Clinical trial results:
First-in-human, Open-label, Dose-escalation Trial With Expansion cohorts to Evaluate Safety of GEN1029 in Patients with Malignant Solid Tumors

Summary

EudraCT number	2017-001394-16
Trial protocol	GB ES FR
Global end of trial date	12 October 2021

Results information

Result version number	v1 (current)
This version publication date	26 October 2022
First version publication date	26 October 2022

Trial information

Trial identification

Sponsor protocol code	GCT1029-01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03576131
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Genmab B.V
Sponsor organisation address	3584 CM, Uterect, Netherlands,
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	23 March 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 October 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the dose escalation part of the study was to determine the maximum tolerated dose (MTD) and/or the recommended Phase 2 dose (RP2D) and to establish the safety profile of GEN1029 in participants with malignant solid tumors. The main objective of the dose expansion part of the study was to evaluate the objective response rate by indication.

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	30 April 2018
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: 13
Country: Number of subjects enrolled	United Kingdom: 15
Country: Number of subjects enrolled	United States: 20
Worldwide total number of subjects	48
EEA total number of subjects	13

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	21
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The sponsor decided to halt the development of GEN1029 due to a narrow therapeutic window after the dose-escalation part, hence the expansion part of the trial was not performed. Therefore, results are reported here only for the dose-escalation part.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Biweekly Regimen (GEN1029 0.1 mg/ kg)

Arm description:

Participants received 0.1 mg/kg of GEN1029 every 2 weeks (Q2W) until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1029
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1029 0.1 mg/kg was administered intravenously Q2W until the end of treatment.

Arm title	Biweekly Regimen (GEN1029 0.2 mg/kg)

Arm description:

Participants received 0.2 mg/kg of GEN1029 Q2W until the end of treatment

Arm type	Experimental
Investigational medicinal product name	GEN1029
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1029 0.2 mg/kg was administered intravenously Q2W until the end of treatment.

Arm title	Biweekly Regimen (GEN1029 0.3 mg/kg)

Arm description:

Participants received 0.3 mg/kg of GEN1029 Q2W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1029
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1029 0.3 mg/kg was administered intravenously Q2W until the end of treatment.

Arm title	Biweekly Regimen (GEN1029 1.0 mg/kg)

Arm description:

Participants received 1.0 mg/kg of GEN1029 Q2W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1029
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1029 1.0 mg/kg was administered intravenously Q2W until the end of treatment.

Arm title	Biweekly Regimen (GEN1029 2.0 mg/kg)

Arm description:

Participants received 2.0 mg/kg of GEN1029 Q2W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1029
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1029 2.0 mg/kg was administered intravenously Q2W until the end of treatment.

Arm title	Biweekly Regimen (GEN1029 3.0 mg/kg)

Arm description:

Participants received 3.0 mg/kg of GEN1029 Q2W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1029
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1029 3.0 mg/kg was administered intravenously Q2W until the end of treatment.

Arm title	Priming Regimen (GEN1029 0.1 mg/kg)

Arm description:

Participants received a priming dose of 0.1 mg/kg of GEN1029 on Cycle 1 Day 1. After 14 days and thereafter once every 14 days, participants received full dose of 0.3 mg/kg until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1029
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1029 0.1 mg/kg was administered intravenously on Cycle 1 Day 1. After 14 days and thereafter once every 14 days, full dose of 0.3 mg/kg was administered until the end of treatment.

Arm title	Intensified Regimen (GEN1029 1.0 mg/kg)

Arm description:

Participants received 1.0 mg/kg of GEN1029 once a week (Q1W) for the first 8 weeks then Q2W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	GEN1029
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GEN1029 1.0 mg/kg was administered intravenously Q1W for the first 8 weeks then Q2W until the end of treatment.

Number of subjects in period 1	Biweekly Regimen (GEN1029 0.1 mg/kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)
Started	10	7	4
Completed	1	2	0
Not completed	9	5	4
Adverse event, serious fatal	1	2	-
Consent withdrawn by subject	1	1	-
Subject non-compliance	-	-	-
Death	2	1	1
Investigator decision	-	-	-
Unspecified	-	-	1
New anti-cancer treatment	5	1	2

Number of subjects in period 1	Biweekly Regimen (GEN1029 1.0 mg/kg)	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)
Started	11	7	7
Completed	0	0	0
Not completed	11	7	7
Adverse event, serious fatal	3	1	-
Consent withdrawn by subject	1	2	3
Subject non-compliance	-	-	1
Death	2	3	1
Investigator decision	1	-	1
Unspecified	1	1	1
New anti-cancer treatment	3	-	-

Number of subjects in period 1	Priming Regimen (GEN1029 0.1 mg/kg)	Intensified Regimen (GEN1029 1.0 mg/kg)
Started	1	1
Completed	0	0
Not completed	1	1
Adverse event, serious fatal	-	-
Consent withdrawn by subject	1	-

Subject non-compliance	-	-
Death	-	1
Investigator decision	-	-
Unspecified	-	-
New anti-cancer treatment	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Biweekly Regimen (GEN1029 0.1 mg/ kg)
Reporting group description:	
Participants received 0.1 mg/kg of GEN1029 every 2 weeks (Q2W) until the end of treatment.	
Reporting group title	Biweekly Regimen (GEN1029 0.2 mg/kg)
Reporting group description:	
Participants received 0.2 mg/kg of GEN1029 Q2W until the end of treatment	
Reporting group title	Biweekly Regimen (GEN1029 0.3 mg/kg)
Reporting group description:	
Participants received 0.3 mg/kg of GEN1029 Q2W until the end of treatment.	
Reporting group title	Biweekly Regimen (GEN1029 1.0 mg/kg)
Reporting group description:	
Participants received 1.0 mg/kg of GEN1029 Q2W until the end of treatment.	
Reporting group title	Biweekly Regimen (GEN1029 2.0 mg/kg)
Reporting group description:	
Participants received 2.0 mg/kg of GEN1029 Q2W until the end of treatment.	
Reporting group title	Biweekly Regimen (GEN1029 3.0 mg/kg)
Reporting group description:	
Participants received 3.0 mg/kg of GEN1029 Q2W until the end of treatment.	
Reporting group title	Priming Regimen (GEN1029 0.1 mg/kg)
Reporting group description:	
Participants received a priming dose of 0.1 mg/kg of GEN1029 on Cycle 1 Day 1. After 14 days and thereafter once every 14 days, participants received full dose of 0.3 mg/kg until the end of treatment.	
Reporting group title	Intensified Regimen (GEN1029 1.0 mg/kg)
Reporting group description:	
Participants received 1.0 mg/kg of GEN1029 once a week (Q1W) for the first 8 weeks then Q2W until the end of treatment.	

Reporting group values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)
Number of subjects	10	7	4
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)	7	3	2
From 65-84 years	3	4	2
85 years and over	0	0	0

Gender categorical Units: Subjects			
Female	6	1	2
Male	4	6	2

Reporting group values	Biweekly Regimen (GEN1029 1.0 mg/kg)	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)
Number of subjects	11	7	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)	7	3	4
From 65-84 years	4	4	3
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	8	5	4
Male	3	2	3

Reporting group values	Priming Regimen (GEN1029 0.1 mg/kg)	Intensified Regimen (GEN1029 1.0 mg/kg)	Total
Number of subjects	1	1	48
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	0	27
From 65-84 years	0	1	21
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	1	0	27
Male	0	1	21

End points

End points reporting groups

Reporting group title	Biweekly Regimen (GEN1029 0.1 mg/ kg)
Reporting group description:	
Participants received 0.1 mg/kg of GEN1029 every 2 weeks (Q2W) until the end of treatment.	
Reporting group title	Biweekly Regimen (GEN1029 0.2 mg/kg)
Reporting group description:	
Participants received 0.2 mg/kg of GEN1029 Q2W until the end of treatment	
Reporting group title	Biweekly Regimen (GEN1029 0.3 mg/kg)
Reporting group description:	
Participants received 0.3 mg/kg of GEN1029 Q2W until the end of treatment.	
Reporting group title	Biweekly Regimen (GEN1029 1.0 mg/kg)
Reporting group description:	
Participants received 1.0 mg/kg of GEN1029 Q2W until the end of treatment.	
Reporting group title	Biweekly Regimen (GEN1029 2.0 mg/kg)
Reporting group description:	
Participants received 2.0 mg/kg of GEN1029 Q2W until the end of treatment.	
Reporting group title	Biweekly Regimen (GEN1029 3.0 mg/kg)
Reporting group description:	
Participants received 3.0 mg/kg of GEN1029 Q2W until the end of treatment.	
Reporting group title	Priming Regimen (GEN1029 0.1 mg/kg)
Reporting group description:	
Participants received a priming dose of 0.1 mg/kg of GEN1029 on Cycle 1 Day 1. After 14 days and thereafter once every 14 days, participants received full dose of 0.3 mg/kg until the end of treatment.	
Reporting group title	Intensified Regimen (GEN1029 1.0 mg/kg)
Reporting group description:	
Participants received 1.0 mg/kg of GEN1029 once a week (Q1W) for the first 8 weeks then Q2W 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][2]
End point description:	
DLT criteria are defined haematologic toxicity including Grade (G) 4 neutropenia/thrombocytopenia for minimal duration of 7 days, G3/4 febrile neutropenia, >=G3 thrombocytopenia with bleeding, or G4 anemia; and non-hematologic toxicity including G4 infusion-related reactions (IRR) or anaphylaxis, G3 IRR did not resolve to =<G1 within 24 hours, >=G3 diarrhea/vomiting (did not respond to optimal treatment within 2 days), G3 nausea (did not respond to optimal treatment within 7 days), or Hy's law or protocol-specified toxicities related to liver function test results or amylase and/or lipase elevations; or any >=G3 possibly related non-haematological AE, which occurred during first 2 cycles (as specified in protocol). Dose-Determining Set (DDS) consists of all participants who received at least one dose of GEN1029 (between 80% and 125% of the planned dose), analyzed according to the actual trial treatment received, and completed DLT observation period, or experienced a DLT during Cycle	
End point type	Primary
End point timeframe:	
From Day 1 to 28 days after the first dose of study drug	

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

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	6	3	10
Units: Participants	0	1	0	3

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	5		
Units: Participants	3	2		

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][4]

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 the following criteria: fatal or life-threatening; results in persistent or significant disability/incapacity; constitutes a congenital anomaly/birth defect; 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 important']); required inpatient hospitalization or prolongation of existing hospitalization. A TEAE is defined as an AE occurring or worsening during the treatment period including the safety follow-up period. The Safety Set consists of all participants who received at least one dose of GEN1029 and analyzed according to the actual trial treatment received.

End point type	Primary

End point timeframe:

Day 1 through Day 565 (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.

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

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	4	11
Units: Participants				
Any TEAE	8	7	4	11
Any TESAE	3	3	2	9

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: Participants				
Any TEAE	7	7		
Any TESAE	6	4		

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

End point description:

Number of participants with laboratory measurements of >= Grade 3 by NCI-CTCAE v4.03 are reported.

End point type	Primary

End point timeframe:

Day 1 through Day 565 (corresponding to maximum observed duration)

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	4	11
Units: Participants				
Prolonged activated partial thromboplastin time	0	1	0	0
Alanine aminotransferase increased	1	1	2	3
Alkaline phosphatase increased	0	0	1	0
Amylase increased	0	1	1	0
Asparate aminotransferase increased	1	2	0	0
Bilirubin increased	0	0	0	1
Calcium decreased	0	1	0	0
Creatinine increased	1	0	0	0
Gamma-glutamyl transferase increased	2	2	1	2
Glucose increased	2	1	1	3
Hemoglobin decreased	0	1	0	0
Lipase increased	1	0	3	1
Lymphocytes decreased	2	3	1	2
Magnesium increased	0	9	0	0
Prothrombin INR - increased	0	1	0	0
Sodium decreased	1	1	1	1
Urate increased	0	1	0	0

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: Participants				
Prolonged activated partial thromboplastin time	0	0		
Alanine aminotransferase increased	1	2		
Alkaline phosphatase increased	1	0		
Amylase increased	0	0		
Asparate aminotransferase increased	0	2		
Bilirubin increased	0	0		
Calcium decreased	0	0		
Creatinine increased	0	0		
Gamma-glutamyl transferase increased	3	1		
Glucose increased	0	0		
Hemoglobin decreased	0	0		
Lipase increased	0	0		
Lymphocytes decreased	2	0		
Magnesium increased	0	1		
Prothrombin INR - increased	2	0		
Sodium decreased	0	1		
Urate increased	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax) of Hx-DR5-01 and Hx-DR5-05

End point title	Maximum Observed Plasma Concentration (Cmax) of Hx-DR5-01 and Hx-DR5-05[7]

End point description:

The Cmax of Hx-DR5-01 and Hx-DR5-05 are reported. Pharmacokinetic (PK) analysis set included all participants who were exposed to at least 1 dose of GEN1029 and who had at least 1 post-dose PK measurement. Here, 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not reached because insufficient number of participants were evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, end of infusion, 2, 4, 24, 48, 168 and 336 hours after end of infusion on Day 1 of Cycles 1, 2, 3

Notes:

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

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	4	11
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cmax Hx-DR5-01 Cycle 1 Day 1 (n=9,6,4,11,7,6)	0.86 (± 36.8)	1.90 (± 38.0)	2.81 (± 28.9)	9.79 (± 20.9)
Cmax Hx-DR5-01 Cycle 2 Day 1 (n=9,4,4,8,5,2)	0.79 (± 42.9)	2.11 (± 18.3)	1.12 (± 59.9)	8.36 (± 22.7)
Cmax Hx-DR5-01 Cycle 3 Day 1 (n=7,4,3,6,3,1)	0.89 (± 16.6)	1.82 (± 53.9)	0.89 (± 146.4)	7.20 (± 11.2)
Cmax Hx-DR5-05 Cycle 1 Day 1 (n=9,6,4,11,7,6)	0.87 (± 45.2)	1.81 (± 35.7)	2.82 (± 31.8)	9.72 (± 17.0)
Cmax Hx-DR5-05 Cycle 2 Day 1 (n=9,4,4,8,4,2)	0.79 (± 25.9)	2.00 (± 18.3)	1.11 (± 76.2)	7.75 (± 25.8)
Cmax Hx-DR5-05 Cycle 3 Day 1 (n=7,4,2,6,3,1)	0.87 (± 26.6)	1.28 (± 93.8)	1.62 (± 108.2)	6.77 (± 20.6)

End point values	Biweekly Regimen	Biweekly Regimen		

	(GEN1029 2.0 mg/kg)	(GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	6		
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cmax Hx-DR5-01 Cycle 1 Day 1 (n=9,6,4,11,7,6)	21.31 (± 24.6)	29.75 (± 24.9)		
Cmax Hx-DR5-01 Cycle 2 Day 1 (n=9,4,4,8,5,2)	13.13 (± 156.3)	29.56 (± 7.7)		
Cmax Hx-DR5-01 Cycle 3 Day 1 (n=7,4,3,6,3,1)	20.35 (± 24.7)	28.80 (± 99999.0)		
Cmax Hx-DR5-05 Cycle 1 Day 1 (n=9,6,4,11,7,6)	20.90 (± 21.9)	29.44 (± 27.9)		
Cmax Hx-DR5-05 Cycle 2 Day 1 (n=9,4,4,8,4,2)	20.37 (± 14.3)	30.52 (± 5.8)		
Cmax Hx-DR5-05 Cycle 3 Day 1 (n=7,4,2,6,3,1)	5.27 (± 577.8)	28.50 (± 99999.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under Plasma Concentration-time Curve From Time Zero to Infinity (AUC[0-inf]) of Hx-DR5-01 and Hx-DR5-05

End point title	Area Under Plasma Concentration-time Curve From Time Zero to Infinity (AUC[0-inf]) of Hx-DR5-01 and Hx-DR5-05[8]

End point description:

The AUC(0-inf) of Hx-DR5-01 and Hx-DR5-05 are reported. PK analysis set included all participants who were exposed to at least 1 dose of GEN1029 and who had at least 1 post-dose PK measurement. Here, 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not reached because insufficient number of participants were evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, end of infusion, 2, 4, 24, 48, 168 and 336 hours after end of infusion on Day 1 of Cycles 1, 2, 3

Notes:

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

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	4	11
Units: µg*h/mL				
geometric mean (geometric coefficient of variation)				
AUC(0-inf) Hx-DR5-01 Cycle1 Day1 (n=8,6,4,11,7,6)	39.44 (± 50.2)	91.20 (± 66.0)	85.80 (± 56.7)	523.66 (± 47.5)

AUC(0-inf) Hx-DR5-01 Cycle2 Day1 (n=8,4,4,7,4,2)	46.37 (± 61.5)	105.32 (± 55.8)	35.24 (± 30.5)	530.48 (± 24.8)
AUC(0-inf) Hx-DR5-01 Cycle3 Day1 (6,4,2,6,3,1)	37.43 (± 74.0)	53.24 (± 133.3)	41.41 (± 84.9)	422.32 (± 26.8)
AUC(0-inf) Hx-DR5-05 Cycle1 Day1 (n=8,6,4,11,6,6)	32.97 (± 55.4)	71.21 (± 66.9)	83.37 (± 51.7)	508.76 (± 33.0)
AUC(0-inf) Hx-DR5-05 Cycle2 Day1 (7,4,3,6,3,2)	39.31 (± 65.9)	93.11 (± 66.6)	44.76 (± 184.4)	414.90 (± 24.1)
AUC(0-inf) Hx-DR5-05 Cycle3 Day1 (n=5,3,2,6,2,1)	25.87 (± 57.3)	51.36 (± 161.6)	67.23 (± 200.5)	231.49 (± 53.2)

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	6		
Units: µg*h/mL				
geometric mean (geometric coefficient of variation)				
AUC(0-inf) Hx-DR5-01 Cycle1 Day1 (n=8,6,4,11,7,6)	1298.0 (± 22.7)	1497.7 (± 58.7)		
AUC(0-inf) Hx-DR5-01 Cycle2 Day1 (n=8,4,4,7,4,2)	1071.5 (± 30.7)	2488.5 (± 10.7)		
AUC(0-inf) Hx-DR5-01 Cycle3 Day1 (6,4,2,6,3,1)	1097.8 (± 36.6)	2653.5 (± 9999.0)		
AUC(0-inf) Hx-DR5-05 Cycle1 Day1 (n=8,6,4,11,6,6)	1052.1 (± 24.7)	1270.0 (± 60.1)		
AUC(0-inf) Hx-DR5-05 Cycle2 Day1 (7,4,3,6,3,2)	609.90 (± 55.2)	2273.6 (± 9.0)		
AUC(0-inf) Hx-DR5-05 Cycle3 Day1 (n=5,3,2,6,2,1)	412.87 (± 64.1)	2398.5 (± 9999.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under Plasma Concentration-time Curve From Time Zero to the Time of Last nonzero Concentration (AUC[0-Clast]) of Hx-DR5-01 and Hx-DR5-05

End point title	Area Under Plasma Concentration-time Curve From Time Zero to the Time of Last nonzero Concentration (AUC[0-Clast]) of Hx-DR5-01 and Hx-DR5-05[9]

End point description:

The AUC(0-Clast) of Hx-DR5-01 and Hx-DR5-05 are reported. PK analysis set included all participants who were exposed to at least 1 dose of GEN1029 and who had at least 1 post-dose PK measurement. Here, 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not reached because insufficient number of participants were evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, end of infusion, 2, 4, 24, 48, 168 and 336 hours after end of infusion on Day 1 of Cycles 1, 2, 3

Notes:

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

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	4	11
Units: µg*h/mL				
geometric mean (geometric coefficient of variation)				
AUC(0-Clast) Hx-DR5-01 Cycle1Day1 (n=9,6,4,11,7,6)	24.36 (± 73.2)	72.25 (± 70.6)	60.78 (± 35.8)	460.37 (± 43.5)
AUC(0-Clast) Hx-DR5-01 Cycle2Day1 (n=9,4,4,8,5,2)	17.34 (± 141.3)	70.33 (± 66.4)	21.85 (± 36.0)	308.74 (± 66.8)
AUC(0-Clast) Hx-DR5-01 Cycle3Day1 (n=7,4,3,6,3,1)	22.34 (± 85.9)	35.31 (± 151.4)	6.85 (± 995.0)	385.54 (± 23.7)
AUC(0-Clast) Hx-DR5-05 Cycle1Day1 (n=9,6,4,11,7,6)	25.41 (± 120.7)	53.76 (± 77.0)	53.80 (± 50.8)	432.18 (± 24.5)
AUC(0-Clast) Hx-DR5-05 Cycle2Day1 (n=9,4,4,8,4,2)	24.85 (± 119.4)	60.75 (± 76.0)	29.17 (± 165.1)	258.67 (± 60.5)
AUC(0-Clast) Hx-DR5-05 Cycle3Day1 (n=7,4,2,6,3,1)	20.12 (± 168.7)	16.95 (± 539.4)	43.56 (± 405.4)	158.98 (± 76.4)

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	6		
Units: µg*h/mL				
geometric mean (geometric coefficient of variation)				
AUC(0-Clast) Hx-DR5-01 Cycle1Day1 (n=9,6,4,11,7,6)	1173.7 (± 15.6)	1058.9 (± 88.6)		
AUC(0-Clast) Hx-DR5-01 Cycle2Day1 (n=9,4,4,8,5,2)	582.57 (± 84.8)	2291.4 (± 18.1)		
AUC(0-Clast) Hx-DR5-01 Cycle3Day1 (n=7,4,3,6,3,1)	986.38 (± 30.1)	2444.7 (± 99999.0)		
AUC(0-Clast) Hx-DR5-05 Cycle1Day1 (n=9,6,4,11,7,6)	956.02 (± 18.8)	964.48 (± 91.1)		
AUC(0-Clast) Hx-DR5-05 Cycle2Day1 (n=9,4,4,8,4,2)	395.50 (± 62.3)	2176.0 (± 11.7)		
AUC(0-Clast) Hx-DR5-05 Cycle3Day1 (n=7,4,2,6,3,1)	52.16 (± 22162.5)	2248.1 (± 99999.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Total Clearance (CL) of Hx-DR5-01 and Hx-DR5-05

End point title	Total Clearance (CL) of Hx-DR5-01 and Hx-DR5-05[10]

End point description:

The CL of Hx-DR5-01 and Hx-DR5-05 are reported. PK analysis set included all participants who were exposed to at least 1 dose of GEN1029 and who had at least 1 post-dose PK measurement. Here, 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not reached because insufficient number of participants were evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, end of infusion, 2, 4, 24, 48, 168 and 336 hours after end of infusion on Day 1 of Cycles 1, 2, 3

Notes:

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

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	4	11
Units: mL/h				
geometric mean (geometric coefficient of variation)				
CL Hx-DR5-01 Cycle 1 Day 1 (n=8,6,4,11,7,6)	95.98 (± 53.8)	91.27 (± 51.4)	123.75 (± 69.9)	65.36 (± 56.5)
CL Hx-DR5-01 Cycle 2 Day 1 (n=8,4,4,7,4,2)	77.36 (± 70.2)	79.97 (± 51.8)	155.76 (± 72.6)	58.07 (± 31.8)
CL Hx-DR5-01 Cycle 3 Day 1 (n=6,4,2,6,3,1)	99.53 (± 57.1)	131.46 (± 76.0)	111.33 (± 12.9)	62.90 (± 42.5)
CL Hx-DR5-05 Cycle 1 Day 1 (n=8,6,4,11,6,6)	111.10 (± 62.5)	116.89 (± 51.3)	127.35 (± 69.3)	67.28 (± 37.4)
CL Hx-DR5-05 Cycle 2 Day 1 (n=7,4,3,6,3,2)	90.18 (± 69.4)	90.45 (± 67.1)	131.51 (± 240.7)	79.72 (± 28.8)
CL Hx-DR5-05 Cycle 3 Day 1 (n=5,3,2,6,2,1)	143.09 (± 50.5)	140.38 (± 77.3)	68.57 (± 42.2)	114.74 (± 59.8)

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	6		
Units: mL/h				
geometric mean (geometric coefficient of variation)				
CL Hx-DR5-01 Cycle 1 Day 1 (n=8,6,4,11,7,6)	59.07 (± 31.4)	69.50 (± 51.0)		
CL Hx-DR5-01 Cycle 2 Day 1 (n=8,4,4,7,4,2)	73.43 (± 28.0)	36.92 (± 2.0)		

CL Hx-DR5-01 Cycle 3 Day 1 (n=6,4,2,6,3,1)	62.64 (± 26.1)	37.87 (± 99999.0)		
CL Hx-DR5-05 Cycle 1 Day 1 (n=8,6,4,11,6,6)	69.39 (± 29.2)	81.96 (± 53.9)		
CL Hx-DR5-05 Cycle 2 Day 1 (n=7,4,3,6,3,2)	134.11 (± 51.9)	40.41 (± 3.7)		
CL Hx-DR5-05 Cycle 3 Day 1 (n=5,3,2,6,2,1)	172.66 (± 78.9)	41.90 (± 99999.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Distribution at Steady State (Vss) of Hx-DR5-01 and Hx-DR5-05

End point title	Volume of Distribution at Steady State (Vss) of Hx-DR5-01 and Hx-DR5-05[11]

End point description:

The Vss of Hx-DR5-01 and Hx-DR5-05 are reported. PK analysis set included all participants who were exposed to at least 1 dose of GEN1029 and who had at least 1 post-dose PK measurement. Here, 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not reached because insufficient number of participants were evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, end of infusion, 2, 4, 24, 48, 168 and 336 hours after end of infusion on Day 1 of Cycles 1, 2, 3

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	4	11
Units: mL				
geometric mean (geometric coefficient of variation)				
Vss Hx-DR5-01 Cycle 1 Day 1 (n=8,6,4,11,7,6)	5366.8 (± 35.0)	4788.6 (± 5.0)	3666.8 (± 49.4)	3834.6 (± 34.3)
Vss Hx-DR5-01 Cycle 2 Day 1 (n=8,4,4,7,4,2)	4720.0 (± 34.9)	4287.5 (± 10.5)	5283.0 (± 62.0)	3998.1 (± 24.0)
Vss Hx-DR5-01 Cycle 3 Day 1 (n=6,4,2,6,3,1)	4622.7 (± 31.1)	4531.9 (± 6.7)	3243.6 (± 14.3)	4075.3 (± 26.2)
Vss Hx-DR5-05 Cycle 1 Day 1 (n=8,6,4,11,6,6)	4722.7 (± 55.6)	5242.9 (± 15.8)	3942.4 (± 63.6)	3611.0 (± 26.5)
Vss Hx-DR5-05 Cycle 2 Day 1 (n=7,4,3,6,3,2)	4899.3 (± 22.7)	4701.6 (± 15.0)	5177.9 (± 100.6)	4054.4 (± 16.4)
Vss Hx-DR5-05 Cycle 3 Day 1 (n=5,3,2,6,2,1)	4812.5 (± 31.9)	5077.6 (± 24.1)	3577.1 (± 15.7)	4951.2 (± 42.4)

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	6		
Units: mL				
geometric mean (geometric coefficient of variation)				
Vss Hx-DR5-01 Cycle 1 Day 1 (n=8,6,4,11,7,6)	4885.9 (± 18.8)	4127.3 (± 19.2)		
Vss Hx-DR5-01 Cycle 2 Day 1 (n=8,4,4,7,4,2)	4185.8 (± 17.3)	3427.5 (± 25.1)		
Vss Hx-DR5-01 Cycle 3 Day 1 (n=6,4,2,6,3,1)	4227.1 (± 8.7)	4118.5 (± 99999.0)		
Vss Hx-DR5-05 Cycle 1 Day 1 (n=8,6,4,11,6,6)	4291.6 (± 9.8)	4142.9 (± 21)		
Vss Hx-DR5-05 Cycle 2 Day 1 (n=7,4,3,6,3,2)	4334.9 (± 14.9)	3187.8 (± 41.0)		
Vss Hx-DR5-05 Cycle 3 Day 1 (n=5,3,2,6,2,1)	5130.8 (± 5.6)	4173.9 (± 99999.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Half-life Lambda-z (t1/2) of Hx-DR5-01 and Hx-DR5-05

End point title	Half-life Lambda-z (t1/2) of Hx-DR5-01 and Hx-DR5-05[12]

End point description:

The t1/2 of Hx-DR5-01 and Hx-DR5-05 are reported. PK analysis set included all participants who were exposed to at least 1 dose of GEN1029 and who had at least 1 post-dose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, end of infusion, 2, 4, 24, 48, 168 and 336 hours after end of infusion on Day 1 of Cycles 1, 2, 3

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	4	11
Units: hours				
median (full range (min-max))				

T1/2 Hx-DR5-01 Cycle 1 Day 1 (n=8,6,4,11,7,6)	41.69 (20.7 to 61.1)	41.31 (16.6 to 60.3)	18.10 (11.4 to 40.5)	40.27 (5.1 to 66.8)
T1/2 Hx-DR5-01 Cycle 2 Day 1 (n=8,4,4,7,4,2)	37.75 (29.1 to 72.3)	39.57 (21.7 to 62.5)	24.47 (16.9 to 29.7)	49.64 (36.2 to 71.5)
T1/2 Hx-DR5-01 Cycle 3 Day 1 (n=6,4,2,6,3,1)	27.64 (16.2 to 84.1)	19.93 (13.1 to 66.9)	20.16 (16.2 to 24.1)	47.86 (30.8 to 60.0)
T1/2 Hx-DR5-05 Cycle 1 Day 1 (n=8,6,4,11,6,6)	35.55 (12.5 to 46.5)	34.50 (15.6 to 52.5)	19.10 (14.6 to 44.0)	36.33 (26.4 to 70.6)
T1/2 Hx-DR5-05 Cycle 2 Day 1 (n=7,4,3,6,3,2)	32.46 (19.3 to 71.4)	37.71 (17.3 to 80.7)	25.43 (13.9 to 62.3)	37.69 (28.4 to 43.5)
T1/2 Hx-DR5-05 Cycle 3 Day 1 (n=5,3,2,6,2,1)	25.30 (12.0 to 39.6)	18.75 (15.4 to 57.4)	41.26 (24.3 to 58.2)	33.90 (14.2 to 62.1)

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	6		
Units: hours				
median (full range (min-max))				
T1/2 Hx-DR5-01 Cycle 1 Day 1 (n=8,6,4,11,7,6)	70.90 (50.5 to 86.2)	42.45 (17.9 to 80.5)		
T1/2 Hx-DR5-01 Cycle 2 Day 1 (n=8,4,4,7,4,2)	33.62 (29.0 to 88.2)	65.85 (54.6 to 77.1)		
T1/2 Hx-DR5-01 Cycle 3 Day 1 (n=6,4,2,6,3,1)	44.51 (40.1 to 64.0)	77.00 (77.00 to 77.00)		
T1/2 Hx-DR5-05 Cycle 1 Day 1 (n=8,6,4,11,6,6)	42.68 (35.3 to 68.8)	37.71 (16.6 to 69.6)		
T1/2 Hx-DR5-05 Cycle 2 Day 1 (n=7,4,3,6,3,2)	26.68 (13.1 to 29.4)	51.97 (30.8 to 73.1)		
T1/2 Hx-DR5-05 Cycle 3 Day 1 (n=5,3,2,6,2,1)	22.83 (13.2 to 32.5)	70.9 (70.9 to 70.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reach Maximum Observed Concentration (Tmax) of Hx-DR5-01 and Hx-DR5-05

End point title	Time to Reach Maximum Observed Concentration (Tmax) of Hx-DR5-01 and Hx-DR5-05[13]

End point description:

The Tmax of Hx-DR5-01 and Hx-DR5-05 are reported. PK analysis set included all participants who were exposed to at least 1 dose of GEN1029 and who had at least 1 post-dose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, end of infusion, 2, 4, 24, 48, 168 and 336 hours after end of infusion on Day 1 of Cycles 1, 2, 3

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	4	11
Units: hours				
median (full range (min-max))				
Tmax Hx-DR5-01 Cycle 1 Day 1 (n=9,6,4,11,7,6)	1.58 (1.1 to 5.8)	1.89 (1.4 to 5.0)	1.23 (1.2 to 1.4)	2.00 (0.1 to 4.7)
Tmax Hx-DR5-01 Cycle 2 Day 1 (n=9,4,4,8,5,2)	1.25 (1.0 to 3.2)	3.03 (3.0 to 5.2)	1.30 (1.1 to 3.2)	3.06 (1.1 to 5.1)
Tmax Hx-DR5-01 Cycle 3 Day 1 (n=7,4,3,6,3,1)	1.08 (0.0 to 3.4)	1.48 (1.0 to 2.1)	1.13 (1.1 to 1.3)	3.08 (1.4 to 3.5)
Tmax Hx-DR5-05 Cycle 1 Day 1 (n=9,6,4,11,7,6)	1.75 (1.1 to 5.4)	2.53 (1.0 to 4.8)	2.36 (1.2 to 5.5)	1.60 (0.1 to 4.7)
Tmax Hx-DR5-05 Cycle 2 Day 1 (n=9,4,4,8,4,2)	3.12 (1.1 to 5.1)	2.19 (1.0 to 3.5)	1.19 (1.0 to 1.4)	2.26 (1.2 to 5.1)
Tmax Hx-DR5-05 Cycle 3 Day 1 (n=7,4,2,6,3,1)	1.08 (0.0 to 1.5)	1.83 (1.0 to 3.3)	1.18 (1.1 to 1.3)	1.42 (1.1 to 3.0)

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	6		
Units: hours				
median (full range (min-max))				
Tmax Hx-DR5-01 Cycle 1 Day 1 (n=9,6,4,11,7,6)	1.30 (1.1 to 3.6)	1.46 (1.0 to 3.1)		
Tmax Hx-DR5-01 Cycle 2 Day 1 (n=9,4,4,8,5,2)	3.25 (1.1 to 163.7)	1.11 (1.0 to 1.2)		
Tmax Hx-DR5-01 Cycle 3 Day 1 (n=7,4,3,6,3,1)	1.82 (1.1 to 3.2)	3.1 (3.1 to 3.1)		
Tmax Hx-DR5-05 Cycle 1 Day 1 (n=9,6,4,11,7,6)	1.35 (1.1 to 3.0)	1.46 (1.0 to 3.1)		
Tmax Hx-DR5-05 Cycle 2 Day 1 (n=9,4,4,8,4,2)	2.31 (1.1 to 3.3)	2.21 (1.2 to 3.2)		
Tmax Hx-DR5-05 Cycle 3 Day 1 (n=7,4,2,6,3,1)	1.13 (1.0 to 1.8)	3.1 (3.1 to 3.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Concentration of Hx-DR5-01 and Hx-DR5-05

End point title	Plasma Concentration of Hx-DR5-01 and Hx-DR5-05[14]

End point description:

The plasma concentration (PC) of Hx-DR5-01 and Hx-DR5-05 are reported. PK analysis set included all participants who were exposed to at least 1 dose of GEN1029 and who had at least 1 post-dose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not reached because insufficient number of participants were evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, end of infusion, 2, 4, 24, 48, 168 and 336 hours after end of infusion on Day 1 of Cycles 1, 2, 3

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	4	11
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
PC Hx-DR5-01 Cycle1 Day 1 (n=9,7,4,11,7,6)	0.085 (± 38.5)	0.075 (± 0.0)	0.075 (± 0.0)	0.075 (± 0.0)
PC Hx-DR5-01 Cycle2 Day 1 (n=8,7,4,8,5,2)	0.091 (± 61.0)	0.075 (± 0.0)	0.075 (± 0.0)	0.084 (± 34.0)
PC Hx-DR5-01 Cycle3 Day 1 (n=7,5,3,6,3,1)	0.075 (± 0.0)	0.125 (± 164.3)	0.075 (± 0.0)	0.090 (± 46.4)
PC Hx-DR5-05 Cycle1 Day 1 (n=9,7,4,11,7,6)	0.094 (± 77.6)	0.075 (± 0.0)	0.075 (± 0.0)	0.075 (± 0.0)
PC Hx-DR5-05 Cycle2 Day 1 (n=8,7,4,8,5,2)	0.097 (± 83.6)	0.075 (± 0.0)	0.075 (± 0.0)	0.075 (± 0.0)
PC Hx-DR5-05 Cycle3 Day 1 (n=7,5,3,6,3,1)	0.101 (± 94.6)	0.119 (± 138.5)	0.075 (± 0.0)	0.094 (± 58.8)

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	6		
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
PC Hx-DR5-01 Cycle1 Day 1 (n=9,7,4,11,7,6)	0.075 (± 0.0)	0.075 (± 0.0)		
PC Hx-DR5-01 Cycle2 Day 1 (n=8,7,4,8,5,2)	0.230 (± 77.8)	0.283 (± 576.2)		
PC Hx-DR5-01 Cycle3 Day 1 (n=7,5,3,6,3,1)	0.224 (± 156.9)	0.739 (± 99999.0)		

PC Hx-DR5-05 Cycle1 Day 1 (n=9,7,4,11,7,6)	0.075 (± 0.0)	0.075 (± 0.0)		
PC Hx-DR5-05 Cycle2 Day 1 (n=8,7,4,8,5,2)	0.155 (± 161.5)	0.240 (± 372.5)		
PC Hx-DR5-05 Cycle3 Day 1 (n=7,5,3,6,3,1)	0.075 (± 0.0)	0.568 (± 99999.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Antidrug Antibodies (ADAs) Positive to GEN1029

End point title	Number of Participants With Antidrug Antibodies (ADAs) Positive to GEN1029[15]

End point description:

From positive ADA samples titer values and neutralizing antibody scores (positive or negative) were determined and reported. A participant was considered positive if negative at baseline (screening) and had at least one positive post-baseline result, or positive at baseline and had at least one positive post-baseline result with a titer higher than baseline. Number of participants with ADA positive to GEN1029 are reported. The Immunogenicity Set consists of all participants who received at least one dose of GEN1029 and analyzed according to the actual treatment received and had at least one immunogenicity measurement taken.

End point type	Secondary

End point timeframe:

From Screening (Day -21 to -1) through Day 478 (corresponding to maximum observed duration)

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	4	11
Units: Participants	5	5	4	7

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: Participants	5	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Anti-tumor Activity Measured by Tumor Shrinkage

End point title	Change From Baseline in Anti-tumor Activity Measured by Tumor Shrinkage[16]

End point description:

Anti-tumor activity measured by tumor shrinkage was evaluated on based on sum of the diameter(s) of all target lesions from the computerized tomography (CT) scan/positron emission tomography (PET)-CT scan. Largest tumor shrinkage is reported. Full analysis set included all participants who received at least one dose of GEN1029 and were analyzed according to the actual treatment received.

End point type	Secondary

End point timeframe:

From Baseline (Day 1) through 8.8 months (corresponding to maximum observed duration)

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	4	10
Units: millimeter				
arithmetic mean (standard deviation)	12.0 (± 11.843)	12.0 (± 17.616)	13.75 (± 9.032)	1.10 (± 9.049)

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	4		
Units: millimeter				
arithmetic mean (standard deviation)	9.0 (± 10.909)	15.50 (± 18.574)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Objective Response (OR) According to Response Evaluation Criteria in Solid Tumors (RECIST) 1.1

End point title	Number of Participants With Objective Response (OR) According to Response Evaluation Criteria in Solid Tumors (RECIST) 1.1[17]

End point description:

The radiological evaluation was based on RECIST v1.1 using CT scan/PET-CT scan. The OR was defined as complete response (CR) or partial response (PR) per RECIST v1.1. The CR was defined as disappearance of all target and non-target lesions and reduction in short axis to <10 mm of any pathological and non-pathological lymph nodes. The PR was defined as >=30% decrease in sum of diameters of target lesions (compared to baseline), no unequivocal progression of existing non-target lesions, and no new lesion. Full analysis set included all participants who received at least one dose of GEN1029 and were analyzed according to actual trial treatment received.

End point type	Secondary

End point timeframe:

From Day 1 through 8.8 months (corresponding to maximum observed duration)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	4	11
Units: Participants	0	0	0	0

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) According to RECIST 1.1

End point title	Progression-Free Survival (PFS) According to RECIST 1.1[18]

End point description:

The PFS was defined as the number of days from the date of first study drug administration to first progressive disease (PD) or death from any cause. The PD was defined as at least 20% (and >= 5 mm) increase in the sum of the longest diameter (LD) of target lesions, compared to the smallest sum of the target LDs recorded while in trial or the appearance of 1 or more new lesions; unequivocal progression of existing non-target lesions; and/or new lesion. The radiological evaluation based on RECIST v1.1 was assessed using CT scan/PET-CT scan. The PFS was estimated using Kaplan-Meier method. Full analysis set included all participants who received at least one dose of GEN1029 and were analyzed according to the actual trial treatment received. The arbitrary number '9999.0' denotes the data for upper limit of 95% confidence interval, which was not reached because insufficient number of participants were evaluated for the specified time point.

End point type	Secondary

End point timeframe:

From Day 1 through 8.8 months (corresponding to maximum observed duration)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	4	11
Units: months				
median (confidence interval 95%)	2.5 (0.5 to 3.9)	1.4 (0.5 to 9999.0)	2.4 (0.8 to 9999.0)	1.9 (1.2 to 9999.0)

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: months				
median (confidence interval 95%)	1.2 (1.1 to 9999.0)	1.2 (1.0 to 9999.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) According to RECIST 1.1

End point title	Overall Survival (OS) According to RECIST 1.1[19]

End point description:

Overall survival (OS) was defined as the number of days from date of first study drug administration to death due to any cause. If a subject was not known to have died, then OS was censored, and the censoring date was the latest date the subject was known to be alive (on or before the cut-off date). The OS was estimated using Kaplan-Meier method. Full analysis set included all participants who received at least one dose of GEN1029 and were analyzed according to the actual trial treatment received. The arbitrary numbers '0.999' and '9999.0' denotes the data for lower limit and upper limit of 95% confidence interval, which was not reached because insufficient number of participants were evaluated for the specified time point.

End point type	Secondary

End point timeframe:

From Day 1 through 8.8 months (corresponding to maximum observed duration)

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	4	11
Units: months				
median (confidence interval 95%)	7.0 (2.3 to 9999.0)	6.4 (1.8 to 9999.0)	4.9 (0.999 to 9999.0)	7.1 (1.7 to 9999.0)

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	7		
Units: months				
median (confidence interval 95%)	4.7 (2.8 to 9999.0)	6.9 (0.999 to 9999.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DoR) According to RECIST 1.1

End point title	Duration of Response (DoR) According to RECIST 1.1[20]

End point description:

The radiological evaluation based on RECIST v1.1 was assessed using CT scan/PET-CT scan. The DoR was defined as duration from the first documentation of confirmed OR (CR or PR) to date of first progressive disease (PD) or death. Full analysis set included all participants who received at least one dose of GEN1029 and were analyzed according to the actual trial treatment received. Participants who achieved confirmed OR by the investigator assessment were evaluated for this outcome measure.

End point type	Secondary

End point timeframe:

From Day 1 through 8.8 months (corresponding to maximum observed duration)

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[21]	0[22]	0[23]	0[24]
Units: Participants				

Notes:

[21] - No participants had achieved confirmed OR.

[22] - No participants had achieved confirmed OR.

[23] - No participants had achieved confirmed OR.

[24] - No participants had achieved confirmed OR.

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[25]	0[26]		
Units: Participants				

Notes:

[25] - No participants had achieved confirmed OR.

[26] - No participants had achieved confirmed OR.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response (TTR) According to RECIST 1.1

End point title	Time to Response (TTR) According to RECIST 1.1[27]

End point description:

TTR is defined as the number of days from first dose of study drug to the first documented CR or PR, which must be subsequently confirmed. Full analysis set included all participants who received at least one dose of GEN1029 and were analyzed according to the actual trial treatment received. Participants who achieved confirmed OR by the investigator assessment were evaluated for this outcome measure.

End point type	Secondary

End point timeframe:

From Day 1 through 8.8 months (corresponding to maximum observed duration)

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Biweekly Regimen (GEN1029 0.1 mg/ kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)	Biweekly Regimen (GEN1029 1.0 mg/kg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[28]	0[29]	0[30]	0[31]
Units: Participants				

Notes:

[28] - No participants had achieved confirmed OR.

[29] - No participants had achieved confirmed OR.

[30] - No participants had achieved confirmed OR.

[31] - No participants had achieved confirmed OR.

End point values	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[32]	0[33]		
Units: Participants				

Notes:

[32] - No participants had achieved confirmed OR.

[33] - No participants had achieved confirmed OR.

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 565; and for All-cause mortality: From date of inform consent form until death

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Biweekly Regimen (GEN1029 0.1 mg/kg)

Reporting group description:

Participants received 0.1 mg/kg of GEN1029 Q2W until the end of treatment.

Reporting group title	Biweekly Regimen (GEN1029 0.2 mg/ kg)

Reporting group description:

Participants received 0.2 mg/kg of GEN1029 Q2W until the end of treatment.

Reporting group title	Biweekly Regimen (GEN1029 0.3 mg/ kg)

Reporting group description:

Participants received 0.3 mg/kg of GEN1029 Q2W until the end of treatment.

Reporting group title	Biweekly Regimen (GEN1029 1.0 mg/ kg)

Reporting group description:

Participants received 1.0 mg/kg of GEN1029 Q2W until the end of treatment.

Reporting group title	Biweekly Regimen (GEN1029 2.0 mg/ kg)

Reporting group description:

Participants received 2.0 mg/kg of GEN1029 Q2W until the end of treatment.

Reporting group title	Biweekly Regimen (GEN1029 3.0 mg/ kg)

Reporting group description:

Participants received 3.0 mg/kg of GEN1029 Q2W until the end of treatment.

Reporting group title	Priming Regimen (GEN1029 0.1 mg/ kg)

Reporting group description:

Participants received a priming dose of 0.1 mg/kg of GEN1029 on Cycle 1 Day 1. After 14 days and thereafter once every 14 days, participants received full dose of 0.3 mg/kg until the end of treatment.

Reporting group title	Intensified Regimen (GEN1029 1.0 mg/kg)

Reporting group description:

Participants received 1.0 mg/kg of GEN1029 Q1W for the first 8 weeks then Q2W until the end of treatment.

Serious adverse events	Biweekly Regimen (GEN1029 0.1 mg/kg)	Biweekly Regimen (GEN1029 0.2 mg/ kg)	Biweekly Regimen (GEN1029 0.3 mg/ kg)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 10 (30.00%)	3 / 7 (42.86%)	2 / 4 (50.00%)
number of deaths (all causes)	3	3	1
number of deaths resulting from adverse events	1	2	0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	1 / 10 (10.00%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prothrombin time prolonged			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 10 (10.00%)	2 / 7 (28.57%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Sinus Tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			

subjects affected / exposed	0 / 10 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Lichenoid keratosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Anal abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinea versicolour			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			

Hypokalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Biweekly Regimen (GEN1029 1.0 mg/kg)	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 11 (81.82%)	6 / 7 (85.71%)	4 / 7 (57.14%)
number of deaths (all causes)	5	4	1
number of deaths resulting from adverse events	3	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	3 / 7 (42.86%)
occurrences causally related to treatment / all	1 / 1	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	2 / 7 (28.57%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Prothrombin time prolonged			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	3 / 11 (27.27%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 0
Injury, poisoning and procedural complications			

Femur fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (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			
Sinus Tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (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 / 11 (0.00%)	0 / 7 (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
Hernia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (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
Pyrexia			
subjects affected / exposed	2 / 11 (18.18%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	2 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (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
Diarrhoea			
subjects affected / exposed	1 / 11 (9.09%)	3 / 7 (42.86%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	3 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			

subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Gastrointestinal inflammation			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Large intestinal obstruction			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (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
Nausea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (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
Small intestinal obstruction			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (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
Vomiting			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (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
Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (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
Hepatitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (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
Hyperbilirubinaemia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (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
Jaundice cholestatic			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (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
Skin and subcutaneous tissue disorders			
Lichenoid keratosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Infections and infestations			
Anal abscess			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (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
Bronchitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (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
Cystitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (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
Peritonitis			

subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (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
Tinea versicolour			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (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
Urinary tract infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (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
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (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	Priming Regimen (GEN1029 0.1 mg/kg)	Intensified Regimen (GEN1029 1.0 mg/kg)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prothrombin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Sinus Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (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 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (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 / 1 (0.00%)	0 / 1 (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 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (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			
Lichenoid keratosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (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			
Anal abscess			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinea versicolour			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (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			
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (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	Biweekly Regimen (GEN1029 0.1 mg/kg)	Biweekly Regimen (GEN1029 0.2 mg/kg)	Biweekly Regimen (GEN1029 0.3 mg/kg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 10 (80.00%)	7 / 7 (100.00%)	4 / 4 (100.00%)
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Spider vein			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Chest discomfort			
subjects affected / exposed	2 / 10 (20.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	2
Chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Face oedema			

subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 10 (40.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	4	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 10 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 10 (10.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Dyspnoea exertional			

subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pleuritic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	3 / 10 (30.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Nervousness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	3 / 10 (30.00%)	3 / 7 (42.86%)	2 / 4 (50.00%)
occurrences (all)	5	5	5
Amylase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			

subjects affected / exposed	4 / 10 (40.00%)	4 / 7 (57.14%)	2 / 4 (50.00%)
occurrences (all)	5	6	5
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
C-reactive protein increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Infusion related reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Dysgeusia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 10 (20.00%)	2 / 7 (28.57%)	1 / 4 (25.00%)
occurrences (all)	2	2	1
Leukocytosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			

subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Extraocular muscle paresis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	1 / 10 (10.00%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ascites			

subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	4 / 10 (40.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Diarrhoea			
subjects affected / exposed	1 / 10 (10.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Dyspepsia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Ileus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 10 (20.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Paraesthesia oral			

subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
Hepatobiliary disorders			
Biliary dilatation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cholangitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Portal vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 10 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			

subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Solar dermatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Bladder spasm			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 10 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Back pain			

subjects affected / exposed	2 / 10 (20.00%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
Hypertrophic osteoarthropathy			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Oral candidiasis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rash pustular			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Trichomoniasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 10 (20.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
Dehydration			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	3	0	2
Diabetes mellitus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Biweekly Regimen (GEN1029 1.0 mg/kg)	Biweekly Regimen (GEN1029 2.0 mg/kg)	Biweekly Regimen (GEN1029 3.0 mg/kg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 11 (100.00%)	7 / 7 (100.00%)	7 / 7 (100.00%)
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hot flush			

subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spider vein			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 11 (18.18%)	2 / 7 (28.57%)	2 / 7 (28.57%)
occurrences (all)	4	5	3
Chest discomfort			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Chills			
subjects affected / exposed	1 / 11 (9.09%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Early satiety			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	5 / 11 (45.45%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	8	2	1
Mucosal inflammation			

subjects affected / exposed	3 / 11 (27.27%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Oedema			
subjects affected / exposed	2 / 11 (18.18%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Oedema peripheral			
subjects affected / exposed	0 / 11 (0.00%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	4 / 11 (36.36%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	5	1	1
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 11 (18.18%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	2	3	0
Dysphonia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	1 / 11 (9.09%)	3 / 7 (42.86%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Dyspnoea exertional			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			

subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	2 / 11 (18.18%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Nervousness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	6 / 11 (54.55%)	3 / 7 (42.86%)	2 / 7 (28.57%)
occurrences (all)	14	3	2
Amylase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	7 / 11 (63.64%)	4 / 7 (57.14%)	3 / 7 (42.86%)
occurrences (all)	14	4	3
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 11 (27.27%)	3 / 7 (42.86%)	1 / 7 (14.29%)
occurrences (all)	4	3	1
Blood creatine phosphokinase increased			

subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 11 (18.18%)	2 / 7 (28.57%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Lipase increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Transaminases increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	1 / 11 (9.09%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Weight increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 11 (9.09%)	2 / 7 (28.57%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Overdose			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Headache			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 11 (27.27%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	3	2	3
Leukocytosis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lymphopenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			

Ear pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Extraocular muscle paresis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	0 / 11 (0.00%)	2 / 7 (28.57%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Abdominal pain			
subjects affected / exposed	2 / 11 (18.18%)	1 / 7 (14.29%)	2 / 7 (28.57%)
occurrences (all)	2	1	2
Abdominal pain upper			
subjects affected / exposed	1 / 11 (9.09%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Ascites			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	1 / 11 (9.09%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			

subjects affected / exposed	3 / 11 (27.27%)	4 / 7 (57.14%)	2 / 7 (28.57%)
occurrences (all)	3	6	2
Dyspepsia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Dysphagia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Enteritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Ileus			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Melaena			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 11 (9.09%)	3 / 7 (42.86%)	1 / 7 (14.29%)
occurrences (all)	1	3	1
Paraesthesia oral			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rectal tenesmus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache			

subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 11 (9.09%)	4 / 7 (57.14%)	2 / 7 (28.57%)
occurrences (all)	1	6	2
Hepatobiliary disorders			
Biliary dilatation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Cholangitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Portal vein thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	2 / 11 (18.18%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Pain of skin			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	2 / 11 (18.18%)	2 / 7 (28.57%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Rash			
subjects affected / exposed	2 / 11 (18.18%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	2	2	1
Solar dermatitis			

subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 11 (27.27%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	6	0	0
Back pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertrophic osteoarthropathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 7 (28.57%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Myopathy			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	2	3
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Trichomoniasis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	2 / 7 (28.57%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	4 / 11 (36.36%)	3 / 7 (42.86%)	2 / 7 (28.57%)
occurrences (all)	4	3	2
Dehydration			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 11 (18.18%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hyperkalaemia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 11 (18.18%)	3 / 7 (42.86%)	0 / 7 (0.00%)
occurrences (all)	3	4	0
Hypocalcaemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	1 / 11 (9.09%)	4 / 7 (57.14%)	0 / 7 (0.00%)
occurrences (all)	1	5	0
Hypomagnesaemia			
subjects affected / exposed	1 / 11 (9.09%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	2	2	1
Hyponatraemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Hypophosphataemia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	0	2	1

Non-serious adverse events	Priming Regimen (GEN1029 0.1 mg/kg)	Intensified Regimen (GEN1029 1.0 mg/kg)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	1 / 1 (100.00%)	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Spider vein			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Chest discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Drug withdrawal syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Early satiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Face oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pain			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pleuritic pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Nervousness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Alanine aminotransferase increased			
subjects affected / exposed	1 / 1 (100.00%)	1 / 1 (100.00%)	
occurrences (all)	2	1	
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
C-reactive protein increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Lipase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Transaminases increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Weight increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Overdose			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Dysgeusia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Leukocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Extraocular muscle paresis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Eye pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Visual impairment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

Enteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Ileus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Melaena			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Paraesthesia oral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Rectal tenesmus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Biliary dilatation			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cholangitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Portal vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pain of skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Solar dermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Bladder spasm			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pollakiuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Proteinuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypertrophic osteoarthropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Joint swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal discomfort			

subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Musculoskeletal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Myopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Rash pustular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

Rhinitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Trichomoniasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dehydration			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
Diabetes mellitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 March 2018	Modified eligibility criteria, DLT definition, safety stopping rule, and trial objectives and trial design.
07 February 2019	Introduction of 2 additional dose regimens (i.e. intensified and Priming regimens) to aim to achieve the best therapeutic response.
18 March 2019	Introduction of a mitigation measures to prevent transaminase elevations.
13 September 2019	Removal of the discontinued Intensified Regimen from the protocol, modified priming regimen dose, and implementation of further precautionary measures and management guidance for mitigation of toxicities.
24 October 2019	Main reason for the present protocol amendment was the addition of mandatory intermediate dose levels (0.6, 2.0, 4.5, 9.0, and 15.0 mg/kg) in dose escalation, based upon health authority feedback. Other individual changes were also implemented as part of this amendment.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
15 August 2019	The sponsor, Genmab, notified FDA on August 9, 2019 that they are implementing a temporary halt to recruitment, based upon the observation of liver toxicity and explained the plan to permanently discontinue future development of the Intensified Regimen of GEN1029.	18 October 2019

Notes:

Limitations and caveats

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

Results for the patient in Priming Regimen and the patient in Intensified Regimen (IR) were only included in the Study Report Listings. Both regimens got discontinued. The IR patient had a DLT. To avoid re-identification, listing data is not included

Notes: