



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, \geq 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 \leq G1 within 24 hours, \geq 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 \geq 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 TESA | 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 TESA | 6 | 4 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With \geq Grade 3 Laboratory Results

| | |
|-----------------|---|
| End point title | Number of Participants With \geq Grade 3 Laboratory |
|-----------------|---|

End point description:

Number of participants with laboratory measurements of \geq 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 $\geq 30\%$ 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 occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Overdose subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| Cardiac disorders Tachycardia subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Nervous system disorders Dizziness subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 1 / 7 (14.29%) 1 | 1 / 4 (25.00%) 1 |
| Dysgeusia subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Paraesthesia subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Peripheral sensory neuropathy subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Somnolence subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) | 2 / 10 (20.00%) 2 | 2 / 7 (28.57%) 2 | 1 / 4 (25.00%) 1 |
| Leukocytosis subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 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 occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Rectal tenesmus subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Toothache subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Vomiting subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 2 | 0 / 7 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| Hepatobiliary disorders Biliary dilatation subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Cholangitis subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Hyperbilirubinaemia subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| Portal vein thrombosis subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Skin and subcutaneous tissue disorders Night sweats subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Pain of skin subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 1 / 7 (14.29%) 1 | 0 / 4 (0.00%) 0 |
| Palmar-plantar erythrodysaesthesia syndrome subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Pruritus | | | |

| | | | |
|--|----------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Rash | | | |
| subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Solar dermatitis | | | |
| subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 1 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Bladder spasm | | | |
| subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Dysuria | | | |
| subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Haematuria | | | |
| subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 1 / 7 (14.29%) 1 | 0 / 4 (0.00%) 0 |
| Pollakiuria | | | |
| subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| Proteinuria | | | |
| subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| subjects affected / exposed occurrences (all) | 0 / 10 (0.00%) 0 | 1 / 7 (14.29%) 1 | 0 / 4 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed occurrences (all) | 1 / 10 (10.00%) 2 | 0 / 7 (0.00%) 0 | 0 / 4 (0.00%) 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 occurrences (all) | 0 / 11 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Nervous system disorders | | | |
| Dizziness subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Dysgeusia subjects affected / exposed occurrences (all) | 1 / 11 (9.09%) 1 | 1 / 7 (14.29%) 1 | 0 / 7 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 0 / 7 (0.00%) 0 | 1 / 7 (14.29%) 1 |
| Paraesthesia subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 1 / 7 (14.29%) 1 | 1 / 7 (14.29%) 1 |
| Peripheral sensory neuropathy subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 1 / 7 (14.29%) 1 | 0 / 7 (0.00%) 0 |
| Somnolence subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 3 / 11 (27.27%) 3 | 2 / 7 (28.57%) 2 | 1 / 7 (14.29%) 3 |
| Leukocytosis subjects affected / exposed occurrences (all) | 1 / 11 (9.09%) 1 | 0 / 7 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Lymphopenia subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Ear and labyrinth disorders | | | |

| | | | |
|--|----------------------|---------------------|---------------------|
| Ear pain subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Eye disorders | | | |
| Diplopia subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Extraocular muscle paresis subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 0 / 7 (0.00%) 0 | 1 / 7 (14.29%) 1 |
| Eye pain subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Visual impairment subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort subjects affected / exposed occurrences (all) | 1 / 11 (9.09%) 1 | 0 / 7 (0.00%) 0 | 0 / 7 (0.00%) 0 |
| Abdominal distension subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 2 / 7 (28.57%) 2 | 0 / 7 (0.00%) 0 |
| Abdominal pain subjects affected / exposed occurrences (all) | 2 / 11 (18.18%) 2 | 1 / 7 (14.29%) 1 | 2 / 7 (28.57%) 2 |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 1 / 11 (9.09%) 1 | 1 / 7 (14.29%) 1 | 1 / 7 (14.29%) 1 |
| Ascites subjects affected / exposed occurrences (all) | 0 / 11 (0.00%) 0 | 1 / 7 (14.29%) 1 | 0 / 7 (0.00%) 0 |
| Constipation subjects affected / exposed occurrences (all) | 1 / 11 (9.09%) 1 | 1 / 7 (14.29%) 1 | 0 / 7 (0.00%) 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 erythrodysesthesia 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 occurrences (all) | 0 / 11 (0.00%) 0 | 1 / 7 (14.29%) 1 | 0 / 7 (0.00%) 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 occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | |
| Pain subjects affected / exposed occurrences (all) | 1 / 1 (100.00%) 1 | 0 / 1 (0.00%) 0 | |
| Pyrexia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | |
| Reproductive system and breast disorders Pelvic pain subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | |
| Dysphonia subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | |
| Dyspnoea subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | |
| Dyspnoea exertional subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | |
| Epistaxis subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | |
| Nasal congestion subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 0 / 1 (0.00%) 0 | 0 / 1 (0.00%) 0 | |
| Pleuritic pain | | | |

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