Clinical trial results:
First-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate safety of GEN1044 in subjects with malignant solid tumors

Summary

EudraCT number	2019-003998-26
Trial protocol	DK ES FR
Global end of trial date	29 October 2021

Results information

Result version number	v1 (current)
This version publication date	01 November 2022
First version publication date	01 November 2022

Trial information

Trial identification

Sponsor protocol code	GCT1044-01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04424641
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Genmab
Sponsor organisation address	Kalvebod Brygge 43, Copenhagen V, Denmark, 1560
Public contact	Clinical Trial Information, Genmab, +45 7020 2728, clinicaltrials@genmab.com
Scientific contact	Clinical Trial Information, Genmab, +45 7020 2728, clinicaltrials@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	24 May 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 October 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study for dose-escalation part was to determine recommended phase 2 dose (RP2D) and to establish safety profile of GEN1044, and for expansion part it was to evaluate anti-tumor activity of GEN1044.

Protection of trial subjects:

The trial was conducted in accordance with the protocol and amendments, the International Council for Harmonisation E6 guideline for Good Clinical Practice, applicable local regulations, and ethical principles that have their origins in the Declaration of Helsinki. In addition, the trial was conducted in accordance with FDA 21 Code of Federal Regulations parts 312, 50, and 56, and the directive 2001/20/EC of the European Parliament.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 July 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 16
Country: Number of subjects enrolled	Denmark: 7
Country: Number of subjects enrolled	Israel: 3
Country: Number of subjects enrolled	United States: 11
Worldwide total number of subjects	37
EEA total number of subjects	23

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)	27
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 48 participants signed the informed consent form of whom 37 received study drug. The Safety Committee decided to stop enrollment during the dose-escalation part and therefore the expansion part of trial never started. Consequently, results are only available for the dose-escalation part.

Period 1

Period 1 title	Dose-escalation Part (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	GEN1044 Doses 0.3/3/3 mg

Arm description:

Participants with locally advanced or metastatic non-central nervous system (non-CNS) solid tumor(s) received intravenous (IV) infusion of GEN1044 weekly (0.3 mg on Cycle [C] 1 Day (D] 1 and 3 mg on C1D8 and C1D15) for the first 4 cycles (each cycle was 21 days), followed by every 3 weeks (Q3W) until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1044
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1044 was administered IV weekly (0.3 mg on C1D1 and 3 mg on C1D8 and C1D15) for the first 4 cycles (each cycle was 21 days), followed by every 3 weeks (Q3W) until the end of treatment.

Arm title	GEN1044 Doses 1/3/10 mg

Arm description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 10 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1044
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1044 was administered IV weekly (1 mg on C1D1, 3 mg on C1D8, and 10 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm title	GEN1044 Doses 1/3/30 mg

Arm description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm type	Experimental

Investigational medicinal product name	GEN1044
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1044 was administered IV weekly (1 mg on C1D1, 3 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm title	GEN1044 Doses 1/5/30 mg

Arm description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1044
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1044 was administered IV weekly (1 mg on C1D1, 5 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm title	GEN1044 Doses 1/10/30 mg

Arm description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 10 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1044
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1044 was administered IV weekly (1 mg on C1D1, 10 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm title	GEN1044 Doses 1/5/37.5 mg

Arm description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 37.5 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1044
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1044 was administered IV weekly (1 mg on C1D1, 5 mg on C1D8, and 37.5 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm title	GEN1044 Doses 1/5/45 mg

Arm description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 45 mg on C1D15) for the first 4 cycles (each cycle

was 21 days), followed by Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1044
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1044 was administered IV weekly (1 mg on C1D1, 5 mg on C1D8, and 45 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm title	GEN1044 Doses 1/3/60 mg

Arm description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 60 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1044
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1044 was administered IV weekly (1 mg on C1D1, 3 mg on C1D8, and 60 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Number of subjects in period 1	GEN1044 Doses 0.3/3/3 mg	GEN1044 Doses 1/3/10 mg	GEN1044 Doses 1/3/30 mg
Started	1	4	7
Completed	0	0	0
Not completed	1	4	7
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Death	1	2	3
Unspecified	-	-	1
Sponsor decision	-	2	3

Number of subjects in period 1	GEN1044 Doses 1/5/30 mg	GEN1044 Doses 1/10/30 mg	GEN1044 Doses 1/5/37.5 mg
Started	7	6	2
Completed	0	0	0
Not completed	7	6	2
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	-	1	-
Death	-	2	-
Unspecified	-	-	-
Sponsor decision	7	2	2

Number of subjects in period 1	GEN1044 Doses 1/5/45 mg	GEN1044 Doses 1/3/60 mg
Started	4	6
Completed	0	0
Not completed	4	6
Adverse event, serious fatal	1	-
Consent withdrawn by subject	-	-
Death	-	2
Unspecified	-	-
Sponsor decision	3	4

Baseline characteristics

Reporting groups	
Reporting group title	GEN1044 Doses 0.3/3/3 mg
Reporting group description:	
Participants with locally advanced or metastatic non-central nervous system (non-CNS) solid tumor(s) received intravenous (IV) infusion of GEN1044 weekly (0.3 mg on Cycle [C] 1 Day (D] 1 and 3 mg on C1D8 and C1D15) for the first 4 cycles (each cycle was 21 days), followed by every 3 weeks (Q3W) until the end of treatment.	
Reporting group title	GEN1044 Doses 1/3/10 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 10 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/3/30 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/5/30 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/10/30 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 10 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/5/37.5 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 37.5 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/5/45 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 45 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/3/60 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 60 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	

Reporting group values	GEN1044 Doses 0.3/3/3 mg	GEN1044 Doses 1/3/10 mg	GEN1044 Doses 1/3/30 mg
Number of subjects	1	4	7
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	1	5
From 65-84 years	0	3	2
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	1	2	3
Male	0	2	4

Reporting group values	GEN1044 Doses 1/5/30 mg	GEN1044 Doses 1/10/30 mg	GEN1044 Doses 1/5/37.5 mg
Number of subjects	7	6	2
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	5	2
From 65-84 years	2	1	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	3	4	1
Male	4	2	1

Reporting group values	GEN1044 Doses 1/5/45 mg	GEN1044 Doses 1/3/60 mg	Total
Number of subjects	4	6	37
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	5	27
From 65-84 years	1	1	10
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	2	3	19
Male	2	3	18

End points

End points reporting groups

Reporting group title	GEN1044 Doses 0.3/3/3 mg
Reporting group description:	
Participants with locally advanced or metastatic non-central nervous system (non-CNS) solid tumor(s) received intravenous (IV) infusion of GEN1044 weekly (0.3 mg on Cycle [C] 1 Day (D] 1 and 3 mg on C1D8 and C1D15) for the first 4 cycles (each cycle was 21 days), followed by every 3 weeks (Q3W) until the end of treatment.	
Reporting group title	GEN1044 Doses 1/3/10 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 10 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/3/30 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/5/30 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/10/30 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 10 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/5/37.5 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 37.5 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/5/45 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 45 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	
Reporting group title	GEN1044 Doses 1/3/60 mg
Reporting group description:	
Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 60 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.	

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

End point title	Number of Participants With Dose Limiting Toxicities (DLTs)[1]
End point description:	
The DLT was defined as Grade (G) >= 3 cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome; any G3 or 4 hematologic and non-hematologic toxicity (with exceptions defined by the protocol); laboratory abnormality that required clinically significant medical intervention, led to hospitalization, persisted for >1 week, or resulted in a drug-induced liver injury; G3 or 4 febrile neutropenia; liver toxicity defined by Hy's law; any treatment-related toxicity that caused treatment discontinuation during Cycle 1; or any G5 toxicity. Dose-determining set (DDS) included all participants who received at least 1 dose of study drug during the dose-escalation part, and who met the minimum	

exposure criterion and had sufficient safety evaluations or experienced a DLT during the first 21 days of dosing.

End point type	Primary

End point timeframe:

From Day 1 to Day 21 of first cycle

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

End point values	GEN1044 Doses 0.3/3/3 mg	GEN1044 Doses 1/3/10 mg	GEN1044 Doses 1/3/30 mg	GEN1044 Doses 1/5/30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	4	4	3
Units: Participants	0	0	0	0

End point values	GEN1044 Doses 1/10/30 mg	GEN1044 Doses 1/5/37.5 mg	GEN1044 Doses 1/5/45 mg	GEN1044 Doses 1/3/60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	0[2]	3	4
Units: Participants	1		3	3

Notes:

[2] - No participant was analysed in DDS for this arm.

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of Participants With Treatment Emergent Adverse Events (TEAEs) and Treatment Emergent Serious Adverse Events (TESAEs)[3]

End point description:

An adverse event (AE) is any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. An SAE is defined as an AE that meets one of following criteria: fatal or life-threatening; results in persistent or significant disability/incapacity; constitutes a congenital anomaly/birth defect; medically significant (an AE that jeopardizes the participant or may require medical/ 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. A TEAE is defined as an AE occurring or worsening between the first dose of GEN1044 and 30 days after the last dose received. The safety set was analysed which included all participants who received at least 1 dose of study drug. Participants were classified according to the assigned dose level cohort.

End point type	Primary

End point timeframe:

Day 1 through Day 263 (corresponding to maximum observed duration)

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

End point values	GEN1044 Doses 0.3/3/3 mg	GEN1044 Doses 1/3/10 mg	GEN1044 Doses 1/3/30 mg	GEN1044 Doses 1/5/30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	4	7	7
Units: Participants				
Any TEAE	1	4	7	7
Any TESAE	1	1	3	5

End point values	GEN1044 Doses 1/10/30 mg	GEN1044 Doses 1/5/37.5 mg	GEN1044 Doses 1/5/45 mg	GEN1044 Doses 1/3/60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	2	4	6
Units: Participants				
Any TEAE	6	2	4	6
Any TESAE	4	1	3	5

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Grade >= 3 Laboratory Results

End point title	Number of Participants With Grade >= 3 Laboratory Results[4]

End point description:

Number of participants with laboratory measurements of Grade >= 3 by NCI-CTCAE v5.0 are reported. The NCI-CTCAE is a descriptive terminology is used for AE reporting. The NCI-CTCAE v4.03 displays Grades 1 through 5 with unique clinical descriptions of severity for each AE. Based on this general guideline: Grade 1 as mild AE, Grade 2 as moderate AE, Grade 3 as severe AE, Grade 4 as life-threatening or disabling AE, and Grade 5 as death. In case a participant reported multiple severity grades for an AE, only the maximum grade was used. The safety set was analysed which included all participants who received at least 1 dose of study drug. Participants were classified according to the assigned dose level cohort.

End point type	Primary

End point timeframe:

Day 1 through Day 263 (corresponding to maximum observed duration)

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

End point values	GEN1044 Doses 0.3/3/3 mg	GEN1044 Doses 1/3/10 mg	GEN1044 Doses 1/3/30 mg	GEN1044 Doses 1/5/30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	4	7	7
Units: Participants				
Lymphocyte count decreased	1	4	7	4
Lipase increased	0	0	1	1
Serum amylase increased	0	0	1	1

Hypomagnesemia	0	0	0	0
Creatinine increased	0	0	0	1
Anemia	0	1	0	0
Hypokalemia	0	1	0	0
Hypoalbuminemia	0	0	0	0
Blood bilirubin increased	0	0	1	0
Gamma-glutamyl transferase increased	1	0	0	0
Hypermagnesemia	0	0	0	0
Platelet count decreased	0	0	0	0

End point values	GEN1044 Doses 1/10/30 mg	GEN1044 Doses 1/5/37.5 mg	GEN1044 Doses 1/5/45 mg	GEN1044 Doses 1/3/60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	2	4	6
Units: Participants				
Lymphocyte count decreased	5	2	2	6
Lipase increased	0	1	2	2
Serum amylase increased	1	1	1	1
Hypomagnesemia	1	0	2	0
Creatinine increased	0	0	1	0
Anemia	0	0	0	1
Hypokalemia	0	0	1	0
Hypoalbuminemia	1	0	0	0
Blood bilirubin increased	0	0	0	0
Gamma-glutamyl transferase increased	0	0	0	0
Hypermagnesemia	0	0	0	1
Platelet count decreased	0	0	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Complete Response (CR) or Partial Response (PR)

End point title	Number of Participants With Complete Response (CR) or Partial Response (PR)

End point description:

The radiological evaluation based on Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) was performed by investigator using computed tomography (CT) scan/ magnetic resonance imaging (MRI) scan/ positron emission tomography (PET) scan. The CR was defined as disappearance of all target and non-target lesions and all pathological lymph nodes must have decreased to < 10 mm in short axis. The PR was defined as at least a 30% decrease in the sum of the longest diameters of target lesions taking as reference the baseline sum of longest diameters. The full analysis set was analysed which included all participants who received at least 1 dose of study drug. Participants were classified according to the assigned dose level cohort.

End point type	Secondary

End point timeframe:

Day 1 through Day 233 (corresponding to maximum observed duration)

End point values	GEN1044 Doses 0.3/3/3 mg	GEN1044 Doses 1/3/10 mg	GEN1044 Doses 1/3/30 mg	GEN1044 Doses 1/5/30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	4	7	7
Units: Participants				
Complete response	0	0	0	0
Partial response	0	0	0	0

End point values	GEN1044 Doses 1/10/30 mg	GEN1044 Doses 1/5/37.5 mg	GEN1044 Doses 1/5/45 mg	GEN1044 Doses 1/3/60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	2	4	6
Units: Participants				
Complete response	0	0	0	0
Partial response	0	0	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Antidrug Antibodies (ADAs) Positive to GEN1044

End point title	Number of Participants With Antidrug Antibodies (ADAs) Positive to GEN1044

End point description:

The detection and titer characterization of ADAs was performed using validated, specific, and sensitive electrochemiluminescence immunoassay (ECLIA) methods. Number of participants with ADA positive post baseline to GEN1044 are reported. Immunogenicity analysis set was analysed which included all participants who received at least 1 dose of study drug and had evaluable immunogenicity samples.

End point type	Secondary

End point timeframe:

Day 1 through Day 263 (predose on Day 1 of Cycles 1, 2, 3, 5, 7, and then on Day 1 of every 4 cycles thereafter, end of treatment [EOT], and 30 days after last study drug)

End point values	GEN1044 Doses 0.3/3/3 mg	GEN1044 Doses 1/3/10 mg	GEN1044 Doses 1/3/30 mg	GEN1044 Doses 1/5/30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	4	7	3
Units: Participants	0	3	2	1

End point values	GEN1044 Doses 1/10/30 mg	GEN1044 Doses 1/5/37.5 mg	GEN1044 Doses 1/5/45 mg	GEN1044 Doses 1/3/60 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	2	4	4
Units: Participants	0	0	1	1

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

For AEs: Day 1 through Day 263 (corresponding to maximum observed duration); For All-cause mortality: From date of inform consent form until death

Adverse event reporting additional description:

The AEs were evaluated per the safety set. The safety set was analysed which included all participants who received at least 1 dose of study drug. Participants were classified according to the assigned dose level cohort.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	GEN1044 doses 0.3/3/3 mg

Reporting group description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (0.3 mg on C1D1 and 3 mg on C1D8 and C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Reporting group title	GEN1044 doses 1/3/10 mg

Reporting group description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 10 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Reporting group title	GEN1044 doses 1/3/30 mg

Reporting group description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Reporting group title	GEN1044 doses 1/5/30 mg

Reporting group description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Reporting group title	GEN1044 doses 1/10/30 mg

Reporting group description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 10 mg on C1D8, and 30 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Reporting group title	GEN1044 doses 1/5/37.5 mg

Reporting group description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 37.5 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Reporting group title	GEN1044 doses 1/5/45 mg

Reporting group description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 5 mg on C1D8, and 45 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Reporting group title	GEN1044 doses 1/3/60 mg

Reporting group description:

Participants with locally advanced or metastatic non-CNS solid tumor(s) received an IV infusion of GEN1044 weekly (1 mg on C1D1, 3 mg on C1D8, and 60 mg on C1D15) for the first 4 cycles (each cycle was 21 days), followed by Q3W until the end of treatment.

Serious adverse events	GEN1044 doses 0.3/3/3 mg	GEN1044 doses 1/3/10 mg	GEN1044 doses 1/3/30 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	1 / 4 (25.00%)	3 / 7 (42.86%)
number of deaths (all causes)	1	2	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour Associated Fever			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 1 (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
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 1 (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
General Physical Health Deterioration			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine Release Syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	10 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleural Effusion			

subjects affected / exposed	0 / 1 (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
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet Count Decreased			
subjects affected / exposed	0 / 1 (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			
Atrial Fibrillation			
subjects affected / exposed	0 / 1 (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 Flutter			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 1 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 1 (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 / 1 (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
Diarrhoea			
subjects affected / exposed	0 / 1 (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
Vomiting			
subjects affected / exposed	0 / 1 (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
Skin and subcutaneous tissue disorders			
Dermatitis Exfoliative Generalised			
subjects affected / exposed	0 / 1 (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
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 1 (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
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 1 (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

Serious adverse events	GEN1044 doses 1/5/30 mg	GEN1044 doses 1/10/30 mg	GEN1044 doses 1/5/37.5 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)	4 / 6 (66.67%)	1 / 2 (50.00%)
number of deaths (all causes)	0	4	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour Associated Fever			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General Physical Health Deterioration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Immune system disorders			
Cytokine Release Syndrome			
subjects affected / exposed	3 / 7 (42.86%)	3 / 6 (50.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	13 / 13	9 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleural Effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet Count Decreased			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
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			
Atrial Fibrillation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (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
Atrial Flutter			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
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	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	6 / 6	1 / 1	6 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis Exfoliative Generalised			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
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	GEN1044 doses 1/5/45 mg	GEN1044 doses 1/3/60 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	5 / 6 (83.33%)	
number of deaths (all causes)	1	2	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour Associated Fever			
subjects affected / exposed	0 / 4 (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	
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 4 (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	
General disorders and administration			

site conditions			
Fatigue			
subjects affected / exposed	0 / 4 (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	
General Physical Health Deterioration			
subjects affected / exposed	0 / 4 (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	
Immune system disorders			
Cytokine Release Syndrome			
subjects affected / exposed	2 / 4 (50.00%)	3 / 6 (50.00%)	
occurrences causally related to treatment / all	9 / 9	9 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pleural Effusion			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	1 / 4 (25.00%)	2 / 6 (33.33%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	1 / 1	0 / 0	
Investigations			
Platelet Count Decreased			
subjects affected / exposed	0 / 4 (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	
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	0 / 4 (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 Flutter			

subjects affected / exposed	0 / 4 (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			
Dizziness			
subjects affected / exposed	1 / 4 (25.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	3 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 4 (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	
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 4 (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	
Skin and subcutaneous tissue disorders			
Dermatitis Exfoliative Generalised			
subjects affected / exposed	0 / 4 (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	
Renal and urinary disorders			
Acute Kidney Injury			

subjects affected / exposed	0 / 4 (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	
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	GEN1044 doses 0.3/3/3 mg	GEN1044 doses 1/3/10 mg	GEN1044 doses 1/3/30 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	4 / 4 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour Pain			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot Flush			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	2 / 7 (28.57%)
occurrences (all)	0	1	5
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	4 / 4 (100.00%)	4 / 7 (57.14%)
occurrences (all)	0	7	8
General Physical Health Deterioration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac Chest Pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	2 / 7 (28.57%)
occurrences (all)	0	3	2
Oedema Peripheral			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Ulcer			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Cytokine Release Syndrome			
subjects affected / exposed	1 / 1 (100.00%)	3 / 4 (75.00%)	2 / 7 (28.57%)
occurrences (all)	4	10	6
Reproductive system and breast disorders			
Vaginal Haemorrhage			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	4	1
Oropharyngeal Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Amylase Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood Bilirubin Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood Creatine Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
C-reactive Protein Increased			

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT Prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
International Normalised Ratio Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet Count Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Infusion Related Reaction			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	2 / 7 (28.57%)
occurrences (all)	0	1	3
Overdose			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Dysarthria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 1 (100.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Presyncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Eye disorders			
Vision Blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Abdominal Pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Constipation			
subjects affected / exposed	1 / 1 (100.00%)	1 / 4 (25.00%)	2 / 7 (28.57%)
occurrences (all)	1	2	4
Diarrhoea			

subjects affected / exposed	1 / 1 (100.00%)	4 / 4 (100.00%)	6 / 7 (85.71%)
occurrences (all)	1	7	23
Dry Mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	1 / 1 (100.00%)	3 / 4 (75.00%)	5 / 7 (71.43%)
occurrences (all)	1	4	9
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	3 / 4 (75.00%)	5 / 7 (71.43%)
occurrences (all)	0	8	10
Skin and subcutaneous tissue disorders			
Dermatitis Exfoliative Generalised			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Hyperhidrosis			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nail Disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Palmar-plantar Erythrodysaesthesia Syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prurigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rash Maculo-papular			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rash Pruritic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back Pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Bone Pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Muscular Weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Infections and infestations			
Candida Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Clostridium Difficile Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nail Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			

subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	3 / 7 (42.86%)
occurrences (all)	0	3	3
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperphosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	GEN1044 doses 1/5/30 mg	GEN1044 doses 1/10/30 mg	GEN1044 doses 1/5/37.5 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	6 / 6 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Flushing			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Hot Flush			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotension			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	1 / 2 (50.00%)
occurrences (all)	4	1	2
Chills			
subjects affected / exposed	2 / 7 (28.57%)	3 / 6 (50.00%)	1 / 2 (50.00%)
occurrences (all)	2	3	2
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	4 / 6 (66.67%)	1 / 2 (50.00%)
occurrences (all)	0	7	1
General Physical Health Deterioration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Non-cardiac Chest Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 7 (0.00%)	4 / 6 (66.67%)	0 / 2 (0.00%)
occurrences (all)	0	5	0
Pyrexia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine Release Syndrome			
subjects affected / exposed	3 / 7 (42.86%)	3 / 6 (50.00%)	2 / 2 (100.00%)
occurrences (all)	4	14	4
Reproductive system and breast disorders			

Vaginal Haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Amylase Increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Aspartate Aminotransferase Increased			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Blood Bilirubin Increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Blood Creatine Increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Blood Creatinine Increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
C-reactive Protein Increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT Prolonged			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
International Normalised Ratio Increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lipase Increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Platelet Count Decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Infusion Related Reaction			
subjects affected / exposed	3 / 7 (42.86%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Overdose			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Dysarthria			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	2
Presyncope			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Vision Blurred			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Constipation			

subjects affected / exposed	0 / 7 (0.00%)	3 / 6 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Diarrhoea			
subjects affected / exposed	4 / 7 (57.14%)	5 / 6 (83.33%)	1 / 2 (50.00%)
occurrences (all)	15	13	2
Dry Mouth			
subjects affected / exposed	0 / 7 (0.00%)	3 / 6 (50.00%)	1 / 2 (50.00%)
occurrences (all)	0	3	2
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 7 (57.14%)	4 / 6 (66.67%)	1 / 2 (50.00%)
occurrences (all)	6	6	1
Stomatitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	2 / 7 (28.57%)	5 / 6 (83.33%)	0 / 2 (0.00%)
occurrences (all)	4	11	0
Skin and subcutaneous tissue disorders			
Dermatitis Exfoliative Generalised			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dry Skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Nail Disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar Erythrodysaesthesia Syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Petechiae			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Prurigo			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rash Maculo-papular			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rash Pruritic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Back Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bone Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscular Weakness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Osteoarthritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Candida Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Clostridium Difficile Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nail Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin Infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 7 (0.00%)	5 / 6 (83.33%)	0 / 2 (0.00%)
occurrences (all)	0	6	0
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hyperphosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	1 / 2 (50.00%)
occurrences (all)	0	2	5
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	GEN1044 doses 1/5/45 mg	GEN1044 doses 1/3/60 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	5 / 6 (83.33%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	

Hot Flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	3	
Chills			
subjects affected / exposed	2 / 4 (50.00%)	2 / 6 (33.33%)	
occurrences (all)	3	3	
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)	1 / 6 (16.67%)	
occurrences (all)	3	2	
General Physical Health Deterioration			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Non-cardiac Chest Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oedema Peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	3	
Ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			

Cytokine Release Syndrome			
subjects affected / exposed	2 / 4 (50.00%)	4 / 6 (66.67%)	
occurrences (all)	4	14	
Reproductive system and breast disorders			
Vaginal Haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Dyspnoea			
subjects affected / exposed	2 / 4 (50.00%)	2 / 6 (33.33%)	
occurrences (all)	6	5	
Oropharyngeal Pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Pneumothorax			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Amylase Increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood Bilirubin Increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood Creatine Increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	2	
Blood Creatinine Increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
C-reactive Protein Increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Electrocardiogram QT Prolonged			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
International Normalised Ratio Increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Lipase Increased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 6 (16.67%)	
occurrences (all)	2	2	
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Platelet Count Decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Weight Decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	2	
Injury, poisoning and procedural complications			
Infusion Related Reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Overdose			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dysarthria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	1 / 4 (25.00%)	2 / 6 (33.33%)	
occurrences (all)	1	5	
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	3	
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Vision Blurred			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abdominal Pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	2	
Diarrhoea			
subjects affected / exposed	4 / 4 (100.00%)	4 / 6 (66.67%)	
occurrences (all)	15	12	
Dry Mouth			
subjects affected / exposed	0 / 4 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	3	
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	2	
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	3 / 4 (75.00%)	5 / 6 (83.33%)	
occurrences (all)	6	10	
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	4 / 4 (100.00%)	4 / 6 (66.67%)	
occurrences (all)	8	8	
Skin and subcutaneous tissue disorders			
Dermatitis Exfoliative Generalised			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dry Skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Erythema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nail Disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Palmar-plantar Erythrodysaesthesia Syndrome			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Petechiae			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Prurigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rash Maculo-papular			
subjects affected / exposed	3 / 4 (75.00%)	1 / 6 (16.67%)	
occurrences (all)	4	1	
Rash Pruritic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Haematuria			

subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Back Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Bone Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Muscular Weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Osteoarthritis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Pain in Extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Candida Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Clostridium Difficile Infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nail Infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Skin Infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 4 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	3	
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperphosphataemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Hypokalaemia			
subjects affected / exposed	1 / 4 (25.00%)	2 / 6 (33.33%)	
occurrences (all)	2	2	
Hypomagnesaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Hyponatraemia			
subjects affected / exposed	0 / 4 (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
10 January 2020	Removed duplicate hematology and biochemistry samples collected for analysis by the central laboratory. Added clarification on which laboratory tests were to be performed by the trial center's local laboratory and which were to be performed by a central laboratory.
03 April 2020	Incorporated Health Authority (Food and Drug Administration) feedback that recommended the following: Modified the inclusion criteria for the prostate cohort, the squamous cell carcinoma of the head and neck cohort, and the non-small cell lung cancer cohort. Relaxed the inclusion criteria to include participants with moderate renal and hepatic impairment. Excluded participants with a marked baseline prolongation of QT/corrected QT interval using Fridericia's QT correction formula. Added pharmacokinetics (PK) collection time points. Clarified the dose administration text. Modified the dose-escalation plan for single-participant cohorts. Lowered the starting dose to 0.3 mg, which was predicted to result in a human maximum observed serum concentration more consistent with half maximal effective concentration values for cytotoxicity in pharmacology studies. Revised the DLT criteria. Revised the protocol to permanently discontinue treatment for any DLT during the dose-escalation part, and for any Grade 3 or 4 cytokine release syndrome (CRS) event during expansion. Provided dose modification guidelines for various toxicities. Provided clinical treatment guidelines for CRS management. Added hepatitis B surface antigen to the required safety laboratory tests and modified exclusion criterion to add a positive hepatitis B surface antigen result as exclusionary. Clarified various statistical sections.
30 March 2021	Updated the visit evaluation schedules tables. Adjusted PK, antidrug antibody, and electrocardiogram sampling schedules. Adjusted the biomarker schedules tables. Clarified the expansion endpoints for the exploratory objective for pharmacodynamics and potential biomarkers. Adjusted inclusion criteria to clarify the number of prior systemic treatments allowed, by cancer type, for the expansion, acceptable liver function for dose-escalation and expansion parts, and tumor biopsy requirements for dose-escalation and expansion parts. Adjusted exclusion criteria to add clarification for SARS-CoV-2 vaccination, add criterion for treatment with chimeric antigen receptor T cells, and clarify on allergic reactions. Added clarification that rescreening may only have been performed once. Updated the details on the management of CRS. Prohibited SARS-CoV-2 vaccine administration during the DLT assessment period. Added clarification on the DLT period and DLT criteria for dose-escalation as well as on the dose modification guidance and safety stopping criteria for the dose-escalation and expansion parts. Updated instructions and clarification for imaging scans, added clarifications on requirements for pregnancy testing, and updated the tests to be performed by a central laboratory. Added clarifications on biomarker assessments and the requirements for tumor biopsy. Updated AEs of special interest section to include immune effector cell associated neurotoxicity syndrome and added details for this in a new section as well as an appendix detailing management thereof.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date

29 September 2021	Upon review and evaluation of the overall safety profile and safety signals of GEN1044 during the Dose-escalation part, the Safety Committee decided to stop further enrollment and Genmab decided to stop the compound development.	-

Notes:

Limitations and caveats

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

During dose-escalation part, Sponsor decided to stop further enrollment and the compound development. Hence, expansion part of the trial was never initiated and PK data collected during the dose-escalation part were not analyzed.

Notes: