, 11, 15, 18, 22, and 25 i.e. two half doses on Days 1 and 4 of each week for the first cycle.

Reporting group title	Part 1: GEN3009 Dose Level E in S1

Reporting group description:

Participants received GEN3009 Dose level E in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Reporting group title	Part 1: GEN3009 Dose Level F in S1

Reporting group description:

Participants received GEN3009 Dose level F in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Reporting group title	Part 1: GEN3009 Dose Level G in S1

Reporting group description:

Participants received GEN3009 Dose level G in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Primary: Number of Participants With Dose Limiting Toxicities (DLTs)

End point title	Number of Participants With Dose Limiting Toxicities (DLTs)[1]

End point description:

DLTs were graded according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0, except for TLS (Cairo-Bishop grading) and CRS/ICANS (Lee et al., 2019). These criteria include: all Grade 5 toxicities; hematologic events including thrombocytopenia Grade 4, neutropenia Grade 4, Febrile neutropenia Grade 3 or 4, Grade 3 or 4 hemorrhage associated with thrombocytopenia of ≥Grade 3, anemia of Grade 4 and tumor lysis syndrome (TLS) Grade 4; and non-hematologic AEs of Grade 3 or higher excluding certain fevers, hypotension, laboratory values, Aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT), nausea, vomiting, diarrhea, fatigue/asthenia, or alopecia (no grading), which meet certain additional criteria. The Safety analysis set included all participants who had received at least 1 dose of GEN3009.

End point type	Primary

End point timeframe:

During the first treatment cycle (Cycle length=28 days)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis was planned to be analysed.

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: participants	0	0	0	0

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: participants	0	0	0	3

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment Emergent Adverse Events (TEAEs) and Serious TEAEs

End point title	Number of Participants With Treatment Emergent Adverse Events (TEAEs) and Serious TEAEs[2]

End point description:

An AE is any untoward medical occurrence in a clinical trial participant, temporally associated with the

use of a medicinal product, whether or not considered related to the medicinal product. An SAE is defined as an AE that meets one of the following criteria: is fatal or life-threatening; results in persistent or significant disability/incapacity; constitutes a congenital anomaly/birth defect; is medically significant (an event that jeopardizes the participant or may require medical or surgical intervention to prevent one of the outcomes listed above [medical and scientific judgment must be exercised in deciding whether an AE is "medically significant"]); required inpatient hospitalization or prolongation of existing hospitalization. TEAEs are defined as AEs which begin, or worsen, during the on-treatment period ending 4 weeks after the last dose of study medication. The Safety analysis set included all participants who had received at least 1 dose of GEN3009.

End point type	Primary

End point timeframe:

From first dose until 30 days after the last dose (up to 15.5 months)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis was planned to be analysed.

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: participants				
Participants with TEAEs	3	4	7	10
Participants with Serious TEAEs	0	0	4	7

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: participants				
Participants with TEAEs	3	10	3	6
Participants with Serious TEAEs	2	4	2	4

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With AEs of Special Interest (AESI)

End point title	Number of Participants With AEs of Special Interest (AESI)[3]

End point description:

AESIs are defined as events (serious or non-serious) that are of scientific and medical concern specific to the sponsor's product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor may be appropriate. The Safety analysis set included all participants who had received at least 1 dose of GEN3009.

End point type	Primary

End point timeframe:

From first dose until 30 days after the last dose (up to 15.5 months)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis was planned to be analysed.

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: participants	1	1	7	9

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: participants	3	10	3	5

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Clinically Significant Laboratory Abnormalities Reported as TEAEs

End point title	Number of Participants With Clinically Significant Laboratory Abnormalities Reported as TEAEs[4]

End point description:

Laboratory parameters included hematology, serum chemistries and urinalysis. Clinically significant laboratory abnormalities were based upon the Investigator's discretion. Laboratory parameters captured as AEs are reported in this outcome measure. The Safety analysis set included all participants who had received at least 1 dose of GEN3009.

End point type	Primary

End point timeframe:

From first dose until 30 days after the last dose (up to 15.5 months)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis was planned to be analysed.

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: participants				
Blood creatinine increased	0	0	2	1
Blood alkaline phosphatase increased	0	0	1	0
Blood lactate dehydrogenase increased	0	0	1	0
Alanine aminotransferase increased	0	0	1	0
Aspartate aminotransferase increased	0	0	1	0
Blood creatine increased	0	0	0	0

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: participants				
Blood creatinine increased	0	0	0	1
Blood alkaline phosphatase increased	0	1	0	1
Blood lactate dehydrogenase increased	0	1	0	0
Alanine aminotransferase increased	0	0	0	0
Aspartate aminotransferase increased	0	0	0	0
Blood creatine increased	0	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Clinically Notable Vital Signs

End point title	Number of Participants With Clinically Notable Vital Signs[5]

End point description:

Criteria for clinically notable (elevated and below normal values respectively) vital signs are as follows: Systolic Blood Pressure (SBP): ≥180 millimeters of mercury (mmHg) and an increase ≥20 mmHg from baseline, ≤90 mmHg and a decrease ≥20 mmHg from baseline; Diastolic Blood Pressure (DBP): ≥105 mmHg and an increase ≥15 mmHg from baseline, ≤50 mmHg and a decrease ≥15 mmHg from baseline; Heart rate: ≥120 beats per minute (bpm) with an increase of ≥15 bpm from baseline, ≤50 bpm and a decrease ≥15 bpm from baseline; Temperature: > 38 degree Celsius (°C), and < 35°C. Number of participants with clinically notable elevated and below normal vital signs values up to end of treatment are reported. The Safety analysis set included all participants who had received at least 1 dose of GEN3009. 'Number of subjects analysed' indicates the number of participants with data available for outcome measure analysis.

End point type	Primary

End point timeframe:

From first dose up to end of treatment (up to 14.5 months)

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 descriptive analysis was planned to be analysed.

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	5	9
Units: participants				
SBP: Elevated	0	0	0	0
SBP: Below Normal	0	0	0	1
DBP: Elevated	0	0	0	0
DBP: Below Normal	0	0	0	0
Heart Rate: Elevated	0	0	0	0
Heart Rate: Below Normal	0	0	0	0
Temperature: Elevated	0	0	0	0
Temperature: Below Normal	0	0	0	0

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	2	5
Units: participants				
SBP: Elevated	0	0	0	0
SBP: Below Normal	0	2	0	1
DBP: Elevated	0	0	0	0
DBP: Below Normal	0	0	0	0
Heart Rate: Elevated	0	0	0	0
Heart Rate: Below Normal	0	0	0	0
Temperature: Elevated	0	0	0	0
Temperature: Below Normal	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Dose Delays and Dose Interruptions

End point title	Number of Participants With Dose Delays and Dose Interruptions[6]

End point description:

Number of participants with dose delays and dose Interruptions due to AE, Coronavirus disease 2019 (COVID-19), drug administration issues and un-specified reason are reported. The Safety analysis set included all participants who had received at least 1 dose of GEN3009.

End point type	Primary

End point timeframe:

From first dose until 30 days after the last dose (up to 15.5 months)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis was planned to be analysed.

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: participants				
Dose delay due to AE	0	0	4	1
Dose delay due to COVID-19	0	0	0	0
Dose delay due to un-specified reason	0	0	1	1
Dose interruption due to AE	0	1	7	9
Dose interruption due to Drug administration issue	1	0	0	0
Dose interruption due to un-specified reason	0	0	1	1

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: participants				
Dose delay due to AE	1	2	1	2
Dose delay due to COVID-19	0	0	0	0
Dose delay due to un-specified reason	0	1	1	0
Dose interruption due to AE	3	10	3	5
Dose interruption due to Drug administration issue	0	1	0	0
Dose interruption due to un-specified reason	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Actual Dose Intensity

End point title	Actual Dose Intensity[7]

End point description:

Actual dose intensity (milligrams per cycle [mg/cycle]) is calculated as cumulative dose/number of cycles initiated. The Safety analysis set included all participants who had received at least 1 dose of

GEN3009. 999 indicates that data was not evaluable at given time point. 9999 indicates that standard deviation was not estimable as there was only 1 participant. 'n' signifies the number of participants analysed at specific timepoint.

End point type	Primary

End point timeframe:

From first dose until 30 days after the last dose (up to 15.5 months)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis was planned to be analysed.

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: mg/cycle				
arithmetic mean (standard deviation)				
Cycle 1-3	114.67 (± 112.10)	720.00 (± 0.00)	1389.46 (± 278.91)	2501.53 (± 992.91)
Cycle 4-9 (n= 0, 1, 4, 1, 0, 1, 2, 0)	999 (± 999)	363.71 (± 9999)	799.71 (± 10.64)	1527.27 (± 9999)
Cycle 10-until end of study (n=0,0,1,0,0,0,0,0)	999 (± 999)	999 (± 999)	999 (± 999)	999 (± 999)

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: mg/cycle				
arithmetic mean (standard deviation)				
Cycle 1-3	2515.85 (± 1053.90)	3903.62 (± 1135.72)	5957.23 (± 766.90)	6973.78 (± 1072.58)
Cycle 4-9 (n= 0, 1, 4, 1, 0, 1, 2, 0)	999 (± 999)	2400.00 (± 9999)	2953.02 (± 349.28)	999 (± 999)
Cycle 10-until end of study (n=0,0,1,0,0,0,0,0)	999 (± 999)	318.94 (± 9999)	999 (± 999)	999 (± 999)

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Total Plasma Clearance (CL) of GEN3009

End point title	Apparent Total Plasma Clearance (CL) of GEN3009

End point description:

The pharmacokinetic analysis set (PAS) includes all participants who have been exposed to GEN3009 and have had at least one pharmacokinetic sample collected that has provided a valid bioanalytical

result.

End point type	Secondary

End point timeframe:

Pre-dose and 5 minutes post-dose on days 1, 2, 4 (S2 only), 8, 15, 22 and 2 hours (h) and 4h post-dose on days 1 and 2, 24h post-dose on day 2 and 72h post-dose on day 4 of Cycles 1 and 2 (Each cycle length=28 days)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[8]	0[9]	0[10]	0[11]
Units: milliliter per day (mL/day)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[8] - Data was not estimable because the values were below the lower limit of quantification (LLOQ).

[9] - Data was not estimable because the values were below the LLOQ.

[10] - Data was not estimable because the values were below the LLOQ.

[11] - Data was not estimable because the values were below the LLOQ.

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[12]	0[13]	0[14]	0[15]
Units: milliliter per day (mL/day)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[12] - Data was not estimable because the values were below the LLOQ.

[13] - Data was not estimable because the values were below the LLOQ.

[14] - Data was not estimable because the values were below the LLOQ.

[15] - Data was not estimable because the values were below the LLOQ.

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Distribution of GEN3009

End point title	Volume of Distribution of GEN3009

End point description:

Volume of distribution is measured in milliliters per cubic centimeters (mL/cm^3). The PAS includes all participants who have been exposed to GEN3009 and have had at least one pharmacokinetic sample collected that has provided a valid bioanalytical result.

End point type	Secondary

End point timeframe:

Pre-dose and 5 minutes post-dose on days 1, 2, 4 (S2 only), 8, 15, 22 and 2h and 4h post-dose on days 1 and 2, 24h post-dose on day 2 and 72h post-dose on day 4 of Cycles 1 and 2 (Each cycle length=28 days)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[16]	0[17]	0[18]	0[19]
Units: mL/cm^3				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[16] - Data was not estimable because the values were below the LLOQ.

[17] - Data was not estimable because the values were below the LLOQ.

[18] - Data was not estimable because the values were below the LLOQ.

[19] - Data was not estimable because the values were below the LLOQ.

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[20]	0[21]	0[22]	0[23]
Units: mL/cm^3				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[20] - Data was not estimable because the values were below the LLOQ.

[21] - Data was not estimable because the values were below the LLOQ.

[22] - Data was not estimable because the values were below the LLOQ.

[23] - Data was not estimable because the values were below the LLOQ.

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-Time Curve (AUC) From Time 0 to Day 7 of GEN3009

End point title	Area Under the Plasma Concentration-Time Curve (AUC) From Time 0 to Day 7 of GEN3009

End point description:

The PAS includes all participants who have been exposed to GEN3009 and had had at least one pharmacokinetic sample collected that has provided a valid bioanalytical result. 999 indicates that data was not evaluable at given time point. 9999 indicates that standard deviation was not estimable as there was only 1 participant. 'n' signifies the number of participants analysed in a specific cycle.

End point type	Secondary

End point timeframe:

Pre-dose and 5 minutes post-dose on days 1, 2 and 4 (S2 only); 2h and 4h post-dose on days 1 and 2, 24h post-dose on day 2 and 72h post-dose on day 4 of Cycles 1 and 2 (Each cycle length=28 days)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[24]	0[25]	7	10
Units: microgram*day per milliliter (ug*day/mL)				
arithmetic mean (standard deviation)				
Cycle 1 (n= 0, 0, 2, 1, 1, 2, 3, 3)	()	()	159.2796 (± 95.7330)	181.5966 (± 22.1333)
Cycle 2 (n= 0, 0, 1, 2, 0, 2, 3, 0)	()	()	132.6580 (± 9999)	159.3302 (± 22.1333)

Notes:

[24] - Data was not estimable because the values were below the LLOQ.

[25] - Data was not estimable because the values were below the LLOQ.

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: microgram*day per milliliter (ug*day/mL)				
arithmetic mean (standard deviation)				
Cycle 1 (n= 0, 0, 2, 1, 1, 2, 3, 3)	260.8704 (± 9999)	219.1863 (± 46.3749)	353.5017 (± 177.2169)	389.0321 (± 126.8407)
Cycle 2 (n= 0, 0, 1, 2, 0, 2, 3, 0)	999 (± 999)	159.3456 (± 98.0641)	363.4413 (± 190.0120)	999 (± 999)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC From Time 0 to Infinity (AUCinf) of GEN3009

End point title	AUC From Time 0 to Infinity (AUCinf) of GEN3009

End point description:

The PAS includes all participants who have been exposed to GEN3009 and have had at least one pharmacokinetic sample collected that has provided a valid bioanalytical result. 999 indicates that data was not evaluable at given time point. 9999 indicates that standard deviation was not estimable as there was only 1 participant. 'n' signifies the number of participants analysed in a specific cycle.

End point type	Secondary

End point timeframe:

Pre-dose and 5 minutes post-dose on days 1, 2, 4 (S2 only), 8, 15, 22 and 2 h and 4h post-dose on days 1 and 2, 24h post-dose on day 2 and 72h post-dose on day 4 of Cycles 1 and 2 (Each cycle length=28 days)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: ug*day/mL				
arithmetic mean (standard deviation)				
Cycle 1 (n= 2, 4, 6, 7, 2, 7, 3, 5)	6.0154 (± 3.8503)	56.3289 (± 22.4400)	136.8615 (± 72.7498)	163.9206 (± 52.0135)
Cycle 2 (n= 2, 3, 5, 4, 3, 5, 3, 0)	5.9939 (± 0.6498)	46.4191 (± 9.8966)	139.9286 (± 61.7235)	127.4566 (± 49.8017)

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: ug*day/mL				
arithmetic mean (standard deviation)				
Cycle 1 (n= 2, 4, 6, 7, 2, 7, 3, 5)	332.1408 (± 73.1435)	192.0412 (± 90.3476)	358.0010 (± 183.3857)	335.8745 (± 117.1831)
Cycle 2 (n= 2, 3, 5, 4, 3, 5, 3, 0)	957.4149 (± 1427.7939)	159.8668 (± 73.6559)	363.7766 (± 190.3613)	999 (± 999)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC From Time 0 to Time of Last Dose (AUClast) of GEN3009

End point title	AUC From Time 0 to Time of Last Dose (AUClast) of GEN3009

End point description:

The PAS includes all participants who have been exposed to GEN3009 and have had at least one pharmacokinetic sample collected that has provided a valid bioanalytical result. ‘n’ signifies the number of participants analysed in a specific cycle. 999 indicates that data was not evaluable at given time point. 9999 indicates that standard deviation was not estimable as there was only 1 participant.

End point type	Secondary

End point timeframe:

Pre-dose and 5 minutes post-dose on days 1, 2, 4 (S2 only), 8, 15, 22 and 2 h and 4h post-dose on days 1 and 2, 24h post-dose on day 2 and 72h post-dose on day 4 of Cycles 1 and 2 (Each cycle length=28 days)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: ug*day/mL				
arithmetic mean (standard deviation)				
Cycle 1 (n= 2, 4, 7, 8, 3, 9, 3, 6)	4.5524 (± 2.3467)	51.0701 (± 17.1901)	103.4129 (± 73.3627)	148.4079 (± 41.7750)
Cycle 2 (n= 2, 3, 5, 5, 3, 5, 3, 0)	4.4707 (± 1.3098)	45.0924 (± 9.1404)	121.5349 (± 53.0658)	103.5413 (± 61.7884)

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: ug*day/mL				
arithmetic mean (standard deviation)				
Cycle 1 (n= 2, 4, 7, 8, 3, 9, 3, 6)	467.9622 (± 283.7778)	150.7393 (± 96.0893)	353.5017 (± 177.2169)	327.1762 (± 109.9472)
Cycle 2 (n= 2, 3, 5, 5, 3, 5, 3, 0)	441.7798 (± 542.0539)	152.4631 (± 74.1040)	363.4413 (± 190.0120)	999 (± 999)

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax) of GEN3009

End point title	Maximum Observed Plasma Concentration (Cmax) of GEN3009

End point description:

The PAS includes all participants who have been exposed to GEN3009 and have had at least one pharmacokinetic sample collected that has provided a valid bioanalytical result. 999 indicates that data was not evaluable at given time point. 9999 indicates that standard deviation was not estimable as there was only 1 participant. 'n' signifies the number of participants analysed in a specific cycle.

End point type	Secondary

End point timeframe:

Pre-dose and 5 minutes post-dose on days 1, 2, 4 (S2 only), 8, 15, 22 and 2 h and 4h post-dose on days 1 and 2, 24h post-dose on day 2 and 72h post-dose on day 4 of Cycles 1 and 2 (Each cycle length=28 days)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: microgram per milliliter (ug/mL)				
arithmetic mean (standard deviation)				
Cycle 1 (n= 2, 4, 7, 8, 3, 9, 3, 6)	8.3000 (± 3.5355)	43.4000 (± 12.7674)	89.8714 (± 39.8257)	139.0000 (± 43.8341)
Cycle 2 (n= 2, 3, 5, 5, 3, 5, 3, 0)	8.1050 (± 3.6699)	46.1667 (± 2.7934)	118.4800 (± 29.9458)	147.4000 (± 52.7286)

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: microgram per milliliter (ug/mL)				
arithmetic mean (standard deviation)				
Cycle 1 (n= 2, 4, 7, 8, 3, 9, 3, 6)	363.0667 (± 460.6843)	144.4778 (± 79.0905)	317.3333 (± 51.4328)	352.6667 (± 58.5514)
Cycle 2 (n= 2, 3, 5, 5, 3, 5, 3, 0)	572.0000 (± 708.4659)	237.0000 (± 30.8869)	394.6667 (± 109.5871)	999 (± 999)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reach Cmax (Tmax) of GEN3009

End point title	Time to Reach Cmax (Tmax) of GEN3009

End point description:

The PAS includes all participants who have been exposed to GEN3009 and have had at least one pharmacokinetic sample collected that has provided a valid bioanalytical result. 999 indicates that data was not evaluable at given time point. 9999 indicates that standard deviation was not estimable as there was only 1 participant. 'n' signifies the number of participants analysed in a specific cycle.

End point type	Secondary

End point timeframe:

Pre-dose and 5 minutes post-dose on days 1, 2, 4 (S2 only), 8, 15, 22 and 2 h and 4h post-dose on days 1 and 2, 24h post-dose on day 2 and 72h post-dose on day 4 of Cycles 1 and 2 (Each cycle length=28 days)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: days				
arithmetic mean (standard deviation)				
Cycle 1 (n= 2, 4, 7, 8, 3, 9, 3, 6)	0.0765 (± 0.0120)	0.1490 (± 0.0957)	0.2084 (± 0.0553)	0.6039 (± 0.6768)
Cycle 2 (n= 2, 3, 5, 5, 3, 5, 3, 0)	0.0445 (± 0.0007)	0.1650 (± 0.1643)	0.1656 (± 0.0820)	0.2740 (± 0.3010)

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: days				
arithmetic mean (standard deviation)				
Cycle 1 (n= 2, 4, 7, 8, 3, 9, 3, 6)	1.2123 (± 1.5987)	0.5030 (± 0.2908)	1.3817 (± 0.0890)	1.2580 (± 0.0771)
Cycle 2 (n= 2, 3, 5, 5, 3, 5, 3, 0)	0.2030 (± 0.0346)	0.1620 (± 0.0595)	0.1983 (± 0.0535)	999 (± 999)

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Concentrations (Ctrough) of GEN3009

End point title	Trough Concentrations (Ctrough) of GEN3009

End point description:

The PAS includes all participants who have been exposed to GEN3009 and have had at least one pharmacokinetic sample collected that has provided a valid bioanalytical result.

End point type	Secondary

End point timeframe:

Pre-dose and 5 minutes post-dose on days 1, 2, 4 (S2 only), 8, 15, 22 and 2 h and 4h post-dose on days 1 and 2, 24h post-dose on day 2 and 72h post-dose on day 4 of Cycles 1 and 2 (Each cycle length=28 days)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[26]	0[27]	0[28]	0[29]
Units: µg/mL				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[26] - Data was not estimable because the values were below the LLOQ.

[27] - Data was not estimable because the values were below the LLOQ.

[28] - Data was not estimable because the values were below the LLOQ.

[29] - Data was not estimable because the values were below the LLOQ.

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[30]	0[31]	0[32]	0[33]
Units: µg/mL				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[30] - Data was not estimable because the values were below the LLOQ.

[31] - Data was not estimable because the values were below the LLOQ.

[32] - Data was not estimable because the values were below the LLOQ.

[33] - Data was not estimable because the values were below the LLOQ.

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal Elimination Half-Life (t 1/2) of GEN3009

End point title	Terminal Elimination Half-Life (t 1/2) of GEN3009

End point description:

The pharmacokinetic analysis set (PAS) includes all participants who have been exposed to GEN3009 and have had at least one pharmacokinetic sample collected that has provided a valid bioanalytical result.

End point type	Secondary

End point timeframe:

Pre-dose and 5 minutes post-dose on days 1, 2, 4 (S2 only), 8, 15, 22 and 2 h and 4h post-dose on days 1 and 2, 24h post-dose on day 2 and 72h post-dose on day 4 of Cycles 1 and 2 (Each cycle length=28 days)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[34]	0[35]	0[36]	0[37]
Units: days				

arithmetic mean (standard deviation)	()	()	()	()

Notes:

[34] - Data was not estimable because the values were below the LLOQ.

[35] - Data was not estimable because the values were below the LLOQ.

[36] - Data was not estimable because the values were below the LLOQ.

[37] - Data was not estimable because the values were below the LLOQ.

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[38]	0[39]	0[40]	0[41]
Units: days				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[38] - Data was not estimable because the values were below the LLOQ.

[39] - Data was not estimable because the values were below the LLOQ.

[40] - Data was not estimable because the values were below the LLOQ.

[41] - Data was not estimable because the values were below the LLOQ.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Positive Anti-drug Antibodies (ADAs)

End point title	Number of Participants With Positive Anti-drug Antibodies (ADAs)

End point description:

Venous blood samples will be collected for measurement of serum concentrations of ADAs. Number of participants with positive ADAs are reported in this outcome measure. The detection of ADAs was performed using validated, specific and sensitive Electrochemiluminescence Immunoassay (ECLIA) method. The immunogenicity analysis set included all participants who had received at least 1 dose of study drug and had a baseline and at least 1 evaluable on-treatment ADA sample.

End point type	Secondary

End point timeframe:

From first dose until 30 days after the last dose (up to 15.5 months)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	7	8
Units: participants	1	0	2	0

End point values	Part 1: GEN3009 Dose Level D in	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1

	Schedule 2 (S2)			
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	9	3	3
Units: participants	0	1	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DoR)

End point title	Duration of Response (DoR)

End point description:

DoR is defined as the time from the first documentation of objective tumor response [Complete response (CR) or Partial response (PR)] to the date of first disease progression (PD) or death as assessed by the investigator based on Lugano criteria for B-cell non-Hodgkin lymphoma (B-cell NHL) and International Workshop on Chronic Lymphocytic Leukemia (iwCLL) for chronic lymphocytic leukemia (CLL). Detailed definition of CR, PR and PD as per Lugano and iwCLL criteria in the protocol appendices. The Full analysis set (FAS) comprises all participants to whom study drug had been assigned and who had received at least 1 dose of GEN3009. 'Number of subjects analysed' signified participants who achieved CR or PR. 99999= Median and limits of CI not reached due to less number of participants with events. 0.9999 indicates "NA" which means that lower limit of CI not reached for Part 1: GEN3009 Dose Level G in S1.

End point type	Secondary

End point timeframe:

From date of first documented CR or PR up to disease progression or death (up to approximately 3 years 4 months)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[42]	0[43]	3	0[44]
Units: months				
median (confidence interval 95%)	(to)	(to)	15.9 (2.9 to 99999)	(to)

Notes:

[42] - No participant analysed for this arm group in this endpoint.

[43] - No participant analysed for this arm group in this endpoint.

[44] - No participant analysed for this arm group in this endpoint.

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	1
Units: months				
median (confidence interval 95%)	99999 (99999	1.4 (1.4 to	99999 (99999	4.1 (0.9999 to

to 99999)	99999)	to 99999)	99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response (TTR)

End point title	Time to Response (TTR)

End point description:

TTR: time from first dose of administration until date of first response as assessed by investigator based on Lugano criteria for B-cell NHL and iwCLL for CLL. It is derived for all participants who achieved PR or CR. Detailed definitions of CR and PR as per Lugano and iwCLL criteria in the protocol appendices. The FAS comprises all participants to whom study drug had been assigned and who had received at least 1 dose of GEN3009. 'Number of subjects analysed' indicates the number of participants who achieved CR or PR. 9999 indicates that standard deviation was not estimable as there was only 1 participant.

End point type	Secondary

End point timeframe:

From date of first documented CR or PR up to disease progression or death (up to approximately 3 years 4 months)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[45]	0[46]	3	0[47]
Units: months				
arithmetic mean (standard deviation)	()	()	1.3361 (± 0.1004)	()

Notes:

[45] - No participant analysed for this arm group in this endpoint.

[46] - No participant analysed for this arm group in this endpoint.

[47] - No participant analysed for this arm group in this endpoint.

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	1
Units: months				
arithmetic mean (standard deviation)	1.8727 (± 9999)	1.2704 (± 0.2138)	2.0370 (± 1.0222)	1.1828 (± 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS)

End point title	Progression-free Survival (PFS)

End point description:

PFS is defined as the time in days from Day 1 of Cycle 1 to the day of first documented PD, or the day of death due to any cause, whichever comes first as assessed by investigator based on Lugano Criteria for B-cell NHL and iwCLL for CLL. Detailed definitions of PD as per Lugano and iwCLL criteria in the protocol appendices. PFS was estimated using the Kaplan-Meier method. Overall number of subjects analysed=number of participants with data available. 99999= Median and limits of CI were not reached due to less number of participants with events. The FAS comprises all participants to whom study drug had been assigned and who had received at least 1 dose of GEN3009.

End point type	Secondary

End point timeframe:

From day of first dose until disease progression or death due to any cause (up to approximately 3 years 4 months)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: months				
median (confidence interval 95%)	1.4 (1.2 to 99999)	2.6 (1.3 to 99999)	4.3 (1.8 to 99999)	1.2 (1.0 to 4.0)

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: months				
median (confidence interval 95%)	2.3 (1.4 to 99999)	1.9 (0.2 to 3.4)	99999 (1.3 to 99999)	0.8 (0.4 to 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

The OS is defined as the time from the start of study treatment until death due to any cause. The OS

was estimated using Kaplan-Meier method. The FAS comprises all participants to whom study drug had been assigned and who had received at least 1 dose of GEN3009. Overall number of subjects analysed = number of participants with data available in this outcome measure. 99999 indicates that median and limits of CI not reached due to less number of participants with events.

End point type	Secondary

End point timeframe:

From day of first dose until disease progression or death due to any cause (up to approximately 3 years 4 months)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	10
Units: months				
median (confidence interval 95%)	99999 (19.1 to 99999)	99999 (5.2 to 99999)	99999 (1.8 to 99999)	10.9 (0.8 to 18.0)

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	3	6
Units: months				
median (confidence interval 95%)	99999 (14.0 to 99999)	13.7 (0.2 to 99999)	13.1 (7.0 to 99999)	6.6 (0.5 to 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)

End point description:

ORR: the percentage of participants who achieved a best overall response (BOR) of CR or PR as assessed by investigator based on Lugano Criteria for B-cell NHL and iwCLL for CLL. Detailed definitions of CR and PR as per Lugano and iwCLL criteria in the protocol appendices. The response evaluable set includes all participants in FAS who have baseline evaluable disease and had at least 1 post-baseline disease evaluation or died within 60 days of first trial treatment. Number of subjects analysed = number of participants with data available in this outcome measure.

End point type	Secondary

End point timeframe:

From day of first dose until disease progression or death due to any cause (up to approximately 3 years 4 months)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	7	8
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 70.8)	0 (0.0 to 70.8)	42.9 (9.9 to 81.6)	0 (0.0 to 36.9)

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	3	6
Units: percentage of participants				
number (confidence interval 95%)	33.3 (0.8 to 90.6)	37.5 (8.5 to 75.5)	66.7 (9.4 to 99.2)	16.7 (0.4 to 64.1)

Statistical analyses

No statistical analyses for this end point

Secondary: CR Rate

End point title	CR Rate

End point description:

CR rate was estimated using Clopper-Pearson method. Detailed definitions of CR as per Lugano and iwCLL criteria in the protocol appendices. Overall number of subjects analysed= number of participants with data available in this outcome measure. The Response Evaluable set includes all participants in FAS who have baseline evaluable disease and had at least 1 post-baseline disease evaluation or died within 60 days of first trial treatment.

End point type	Secondary

End point timeframe:

From day of first dose until disease progression or death due to any cause (up to approximately 3 years 4 months)

End point values	Part 1: GEN3009 Dose Level A in Schedule 1 (S1)	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1	Part 1: GEN3009 Dose Level D in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	7	8
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 70.8)	0 (0.0 to 70.8)	28.6 (3.7 to 71.0)	0 (0.0 to 36.9)

End point values	Part 1: GEN3009 Dose Level D in Schedule 2 (S2)	Part 1: GEN3009 Dose Level E in S1	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	3	6
Units: percentage of participants				
number (confidence interval 95%)	33.3 (0.8 to 90.6)	0 (0.0 to 36.9)	33.3 (0.8 to 90.6)	0 (0.0 to 45.9)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose until 30 days after the last dose (up to 15.5 months)

Adverse event reporting additional description:

The Safety analysis set included all participants who had received at least 1 dose of GEN3009.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Part 1: GEN3009 Dose Level A in S1

Reporting group description:

Participants received GEN3009 Dose level A in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Reporting group title	Part 1: GEN3009 Dose Level B in S1

Reporting group description:

Participants received GEN3009 Dose level B in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Reporting group title	Part 1: GEN3009 Dose Level C in S1

Reporting group description:

Participants received GEN3009 Dose level C in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study.

Reporting group title	Part 1: GEN3009 Dose Level D in S1

Reporting group description:

Participants received GEN3009 Dose level D in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Reporting group title	Part 1: GEN3009 Dose Level D in S2

Reporting group description:

Participants received GEN3009 Dose level D in S2 (in US only) by IV infusion on Days 1, 4, 8, 11, 15, 18, 22 and 25 in cycles 1, Day 1, 8, 15 and 22 in Cycles 2-3, Day 1 and 15 in Cycles 4-9 and Day 1 starting Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. Participants received half of the full dose on Days 1, 4, 8, 11, 15, 18, 22, and 25 i.e. two half doses on Days 1 and 4 of each week for the first cycle.

Reporting group title	Part 1: GEN3009 Dose Level E in S1

Reporting group description:

Participants received GEN3009 Dose level E in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Reporting group title	Part 1: GEN3009 Dose Level F in S1

Reporting group description:

Participants received GEN3009 Dose level F in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Reporting group title	Part 1: GEN3009 Dose Level G in S1

Reporting group description:

Participants received GEN3009 Dose level G in S1 by IV infusion on Days 1, 8, 15, and 22 in cycles 1-3, on Days 1 and 15 in cycles 4-9 and on Day 1 (every 4 weeks) in Cycle 10 until disease progression, unacceptable toxicity, death or end of trial. Each cycle was 28 days in this study. For cycle 1, participants received the dose split into 2 consecutive days. i.e., at C1D1 and the remaining amount at C1D2.

Serious adverse events	Part 1: GEN3009 Dose Level A in S1	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	4 / 7 (57.14%)
number of deaths (all causes)	1	1	3
number of deaths resulting from adverse events	0	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
COVID-19			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1: GEN3009 Dose Level D in S1	Part 1: GEN3009 Dose Level D in S2	Part 1: GEN3009 Dose Level E in S1
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 10 (70.00%)	2 / 3 (66.67%)	4 / 10 (40.00%)
number of deaths (all causes)	8	1	6
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
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			
Subdural haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			

subjects affected / exposed	3 / 10 (30.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Atrial fibrillation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
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			
Syncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (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
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (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
Febrile neutropenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (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
Pneumonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (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
Infections and infestations			
Paronychia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (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
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (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
Infection			

subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
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	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	4 / 6 (66.67%)	
number of deaths (all causes)	2	3	
number of deaths resulting from adverse events	0	0	

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Paronychia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Part 1: GEN3009 Dose Level A in S1	Part 1: GEN3009 Dose Level B in S1	Part 1: GEN3009 Dose Level C in S1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 4 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	3
Vein disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Feeling jittery			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site paraesthesia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Scrotal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Haemoptysis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood creatine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Ankle fracture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Scratch			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Infusion related reaction			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	7 / 7 (100.00%)
occurrences (all)	1	6	19
Congenital, familial and genetic disorders			
Dermoid cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Meralgia paraesthetica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Dizziness postural			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	3	1	5
Coordination abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocytosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	2 / 3 (66.67%)	4 / 4 (100.00%)	7 / 7 (100.00%)
occurrences (all)	8	10	36
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	3 / 7 (42.86%)
occurrences (all)	1	2	3
Lymphopenia			
subjects affected / exposed	2 / 3 (66.67%)	2 / 4 (50.00%)	3 / 7 (42.86%)
occurrences (all)	5	3	9
Leukopenia			
subjects affected / exposed	2 / 3 (66.67%)	2 / 4 (50.00%)	2 / 7 (28.57%)
occurrences (all)	7	3	10
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 4 (75.00%)	3 / 7 (42.86%)
occurrences (all)	0	4	10
Ear and labyrinth disorders			

Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Scleral haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Refractive amblyopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			

subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	3
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin atrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Urinary tract pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bone pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Cellulitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Rhinovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	3
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Hyperglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Steroid diabetes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypermagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1: GEN3009 Dose Level D in S1	Part 1: GEN3009 Dose Level D in S2	Part 1: GEN3009 Dose Level E in S1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 10 (90.00%)	3 / 3 (100.00%)	10 / 10 (100.00%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
Flushing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vein disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Orthostatic hypotension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	5
General disorders and administration site conditions			
Pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Injection site phlebitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 10 (30.00%)	0 / 3 (0.00%)	3 / 10 (30.00%)
occurrences (all)	4	0	3
Oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Pyrexia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Feeling jittery			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Infusion site paraesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Reproductive system and breast disorders			
Scrotal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Haemoptysis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
Dysphonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
CD4 lymphocytes decreased			

subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Contusion			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Vascular access complication			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	7 / 10 (70.00%)	3 / 3 (100.00%)	10 / 10 (100.00%)
occurrences (all)	14	4	19
Congenital, familial and genetic disorders			
Dermoid cyst			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Palpitations			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Anosmia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Tremor			

subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Meralgia paraesthetica			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Dizziness postural			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	1	2	0
Coordination abnormal			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Lymph node pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Lymphocytosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	9 / 10 (90.00%)	3 / 3 (100.00%)	7 / 10 (70.00%)
occurrences (all)	24	15	37

Anaemia			
subjects affected / exposed	4 / 10 (40.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	6	0	0
Lymphopenia			
subjects affected / exposed	3 / 10 (30.00%)	1 / 3 (33.33%)	2 / 10 (20.00%)
occurrences (all)	6	1	2
Leukopenia			
subjects affected / exposed	3 / 10 (30.00%)	0 / 3 (0.00%)	4 / 10 (40.00%)
occurrences (all)	9	0	10
Febrile neutropenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	6 / 10 (60.00%)	0 / 3 (0.00%)	6 / 10 (60.00%)
occurrences (all)	9	0	6
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Scleral haemorrhage			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Refractive amblyopia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Diplopia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Photophobia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			

subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Diarrhoea			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
Toothache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	2 / 10 (20.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	3	1	0
Constipation			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Dyspepsia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Gingival pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin atrophy			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
Pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Urinary tract pain			

subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Groin pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	2 / 3 (66.67%)	1 / 10 (10.00%)
occurrences (all)	0	2	1
Bone pain			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Arthralgia			

subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Pain in extremity			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Staphylococcal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	2 / 10 (20.00%)
occurrences (all)	0	1	2
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Candida infection			

subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 3 (33.33%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

Hypomagnesaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 3 (33.33%)	1 / 10 (10.00%)
occurrences (all)	1	3	1
Malnutrition			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	2 / 10 (20.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Steroid diabetes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 3 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Part 1: GEN3009 Dose Level F in S1	Part 1: GEN3009 Dose Level G in S1	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Vascular disorders			
Hypotension			
subjects affected / exposed	2 / 3 (66.67%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vein disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Orthostatic hypotension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	2	0	

Phlebitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Injection site phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	2 / 6 (33.33%)	
occurrences (all)	6	3	
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Asthenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Oedema peripheral			

subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Feeling jittery			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infusion site paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Scrotal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Dyspnoea			

subjects affected / exposed	2 / 3 (66.67%)	4 / 6 (66.67%)	
occurrences (all)	4	4	
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dysphonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood creatine increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural			

complications			
Ankle fracture			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Fall			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vascular access complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Scratch			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infusion related reaction			
subjects affected / exposed	2 / 3 (66.67%)	4 / 6 (66.67%)	
occurrences (all)	3	5	
Congenital, familial and genetic disorders			
Dermoid cyst			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Sinus tachycardia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	

Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Peripheral motor neuropathy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Anosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Meralgia paraesthetica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dizziness			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Dizziness postural			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
Coordination abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lymphocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Neutropenia			
subjects affected / exposed	3 / 3 (100.00%)	6 / 6 (100.00%)	
occurrences (all)	19	7	
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	
occurrences (all)	1	3	
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	2	
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	2	
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Scleral haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Refractive amblyopia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			

subjects affected / exposed	2 / 3 (66.67%)	1 / 6 (16.67%)	
occurrences (all)	2	1	
Abdominal pain upper			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	2	1	
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	
occurrences (all)	3	2	
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Alopecia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Skin atrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urinary tract pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urinary retention			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Bone pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	2	1	
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Staphylococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rhinovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cytomegalovirus infection reactivation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
COVID-19			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	2	
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypomagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	2	
Steroid diabetes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypermagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 July 2021	- Updated Assessments, section references, and timepoints updated for Dose Escalation and Dose Expansion GEN3009 monotherapy. - Revised to include details of new trial design including the rationale behind the design, dose and schedule rationale for GEN3009 monotherapy and GEN3009 +GEN3013 combination, and end of trial and end of treatment definitions.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The trial was terminated due to strategic evaluation of GEN3009 within context of Genmab’s portfolio, decision not based on any safety or regulatory concerns.

Notes: