Clinical trial results:
A Phase II, Open Label, Randomized, Two-Arm Study to Investigate the Efficacy and Safety of Two Doses of the Antibody Drug Conjugate GSK2857916 in Participants with Multiple Myeloma Who Had 3 or More Prior Lines of Treatment, Are Refractory to a Proteasome Inhibitor and an Immunomodulatory Agent and Have Failed an Anti-CD38 Antibody (DREAMM 2)

Summary

EudraCT number	2017-004810-25
Trial protocol	GB DE ES IT
Global end of trial date	12 September 2024

Results information

Result version number	v4 (current)
This version publication date	03 September 2025
First version publication date	26 April 2020
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	205678

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	79 New Oxford Street, London, United Kingdom, WC1A 1DG
Public contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.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	04 May 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 June 2019
Global end of trial reached?	Yes
Global end of trial date	12 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the clinical efficacy of 2 doses of GSK2857916 in participants with relapsed/refractory multiple myeloma

Protection of trial subjects:

In order to minimize corneal events associated with GSK2857916 prophylactic preservative-free artificial tears should be administered in each eye at least 4 to 8 times daily beginning on Cycle 1 Day 1 until the end of treatment. In the event of ocular symptoms (e.g., dry eyes), the use of artificial tears may be increased up to every 2 hours as needed. While not yet clinically demonstrated, it is theoretically possible that the application of a cooling eye mask during GSK2857916 administration, and in the first few hours after infusion may subsequently decrease ocular side effects. On the day of infusion at the discretion of the participant and the investigator, the following may be considered: • Beginning with the start of each GSK2857916 infusion, participants may apply cooling eye masks to their eyes for approximately 1 hour or as much as tolerated. • Participants may continue using the cooling eye mask beyond the first hour for up to 4 hours. Further use beyond 4 hours is at the participant’s discretion. Participants should receive full supportive care during the study, including transfusions of blood products, growth factors, and treatment with antibiotics, anti-emetics, antidiarrheal, and analgesics, as appropriate. Concomitant therapy with bisphosphonates is allowed. Participants may receive local irradiation for pain or stability control.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 June 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Scientific research
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 5
Country: Number of subjects enrolled	Canada: 12
Country: Number of subjects enrolled	France: 26
Country: Number of subjects enrolled	Germany: 16
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Spain: 17
Country: Number of subjects enrolled	United Kingdom: 12
Country: Number of subjects enrolled	United States: 126
Worldwide total number of subjects	221
EEA total number of subjects	66

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)	91
From 65 to 84 years	127
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

This was an open-label, randomized, multicenter study to evaluate the efficacy and safety of belantamab mafodotin monotherapy at a dose of 2.5 milligram per kilogram (mg/kg) or 3.4 mg/kg, given intravenously (IV) in participants with relapsed/refractory multiple myeloma (RRMM).

Pre-assignment

Screening details:

A total of 221 participants were enrolled in this study. The study consisted of two phases - Main Study Phase and Post Analysis Continued Treatment (PACT) Phase. In PACT phase those participants benefiting from drug continued to receive study drug until discontinuation or withdrawal from study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK2857916 2.5 mg/kg (Frozen liquid)

Arm description:

Participants were administered frozen liquid (30 mg/vial solution in a single use vial) at a dose of 2.5 mg/kg GSK2857916 as IV solution once every three weeks for a maximum of up to 39 cycles (1 cycle= 21 days). Frozen liquid was diluted with 0.9 percent saline.

Arm type	Experimental
Investigational medicinal product name	GSK2857916
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GSK2857916 frozen liquid was available as 30 milligrams pervial solution in single-use vial. It was diluted with 0.9 percent saline to the appropriate concentration for the dose (2.5milligram per kilogram [mg/kg]).Participants were administered GSK2857916 via intravenous route

Arm title	GSK2857916 3.4 mg/kg (Frozen liquid)

Arm description:

Participants were administered frozen liquid (30 mg/vial solution in a single use vial) at a dose of 3.4 mg/kg GSK2857916 as IV solution once every three weeks for a maximum of up to 32 cycles (1 cycle= 21 days). Frozen liquid was diluted with 0.9 percent saline.

Arm type	Experimental
Investigational medicinal product name	GSK2857916
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GSK2857916 frozen liquid wasavailable as 30 milligrams pervial solution in single-use vial. Itwas diluted with 0.9 percent saline to the appropriate concentration for the dose (3.4mg/kg]. Participants were administered GSK2857916 viaintravenous route.

Arm title	GSK2857916 3.4 mg/kg (Lyophilized)

Arm description:

Participants were administered lyophilized powder (100 mg/vial in a single use vial) at a dose of 3.4 mg/kg GSK2857916 given IV for a maximum of up to 35 cycles (1 cycle= 21 days). Lyophilized powder was reconstituted using water for injection.

Arm type	Experimental
Investigational medicinal product name	GSK2857916
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

GSK2857916 lyophilized powderwas available as 100 milligramsper vial in single-use vial forreconstitution. It wasreconstituted using water for injection and diluted with 0.9percent saline to the appropriate concentration for the dose (3.4mg/kg). Participants were administered GSK2857916 viaintravenous route.

Number of subjects in period 1	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)
Started	97	99	25
Received Study Treatment	95	99	24
Completed	1	2	0
Not completed	96	97	25
Consent withdrawn by subject	8	2	2
Physician decision	2	4	-
other reasons	14	10	5
Death	70	80	16
Lost to follow-up	2	1	2

Baseline characteristics

Reporting groups	
Reporting group title	GSK2857916 2.5 mg/kg (Frozen liquid)
Reporting group description:	
Participants were administered frozen liquid (30 mg/vial solution in a single use vial) at a dose of 2.5 mg/kg GSK2857916 as IV solution once every three weeks for a maximum of up to 39 cycles (1 cycle= 21 days). Frozen liquid was diluted with 0.9 percent saline.	
Reporting group title	GSK2857916 3.4 mg/kg (Frozen liquid)
Reporting group description:	
Participants were administered frozen liquid (30 mg/vial solution in a single use vial) at a dose of 3.4 mg/kg GSK2857916 as IV solution once every three weeks for a maximum of up to 32 cycles (1 cycle= 21 days). Frozen liquid was diluted with 0.9 percent saline.	
Reporting group title	GSK2857916 3.4 mg/kg (Lyophilized)
Reporting group description:	
Participants were administered lyophilized powder (100 mg/vial in a single use vial) at a dose of 3.4 mg/kg GSK2857916 given IV for a maximum of up to 35 cycles (1 cycle= 21 days). Lyophilized powder was reconstituted using water for injection.	

Reporting group values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)
Number of subjects	97	99	25
Age categorical			
Baseline characteristics were presented for all randomized participants including 3 randomized participants who never received treatment (2-withdrawal by physician decision and 1-death).			
Units: Participants			
Total Participants	97	99	25
Age Continuous			
Baseline characteristics were presented for all randomized participants including 3 randomized participants who never received treatment (2-withdrawal by physician decision and 1-death).			
Units: years			
arithmetic mean	64.1	66.0	67.2
standard deviation	± 10.01	± 9.09	± 10.78
Sex: Female, Male			
Baseline characteristics were presented for all randomized participants including 3 randomized participants who never received treatment (2-withdrawal by physician decision and 1-death).			
Units: Participants			
Female	46	43	11
Male	51	56	14
Race/Ethnicity, Customized			
Baseline characteristics were presented for all randomized participants including 3 randomized participants who never received treatment (2-withdrawal by physician decision and 1-death).			
Units: Subjects			
Black or African American	16	11	3
Asian - Central/South Asian Heritage	1	0	0
Asian - East Asian Heritage	1	0	0
Asian - South East Asian Heritage	0	1	1
White - Arabic/North African Heritage	4	2	0
White - White/Caucasian/European Heritage	72	83	21
Mixed Asian Race	0	1	0

Mixed White Race	0	1	0
Unknown	1	0	0
Missing	2	0	0

Reporting group values	Total		
Number of subjects	221		
Age categorical			
Baseline characteristics were presented for all randomized participants including 3 randomized participants who never received treatment (2-withdrawal by physician decision and 1-death).			
Units: Participants			
Total Participants	221		
Age Continuous			
Baseline characteristics were presented for all randomized participants including 3 randomized participants who never received treatment (2-withdrawal by physician decision and 1-death).			
Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Baseline characteristics were presented for all randomized participants including 3 randomized participants who never received treatment (2-withdrawal by physician decision and 1-death).			
Units: Participants			
Female	100		
Male	121		
Race/Ethnicity, Customized			
Baseline characteristics were presented for all randomized participants including 3 randomized participants who never received treatment (2-withdrawal by physician decision and 1-death).			
Units: Subjects			
Black or African American	30		
Asian - Central/South Asian Heritage	1		
Asian - East Asian Heritage	1		
Asian - South East Asian Heritage	2		
White - Arabic/North African Heritage	6		
White - White/Caucasian/European Heritage	176		
Mixed Asian Race	1		
Mixed White Race	1		
Unknown	1		
Missing	2		

End points

End points reporting groups

Reporting group title	GSK2857916 2.5 mg/kg (Frozen liquid)

Reporting group description:

Participants were administered frozen liquid (30 mg/vial solution in a single use vial) at a dose of 2.5 mg/kg GSK2857916 as IV solution once every three weeks for a maximum of up to 39 cycles (1 cycle= 21 days). Frozen liquid was diluted with 0.9 percent saline.

Reporting group title	GSK2857916 3.4 mg/kg (Frozen liquid)

Reporting group description:

Participants were administered frozen liquid (30 mg/vial solution in a single use vial) at a dose of 3.4 mg/kg GSK2857916 as IV solution once every three weeks for a maximum of up to 32 cycles (1 cycle= 21 days). Frozen liquid was diluted with 0.9 percent saline.

Reporting group title	GSK2857916 3.4 mg/kg (Lyophilized)

Reporting group description:

Participants were administered lyophilized powder (100 mg/vial in a single use vial) at a dose of 3.4 mg/kg GSK2857916 given IV for a maximum of up to 35 cycles (1 cycle= 21 days). Lyophilized powder was reconstituted using water for injection.

Primary: Overall response rate (ORR) by Independent Review Committee (IRC) (Full Analysis Population)

End point title	Overall response rate (ORR) by Independent Review Committee (IRC) (Full Analysis Population)[1]

End point description:

ORR was determined according to the 2016 international myeloma working group (IMWG) response criteria by IRC. ORR was calculated as the percentage of participants with a confirmed partial response (PR) or better (that is [i.e.], PR, very good partial response [VGPR], complete response [CR] and stringent complete response [sCR]). Confidence intervals were based on the exact method. Full Analysis Population comprised of all randomized participants (any participant who received a treatment randomization number was considered as randomized) whether or not randomized treatment was administered. This population was based on the treatment the participant was randomized to.

End point type	Primary

End point timeframe:

Up to 48 weeks

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: There are no statistical data to report.

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97[2]	99[3]	25[4]	
Units: Percentage of Participants				
number (confidence interval 97.5%)	31 (20.8 to 42.6)	34 (23.9 to 46.0)	48 (25.5 to 71.1)	

Notes:

[2] - Full Analysis Population

[3] - Full Analysis Population

[4] - Full Analysis Population

Statistical analyses

No statistical analyses for this end point

Primary: Overall response rate by Independent Review Committee (Efficacy Population)

End point title	Overall response rate by Independent Review Committee (Efficacy Population)[5][6]

End point description:

ORR was determined according to the 2016 IMWG response criteria by IRC. ORR was calculated as the percentage of participants with a confirmed PR or better (i.e., PR, VGPR, CR and sCR). Confidence intervals were based on the exact method. Efficacy Population comprised of first 130 intent-to-treat participants whether or not randomized treatment (frozen solution) was administered. Intent-to-treat Population comprised of all randomized participants whether or not randomized treatment was administered. Data is not presented for 'GSK2857916 3.4 mg/kg (Lyophilized)' arm as it is not included in Efficacy Population.

End point type	Primary

End point timeframe:

Up to 48 weeks

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: There are no statistical data to report.

[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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64[7]	66[8]		
Units: Percentage of Participants				
number (confidence interval 95%)	30 (18.9 to 42.4)	30 (19.6 to 42.9)		

Notes:

[7] - Efficacy Population

[8] - Efficacy Population

Statistical analyses

No statistical analyses for this end point

Secondary: Overall response rate by investigator assessment (IA) (Full Analysis Population)

End point title	Overall response rate by investigator assessment (IA) (Full Analysis Population)

End point description:

ORR was determined by the investigator according to the 2016 IMWG response criteria. ORR was calculated as the percentage of participants with a confirmed PR or better (i.e., PR, VGPR, CR and sCR). Confidence intervals were based on the exact method. Percentage values are rounded off.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97[9]	99[10]	25[11]	
Units: Percentage of Participants				
number (confidence interval 95%)	33 (23.8 to 43.3)	32 (23.3 to 42.5)	52 (31.3 to 72.2)	

Notes:

[9] - Full Analysis Population

[10] - Full Analysis Population

[11] - Full Analysis Population

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical benefit rate (CBR) by investigator assessment (Full Analysis Population)

End point title	Clinical benefit rate (CBR) by investigator assessment (Full Analysis Population)

End point description:

CBR was determined by the investigator according to the 2016 IMWG response criteria. CBR was calculated as the percentage of participants with a confirmed minimal response (MR) or better (i.e., MR, PR, VGPR, CR and sCR). Confidence intervals were based on the exact method. Percentage values are rounded off.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97[12]	99[13]	25[14]	
Units: Percentage of Participants				
number (confidence interval 95%)	35 (25.6 to 45.4)	38 (28.8 to 48.7)	60 (38.7 to 78.9)	

Notes:

[12] - Full Analysis Population

[13] - Full Analysis Population

[14] - Full Analysis Population

Statistical analyses

No statistical analyses for this end point

Secondary: Overall response rate by investigator assessment (Efficacy Population)

End point title	Overall response rate by investigator assessment (Efficacy Population)[15]

End point description:

ORR was determined by the investigator according to the 2016 IMWG response criteria. ORR was calculated as the percentage of participants with a confirmed PR or better (i.e., PR, VGPR, CR and sCR).

Confidence intervals were based on the exact method. Data is not presented for 'GSK2857916 3.4 mg/kg (Lyophilized)' arm as it is not included in Efficacy Population. Percentage values are rounded off.

End point type	Secondary

End point timeframe:

Up to 186 weeks

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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64[16]	66[17]		
Units: Percentage of Participants				
number (confidence interval 95%)	33 (21.6 to 45.7)	26 (15.8 to 38.0)		

Notes:

[16] - Efficacy Population.

[17] - Efficacy Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical benefit rate by Independent Review Committee (Full Analysis Population)

End point title	Clinical benefit rate by Independent Review Committee (Full Analysis Population)

End point description:

CBR was determined according to the 2016 IMWG response criteria by IRC. CBR was calculated as the percentage of participants with a confirmed MR or better (i.e., MR, PR, VGPR, CR and sCR). Confidence intervals were based on the exact method. Percentage values are rounded off.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97[18]	99[19]	25[20]	
Units: Percentage of Participants				
number (confidence interval 95%)	36 (26.6 to 46.5)	40 (30.7 to 50.7)	56 (34.9 to 75.6)	

Notes:

[18] - Full Analysis Population

[19] - Full Analysis Population

[20] - Full Analysis Population

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical benefit rate by investigator assessment (Efficacy Population)

End point title	Clinical benefit rate by investigator assessment (Efficacy Population)[21]

End point description:

CBR was determined by the investigator according to the 2016 IMWG response criteria. CBR was calculated as the percentage of participants with a confirmed MR or better (i.e., MR, PR, VGPR, CR and sCR). Confidence intervals were based on the exact method. Data is not presented for 'GSK2857916 3.4 mg/kg (Lyophilized)' arm as it is not included in Efficacy Population. Percentage values are rounded off.

End point type	Secondary

End point timeframe:

Up to 186 weeks

Notes:

[21] - 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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64[22]	66[23]		
Units: Percentage of Participants				
number (confidence interval 95%)	34 (22.9 to 47.3)	35 (23.5 to 47.6)		

Notes:

[22] - Efficacy Population.

[23] - Efficacy Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response (DoR) by investigator assessment (Full Analysis Population)

End point title	Duration of response (DoR) by investigator assessment (Full Analysis Population)

End point description:

DoR is defined as the time from first documented evidence of PR or better until the earliest date of documented disease progression (PD) per IMWG response criteria; or death due to PD among participants who achieved an overall response, i.e., confirmed PR or better. DOR based on responses assessed by investigator is presented. Median and inter-quartile range (first quartile and third quartile) of DOR are presented. Only responders (confirmed PR or better) by investigator assessment were included in this analysis.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32[24]	32[25]	13[26]	
Units: Months				
median (inter-quartile range (Q1-Q3))	12.4 (4.2 to 21.4)	12.6 (5.6 to 22.8)	5.3 (2.8 to 9.0)	

Notes:

[24] - Full Analysis Population.

[25] - Full Analysis Population.

[26] - Full Analysis Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical benefit rate by Independent Review Committee (Efficacy Population)

End point title	Clinical benefit rate by Independent Review Committee (Efficacy Population)[27]

End point description:

CBR was determined according to the 2016 IMWG response criteria by IRC. CBR was calculated as the percentage of participants with a confirmed MR or better (i.e., MR, PR, VGPR, CR and sCR). Confidence intervals were based on the exact method. Data is not presented for 'GSK2857916 3.4 mg/kg (Lyophilized)' arm as it is not included in Efficacy Population. Percentage values are rounded off.

End point type	Secondary

End point timeframe:

Up to 186 weeks

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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64[28]	66[29]		
Units: Percentage of Participants				
number (confidence interval 95%)	34 (22.9 to 47.3)	38 (26.2 to 50.7)		

Notes:

[28] - Efficacy Population.

[29] - Efficacy Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response by investigator assessment (Efficacy Population)

End point title	Duration of response by investigator assessment (Efficacy Population)[30]

End point description:

DoR is defined as the time from first documented evidence of PR or better until the earliest date of

documented PD per IMWG response criteria; or death due to PD among participants who achieved an overall response, i.e., confirmed PR or better. DOR based on responses assessed by investigator is presented. Median and inter-quartile range (first quartile and third quartile) of DOR are presented. Data is not presented for 'GSK2857916 3.4 mg/kg (Lyophilized)' arm as it is not included in Efficacy Population. Only responders (confirmed PR or better) by investigator assessment were included in this analysis. 88888 indicates <75% of participants experienced the event within the treatment arm. Hence, third-quartile could not be derived

End point type	Secondary

End point timeframe:

Up to 186 weeks

Notes:

[30] - 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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21[31]	17[32]		
Units: Months				
median (inter-quartile range (Q1-Q3))	6.9 (4.2 to 20.8)	15.9 (12.6 to 88888)		

Notes:

[31] - Efficacy Population.

[32] - Efficacy Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response by Independent Review Committee (Full Analysis Population)

End point title	Duration of response by Independent Review Committee (Full Analysis Population)

End point description:

DoR is defined as the time from first documented evidence of PR or better until the earliest date of documented PD per IMWG response criteria; or death due to PD among participants who achieved an overall response, i.e., confirmed PR or better. DOR based on responses assessed by IRC is presented. Median and inter-quartile range (first quartile and third quartile) of DOR are presented. Only responders (confirmed PR or better) by Independent Review committee were included in this analysis.88888 indicates <75% of participants experienced the event within the treatment arm. Hence, third-quartile could not be derived.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31[33]	35[34]	13[35]	
Units: Months				
median (inter-quartile range (Q1-Q3))	12.5 (4.2 to 19.4)	6.2 (4.2 to 88888)	9.0 (3.4 to 10.4)	

Notes:

[33] - Full Analysis Population.

[34] - Full Analysis Population.

[35] - Full Analysis Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response by Independent Review Committee (Efficacy Population)

End point title	Duration of response by Independent Review Committee (Efficacy Population)[36]

End point description:

DoR is defined as the time from first documented evidence of PR or better until the earliest date of documented PD per IMWG response criteria; or death due to PD among participants who achieved an overall response, i.e., confirmed PR or better. DOR based on responses assessed by IRC is presented. Median and inter-quartile range (first quartile and third quartile) of DOR are presented. Data is not presented for 'GSK2857916 3.4 mg/kg (Lyophilized)' arm as it is not included in Efficacy Population. Only responders (confirmed PR or better) by Independent Review Committee were included in this analysis. 88888 indicates <75% of participants experienced the event within the treatment arm. Hence, third-quartile could not be derived

End point type	Secondary

End point timeframe:

Up to 186 weeks

Notes:

[36] - 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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20[37]	20[38]		
Units: Months				
median (inter-quartile range (Q1-Q3))	11.0 (4.0 to 19.4)	15.9 (4.2 to 88888)		

Notes:

[37] - Efficacy Population.

[38] - Efficacy Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to response by investigator assessment (Full Analysis Population)

End point title	Time to response by investigator assessment (Full Analysis Population)

End point description:

Time to response is defined as the time between the date of randomization and the first documented evidence of response (PR or better), among participants who achieve a response (i.e., confirmed PR or better). Time to response based on responses assessed by investigator is presented. Median and inter-quartile range (first quartile and third quartile) of time to response are presented. Only responders (confirmed PR or better) by investigator assessment were included in this analysis

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32[39]	32[40]	13[41]	
Units: Months				
median (inter-quartile range (Q1-Q3))	1.5 (0.8 to 2.5)	1.5 (0.9 to 3.0)	0.9 (0.8 to 1.0)	

Notes:

[39] - Full Analysis Population.

[40] - Full Analysis Population.

[41] - Full Analysis Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to response by investigator assessment (Efficacy Population)

End point title	Time to response by investigator assessment (Efficacy Population)[42]

End point description:

Time to response is defined as the time between the date of randomization and the first documented evidence of response (PR or better), among participants who achieve a response (i.e., confirmed PR or better). Time to response based on responses assessed by investigator is presented. Median and inter-quartile range (first quartile and third quartile) of time to response are presented. Data is not presented for 'GSK2857916 3.4 mg/kg (Lyophilized)' arm as it is not included in Efficacy Population. Only responders (confirmed PR or better) by investigator assessment were included in this analysis.

End point type	Secondary

End point timeframe:

Up to 186 weeks

Notes:

[42] - 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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21[43]	17[44]		
Units: Months				
median (inter-quartile range (Q1-Q3))	1.4 (0.8 to 2.8)	1.5 (1.4 to 2.8)		

Notes:

[43] - Efficacy Population

[44] - Efficacy Population

Statistical analyses

No statistical analyses for this end point

Secondary: Time to response by Independent Review Committee (Full Analysis Population)

End point title	Time to response by Independent Review Committee (Full Analysis Population)

End point description:

Time to response is defined as the time between the date of randomization and the first documented evidence of response (PR or better), among participants who achieve a response (i.e., confirmed PR or better). Time to response based on responses assessed by IRC is presented. Median and inter-quartile range (first quartile and third quartile) of time to response are presented. Only responders (confirmed PR or better) by Independent Review Committee were included in this analysis

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31[45]	35[46]	13[47]	
Units: Months				
median (inter-quartile range (Q1-Q3))	1.5 (0.8 to 2.2)	1.4 (0.8 to 2.8)	0.9 (0.8 to 2.3)	

Notes:

[45] - Full Analysis Population.

[46] - Full Analysis Population.

[47] - Full Analysis Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to response by Independent Review Committee (Efficacy Population)

End point title	Time to response by Independent Review Committee (Efficacy Population)[48]

End point description:

Time to response is defined as the time between the date of randomization and the first documented evidence of response (PR or better), among participants who achieve a response (i.e., confirmed PR or better). Time to response based on responses assessed by IRC is presented. Median and inter-quartile

range (first quartile and third quartile) of time to response are presented. Data is not presented for 'GSK2857916 3.4 mg/kg (Lyophilized)' arm as it is not included in Efficacy Population. Only responders (confirmed PR or better) by Independent Review Committee were included in this analysis

End point type	Secondary

End point timeframe:

Up to 186 weeks

Notes:

[48] - 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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20[49]	20[50]		
Units: Months				
median (inter-quartile range (Q1-Q3))	1.5 (0.8 to 2.5)	1.4 (1.1 to 1.9)		

Notes:

[49] - Efficacy Population.

[50] - Efficacy Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression free survival by investigator assessment

End point title	Progression free survival by investigator assessment

End point description:

Progression free survival is defined as the time from randomization until the earliest date of documented PD per IMWG, or death due to any cause. Progressive Disease is defined as at least a 20% increase in the sum of the diameters of target lesions, taking as reference the smallest sum on study. Progression free survival based on responses assessed by investigator is presented. Median and inter-quartile range (first quartile and third quartile) of progression free survival are presented.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97[51]	99[52]	25[53]	
Units: Months				
median (inter-quartile range (Q1-Q3))	2.2 (0.8 to 7.7)	3.2 (1.0 to 9.8)	3.6 (1.5 to 8.7)	

Notes:

[51] - Full Analysis Population

[52] - Full Analysis Population

[53] - Full Analysis Population

Statistical analyses

No statistical analyses for this end point

Secondary: Progression free survival by Independent Review Committee

End point title	Progression free survival by Independent Review Committee

End point description:

Progression free survival is defined as the time from randomization until the earliest date of documented PD per IMWG, or death due to any cause. Progressive Disease is defined as at least a 20% increase in the sum of the diameters of target lesions, taking as reference the smallest sum on study. Progression free survival based on responses assessed by IRC is presented. Median and inter-quartile range (first quartile and third quartile) of progression free survival are presented.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97[54]	99[55]	25[56]	
Units: Months				
median (inter-quartile range (Q1-Q3))	2.8 (0.9 to 9.7)	3.9 (0.8 to 9.0)	5.7 (2.2 to 9.7)	

Notes:

[54] - Full Analysis Population

[55] - Full Analysis Population

[56] - Full Analysis Population

Statistical analyses

No statistical analyses for this end point

Secondary: Time to progression by investigator assessment

End point title	Time to progression by investigator assessment

End point description:

Time to progression is defined as the time from randomization until the earliest date of documented PD per IMWG, or death due to PD. Time to Progression based on responses assessed by investigator is presented. Median and inter-quartile range (first quartile and third quartile) of time to progression are presented.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97[57]	99[58]	25[59]	
Units: Months				
median (inter-quartile range (Q1-Q3))	2.2 (0.8 to 7.7)	3.9 (1.0 to 11.9)	3.6 (1.5 to 9.7)	

Notes:

[57] - Full Analysis Population

[58] - Full Analysis Population

[59] - Full Analysis Population

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival

End point title	Overall survival

End point description:

Overall survival is defined as the time from randomization until death due to any cause. Overall survival was analyzed using the Kaplan-Meier method by dose level. Median and inter-quartile range (first quartile and third quartile) of overall survival are presented. 88888 indicates <75% of participants experienced the event within the treatment arm. Hence, third-quartile could not be derived

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97[60]	99[61]	25[62]	
Units: Months				
median (inter-quartile range (Q1-Q3))	15.3 (4.8 to 36.4)	14.0 (6.2 to 26.6)	24.5 (7.7 to 88888)	

Notes:

[60] - Full Analysis Population

[61] - Full Analysis Population

[62] - Full Analysis Population

Statistical analyses

No statistical analyses for this end point

Secondary: Time to progression by Independent Review Committee

End point title	Time to progression by Independent Review Committee

End point description:

Time to progression is defined as the time from randomization until the earliest date of documented PD per IMWG, or death due to PD. Time to Progression based on responses assessed by IRC is presented. Median and inter-quartile range (first quartile and third quartile) of time to progression are presented.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97[63]	99[64]	25[65]	
Units: Months				
median (inter-quartile range (Q1-Q3))	2.9 (0.9 to 9.7)	4.9 (0.8 to 11.1)	5.7 (2.2 to 9.7)	

Notes:

[63] - Full Analysis Population

[64] - Full Analysis Population

[65] - Full Analysis Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with change from Baseline in hematology parameters with respect to the normal range

End point title	Number of participants with change from Baseline in hematology parameters with respect to the normal range

End point description:

Blood samples were collected for assessment of basophils,eosinophils,hematocrit,mean corpuscular hemoglobin (MCH),MCH concentration(MCHC),MC volume(MCV),monocyte,erythrocytes, reticulocytes.Baseline is latest pre-dose assessment(Day1)with non-missing value, including unscheduled visits.If values were unchanged(eg.high to high) or whose value became normal,were recorded in change to normal/NC category.Participants were counted twice if participant had both decreased to low/increased to high during post-Baseline(PB).Data for worst case PB is presented.Full Safety Population(FSP) comprised of all participants who received at least 1dose of study drug(frozen liquid or lyophilized powder). 3out of 221 participants did not receive any study treatment were excluded from FSP. All participants in study were included in analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[66]	99[67]	24[68]	
Units: Participants				
Basophils, decrease to low, n=94,96,23	2	7	0	
Basophils, change to normal or NC, n=94,96,23	87	85	19	
Basophils, increase to high, n=94,96,23	5	5	4	
Eosinophils, decrease to low, n=95,97,23	14	13	0	
Eosinophils, change to normal or NC, n=95,97,23	71	78	16	
Eosinophils, increase to high, n=95,97,23	10	8	7	
Hematocrit, decrease to low, n=95,97,24	10	3	1	

Hematocrit, change to normal or NC, n=95,97,24	84	94	23	
Hematocrit, increase to high, n=95,97,24	3	0	0	
MCH, decrease to low, n=95,95,21	14	17	5	
MCH, change to normal or NC, n=95,95,21	79	68	14	
MCH, increase to high, n=95,95,21	2	12	2	
MCHC, decrease to low, n=94,96,21	20	28	6	
MCHC, change to normal or NC, n=94,96,21	70	66	14	
MCHC, increase to high, n=94,96,21	5	2	1	
MCV,decrease to low, n=95,97,24	12	15	4	
MCV, change to normal or NC, n=95,97,24	77	73	18	
MCV, increase to high, n=95,97,24	7	10	3	
Monocytes, decrease to low, n=95,97,24	6	10	1	
Monocytes, change to normal or NC, n=95,97,24	62	50	12	
Monocytes, increase to high, n=95,97,24	28	45	12	
Erythrocytes, decrease to low, n=95,97,24	4	1	0	
Erythrocytes, change to normal or NC, n=95,97,24	91	95	21	
Erythrocytes, increase to high, n=95,97,24	2	1	3	
Reticulocytes, decrease to low, n=73,65,19	11	15	7	
Reticulocytes, change to normal or NC, n=73,65,19	49	33	3	
Reticulocytes, increase to high, n=73,65,19	16	21	10	

Notes:

[66] - Full Safety Population.

[67] - Full Safety Population.

[68] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with grade change from Baseline in hematology parameters

End point title	Number of participants with grade change from Baseline in hematology parameters

End point description:

Blood samples were collected for the analysis of following hematology parameters: hemoglobin (Hb), lymphocyte count (Lymph), neutrophil count (Neutro), platelet count (PC), and leukocyte count (leuko).The laboratory parameters were graded according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 4.03. Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; Grade 4: life–threatening consequences. Baseline was defined as latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. An increase is defined as an increase in CTCAE grade relative to Baseline grade. Data for worst-case post Baseline is presented. Only those participants with increase to grade 3 and increase to grade 4 have been presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[69]	97[70]	24[71]	
Units: Participants				
Hb, Hb increased, increase to Grade 3	0	0	0	
Hb, Hb increased, increase to Grade 4	0	0	0	
Hb, Anemia, increase to Grade 3	19	30	5	
Hb, Anemia, increase to Grade 4	0	0	0	
Lymph, Lymph count increased, increase to Grade 3	0	0	0	
Lymph, Lymph count increased, increase to Grade 4	0	0	0	
Lymph, Lymph count decreased, increase to Grade 3	16	24	6	
Lymph, Lymph count decreased, increase to Grade 4	5	5	2	
Neutro, increase to Grade 3	4	10	2	
Neutro, increase to Grade 4	6	3	1	
PC, increase to Grade 3	9	11	1	
PC, increase to Grade 4	13	25	2	
Leuko, Leukocytosis, increase to Grade 3	0	0	0	
Leuko, Leukocytosis, increase to Grade 4	0	0	0	
Leuko, Leuko decreased, increase to Grade 3	5	9	2	
Leuko, Leuko decreased, increase to Grade 4	3	3	0	

Notes:

[69] - Full Safety Population.

[70] - Full Safety Population.

[71] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with change from Baseline in clinical chemistry parameters with respect to the normal range

End point title	Number of participants with change from Baseline in clinical chemistry parameters with respect to the normal range

End point description:

Blood samples were collected for analysis of bicarbonate, direct bilirubin(D.Bil), calcium, chloride, lactate dehydrogenase(LDH), total protein,Urea enzymatic colorimetry.Baseline is latest pre-dose assessment(Day 1) with a non-missing value, including unscheduled visits. If values were unchanged (example: high to high), or whose value became normal, were recorded in the change to normal or NC category. Participants were counted twice if the participant had both decreased to low and increased to high during post Baseline. 3 out of 221participants did not receive any study treatment, were excluded from FSP.All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by

the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[72]	99[73]	24[74]	
Units: Participants				
Bicarbonate, decrease to low, n=90,93,24	12	22	4	
Bicarbonate, change to normal or NC, n=90,93,24	67	59	16	
Bicarbonate, increase to high, n=90,93,24	12	16	4	
D.Bil, decrease to low, n=70,72,21	0	2	0	
D.Bil, change to normal or NC, n=70,72,21	60	60	20	
D.Bil, increase to high, n=70,72,21	10	10	1	
Calcium, decrease to low, n=95,98,24	26	28	8	
Calcium, change to normal or NC, n=95,98,24	49	48	9	
Calcium, increase to high, n=95,98,24	29	27	9	
Chloride, decrease to low, n=94,97,24	17	14	2	
Chloride, change to normal or NC, n=94,97,24	63	63	20	
Chloride, increase to high, n=94,97,24	14	24	2	
LDH, decrease to low, n=92,98,23	1	1	0	
LDH, change to normal or NC, n=92,98,23	46	51	12	
LDH, increase to high, n=92,98,23	45	47	11	
Protein, decrease to low, n=94,98,24	32	32	8	
Protein, change to normal or NC, n=94,98,24	49	58	14	
Protein, increase to high, n=94,98,24	17	11	2	
Ureaenzymaticcolorimetrydecrease tolow, n=90,93,24	10	13	0	
Ureaenzymaticcolorimetrychangenormal /NCn=90,93,24	66	56	16	
Ureaenzymaticcolorimetryincreasetohigh , n=90,93,24	15	26	8	

Notes:

[72] - Full Safety Population.

[73] - Full Safety Population.

[74] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with grade change from Baseline in clinical

chemistry parameters

End point title	Number of participants with grade change from Baseline in clinical chemistry parameters

End point description:

Bloodsamples collected analysis of glucose(Gl),albumin,alkaline phosphatase (ALP),alanine aminotransferase(ALT), aspartate aminotransferase(AST), total bilirubin(T.Bil), creatinine kinase (CK), creatinine, gamma glutamyl transferase (GGT), potassium (Pot), magnesium (Mg), sodium (Sod), phosphate (Ph)urate &estimated glomerular filtration rate (eGFR).Grading was as per NCI-CTCAE version 4.03. Grade1: mild; Grade2: moderate; Grade3: severe or medically significant; Grade4: life–threatening consequences.Baseline is latest pre-dose assessment(Day 1) with a non-missing value, including unscheduled visits.An increase is defined as increase in CTCAE grade relative to Baseline grade. 3 out of 221participants did not receive any study treatment, were excluded from FSP. All participants in study were included in analysis (95, 99 and 24 Participants), but only those participants with data available at specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[75]	99[76]	24[77]	
Units: Participants				
Gl, Hyper, increase to Grade 3, n=94,95,24	3	5	0	
Gl, Hyper, increase to Grade 4, n=94,95,24	0	0	0	
Gl, Hypo, increase to Grade 3, n=94,95,24	0	0	0	
Gl, Hypo, increase to Grade 4, n=94,95,24	0	0	0	
Albumin, increase to Grade 3, n=94,98,24	4	7	1	
Albumin, increase to Grade 4, n=94,98,24	0	0	0	
ALP, increase to Grade 3, n=93,97,24	1	0	0	
ALP, increase to Grade 4, n=93,97,24	0	0	0	
ALT, increase to Grade 3, n=93,97,24	0	0	0	
ALT, increase to Grade 4, n=93,97,24	0	0	0	
AST, increase to Grade 3, n=93,96,24	3	7	0	
AST, increase to Grade 4, n=93,96,24	0	0	0	
T.Bil, increase to Grade 3, n=92,97,23	0	0	0	
T.Bil, increase to Grade 4, n=92,97,23	0	0	0	
CK, increase to Grade 3, n= 87,91,24	1	0	1	
CK, increase to Grade 4, n= 87,91,24	2	0	0	
Creatinine, increase to Grade 3, n= 95,97,24	4	3	0	
Creatinine, increase to Grade 4, n= 95,97,24	1	0	0	
GGT, increase to Grade 3, n= 91,95,24	5	11	1	
GGT, increase to Grade 4, n= 91,95,24	1	1	0	
Pot, Hyper,increase to Grade 3, n= 95,97,24	0	1	0	

Pot, Hyper,increase to Grade 4, n= 95,97,24	0	0	0	
Pot, Hypo, increase to Grade 3, n= 95,97,24	0	4	1	
Pot, Hypo, increase to Grade 4, n= 95,97,24	2	0	0	
Mg, Hyper, increase to Grade 3, n= 91,96,24	3	1	0	
Mg, Hyper, increase to Grade 4, n= 91,96,24	0	0	0	
Mg, Hypo, increase to Grade 3, n= 91,96,24	0	0	0	
Mg, Hypo, increase to Grade 4, n= 91,96,24	0	0	0	
Phosphate, increase to Grade 3, n= 90,93,24	4	8	2	
Phosphate, increase to Grade 4, n= 90,93,24	0	0	0	
Sod, Hyper, increase to Grade 3, n= 95,97,24	0	0	0	
Sod, Hyper, increase to Grade 4, n= 95,97,24	0	0	0	
Sod, Hypo, increase to Grade 3, n= 95,97,24	2	6	1	
Sod, Hypo, increase to Grade 4, n= 95,97,24	0	0	0	
Urate, increase to Grade 3, n= 93,96,24	0	0	0	
Urate, increase to Grade 4, n= 93,96,24	3	5	1	
eGFR, increase to Grade 3, n= 84,85,23	8	11	0	
eGFR, increase to Grade 4, n= 84,85,23	3	1	0	

Notes:

[75] - Full Safety Population.

[76] - Full Safety Population.

[77] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings during physical examination

End point title	Number of participants with abnormal findings during physical examination

End point description:

Physical examination included assessment of the head, eyes, ears, nose, throat, skin, thyroid, lungs, cardiovascular, abdomen (liver and spleen), lymph nodes, and extremities. This analysis was planned, but data was not collected and captured in the database.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[78]	0[79]	0[80]	
Units: Participants				

Notes:

[78] - Full Safety Population.

[79] - Full Safety Population.

[80] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with change from Baseline in pulse rate

End point title	Number of participants with change from Baseline in pulse rate

End point description:

Baseline was defined as the latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. Number of participants with worst case change from Baseline in pulse rate is presented. Data is categorized as: pulse rate 'decrease to <60 beats per minute [bpm]', 'increase to >100 bpm' and 'change to normal or no change'. If values were unchanged (example: increase to >100 bpm to increase to >100 bpm), or whose value became normal, were recorded in the 'change to normal or no change' category. Participants were counted twice if the participant had both ‘decreased to <60 bpm’ and ‘increased to >100 bpm’ during post Baseline. Data for worst-case post Baseline is presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[81]	99[82]	24[83]	
Units: Participants				
Decrease to <60	14	17	6	
Change to normal or no change	57	55	15	
Increase to >100	25	28	3	

Notes:

[81] - Full Safety Population.

[82] - Full Safety Population.

[83] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with change from Baseline in body temperature

End point title	Number of participants with change from Baseline in body temperature

End point description:

Baseline was defined as the latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. Number of participants with worst case change from Baseline in body temperature are presented. Data is categorized as: body temperature 'decrease to <=35 degrees celsius', 'increase to >=38 degrees celsius' and 'change to normal or no change'. If values were unchanged (example: increase to >=38 to increase to >=38 degrees celsius), or whose value became normal, were recorded in the 'change to normal or no change' category. Participants were counted twice if the participant had both 'decreased to <=35' and 'increased to >=38 degrees celsius' during post Baseline. Data for worst-case post Baseline is presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[84]	98[85]	24[86]	
Units: Participants				
Decrease to <=35	1	3	0	
Change to normal or no change	86	85	21	
Increase to >=38	8	10	3	

Notes:

[84] - Full Safety Population.

[85] - Full Safety Population.

[86] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with grade change from Baseline in systolic blood pressure (SBP) and diastolic blood pressure (DBP)

End point title	Number of participants with grade change from Baseline in systolic blood pressure (SBP) and diastolic blood pressure (DBP)

End point description:

SBP and DBP were graded using NCI CTCAE version 4.03. For SBP: Grade 0: <120 millimeter mercury (mmHg); Grade 1: 120-139 mmHg; Grade 2: 140-159 mmHg; Grade 3: >=160 mmHg. For DBP: Grade 0: <80 mmHg; Grade 1: 80-89 mmHg; Grade 2: 90-99 mmHg; Grade 3: >=100 mmHg. Baseline was defined as the latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. An increase is defined as an increase in CTCAE grade relative to Baseline grade. Data for worst-case post Baseline is presented. Only those participants with increase to grade 2 and increase to grade 3 have been presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[87]	99[88]	24[89]	
Units: Participants				
SBP, increase to Grade 2	29	41	4	
SBP, increase to Grade 3	14	22	8	
DBP, increase to Grade 2	18	16	2	
DBP, increase to Grade 3	9	8	1	

Notes:

[87] - Full Safety Population.

[88] - Full Safety Population.

[89] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with serious adverse events (SAEs), common (>=5%) non-serious adverse events and adverse events of special interest (AESI)

End point title	Number of Participants with serious adverse events (SAEs), common (>=5%) non-serious adverse events and adverse events of special interest (AESI)

End point description:

An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.SAE defined as any untoward medical occurrence that; results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is congenital anomaly/birth defect,other situations judged by physician, is associated with liver injury and impaired liver function. Adverse events which were not Serious were considered as non-serious adverse events. Number of participants who had SAEs and common(>=5%) nonSAEs are presented. Number of participants with AESI (keratopathy, dry eye events, blurred vision, thrombocytopenia, infusion-related reactions, corneal events and neutropenia) are presented.3 out of 221 participants did not receive any study treatment and thus were excluded from the Full Safety Population.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[90]	99[91]	24[92]	
Units: Participants				
Common non-SAE	93	96	24	
SAE	43	53	15	
Keratopathy	67	74	23	
Dry eye events	17	25	6	
Blurred vision	24	36	10	
Thrombocytopenia	36	56	10	
Infusion-related reactions	20	16	4	
Corneal events	68	76	23	

Neutropenia	14	28	2	

Notes:

[90] - Full Safety Population

[91] - Full Safety Population

[92] - Full Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with change from Baseline in best corrected visual acuity (BCVA) test scores

End point title	Number of participants with change from Baseline in best corrected visual acuity (BCVA) test scores

End point description:

Baseline was defined as latest pre-dose assessment (Day 1) with non-missing value,including unscheduled visits. BCVA score was assessed individually for each eye. BCVA test scores were categorized as no change/improved vision, possible worsened vision & definite worsened vision. No change/improved vision was defined as change from Baseline <0.12 Logarithm of the Minimum Angle of Resolution (logMAR) score; a possible worsened vision was defined as change from Baseline >=0.12 to <0.3 logMAR score; a definite worsened vision was defined as a change from Baseline >=0.3 logMAR score. Data for worst-case change from Baseline is presented. 3 out of 221 participants did not receive any study treatment & thus,were excluded from Full Safety Population. Only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88[93]	94[94]	24[95]	
Units: Participants				
Left eye, no change/improved vision, n=88,94,24	35	45	4	
Left eye, possible worsened vision, n=88,94,24	11	15	4	
Left eye, definite worsened vision, n=88,94,24	42	34	16	
Right eye, no change/improved vision, n=87,93,23	32	38	5	
Right eye, possible worsened vision, n=87,93,23	21	13	6	
Right eye, definite worsened vision, n=87,93,23	34	42	12	

Notes:

[93] - Full Safety Population.

[94] - Full Safety Population.

[95] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with intraocular pressure (IOP) >=22 mmHg anytime post-Baseline

End point title	Number of participants with intraocular pressure (IOP) >=22 mmHg anytime post-Baseline

End point description:

Baseline was defined as latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. IOP was assessed individually for each eye. Number of participants with IOP >=22 mmHg anytime post-Baseline are presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population. only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88[96]	93[97]	24[98]	
Units: Participants				
Right eye, n=88,93,23	17	16	8	
Left eye, n=88,92,24	14	15	7	

Notes:

[96] - Full Safety Population

[97] - Full Safety Population

[98] - Full Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with shift in pupillary examination findings from normal (Baseline) to abnormal (worst post-Baseline)

End point title	Number of participants with shift in pupillary examination findings from normal (Baseline) to abnormal (worst post-Baseline)

End point description:

Baseline was defined as latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. Number of participants with shift in pupillary examination findings from normal (Baseline) to abnormal (worst post-Baseline) are presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Baseline and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	91[99]	90[100]	23[101]	
Units: Participants	4	12	3	

Notes:

[99] - Full Safety Population.

[100] - Full Safety Population.

[101] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with shift in corneal epithelium findings from normal (Baseline) to abnormal (worst post-Baseline) for corneal epithelium (CE) and corneal stroma (CS)

End point title	Number of participants with shift in corneal epithelium findings from normal (Baseline) to abnormal (worst post-Baseline) for corneal epithelium (CE) and corneal stroma (CS)

End point description:

Baseline was defined as latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. Corneal epithelium findings for CE and CS were assessed individually for each eye. Number of participants with shift in corneal epithelium findings from normal (Baseline) to abnormal (worst post-Baseline) for CE and CS are presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population. Only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	92[102]	94[103]	24[104]	
Units: Participants				
CE, Right eye, n=53,54,17	39	40	16	
CE, Left eye,n=55,55,15	39	44	14	
CS, Right eye,n=92,94,24	5	7	3	
CS, Left eye,n=92,89,23	8	5	3	

Notes:

[102] - Full Safety Population.

[103] - Full Safety Population.

[104] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with shift in extraocular muscle movement from

yes (Baseline) to no (worst post-Baseline)

End point title	Number of participants with shift in extraocular muscle movement from yes (Baseline) to no (worst post-Baseline)

End point description:

Baseline was defined as latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. Extraocular muscle movement was assessed individually for each eye. Number of participants with shift in extraocular muscle movement from yes (Baseline) to no (worst post-Baseline) are presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population. Only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[105]	93[106]	23[107]	
Units: Participants				
Right eye,n=95,93,23	0	4	0	
Left eye,n=93,92,22	0	2	0	

Notes:

[105] - Full Safety Population.

[106] - Full Safety Population.

[107] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with shift in corneal epithelium findings from no (Baseline) to yes (worst post-Baseline)

End point title	Number of participants with shift in corneal epithelium findings from no (Baseline) to yes (worst post-Baseline)

End point description:

Baseline was defined as latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. Corneal epithelium findings like active edema, active opacity, corneal neovascularization (CN), corneal ulcer, epithelial microcystic edema (EME) and subepithelial were performed using a slit lamp. Number of participants with shift in corneal epithelium findings from no (Baseline) to yes (worst post-Baseline) are presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[108]	99[109]	24[110]	
Units: Participants				
Active edema, Right eye, n=94,99,24	3	5	1	
Active edema, Left eye,n=95,99,24	4	4	1	
Active opacity, Right eye,n=93,97,24	3	3	3	
Active opacity, Left eye,n=94,95,24	4	4	3	
Corneal Neovascularization, Right eye,n=93,99,24	1	1	1	
Corneal Neovascularization, Left eye,n=93,99,23	1	0	1	
Corneal ulcer, Right eye,n=61,60,22	1	1	0	
Corneal ulcer, Left eye,n=63,61,20	1	2	0	
Epithelial Microcystic Edema, Right eye,n=95,99,24	15	24	9	
Epithelial Microcystic Edema, Left eye,n=95,99,23	16	25	8	
Subepithelial haze, Right eye,n=95,98,24	18	28	8	
Subepithelial haze, Left eye,n=95,97,23	18	29	6	

Notes:

[108] - Full Safety Population.

[109] - Full Safety Population.

[110] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with shift in tear break-up time from >10 seconds (Baseline) to <=5 seconds (worst post-Baseline)

End point title	Number of participants with shift in tear break-up time from >10 seconds (Baseline) to <=5 seconds (worst post-Baseline)

End point description:

Baseline was defined as latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. Number of participants with shift in tear break-up time from >10 seconds (Baseline) to <=5 seconds (worst post-Baseline) are presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34[111]	31[112]	2[113]	
Units: Participants				
Left eye,n=34,30,2	14	12	2	
Right eye,n=30,31,2	11	12	1	

Notes:

[111] - Full Safety Population.

[112] - Full Safety Population.

[113] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration-time curve from time zero extrapolated to infinite time (AUC[0-infinity]) of GSK2857916 following IV dose in participants with RRMM

End point title	Area under the concentration-time curve from time zero extrapolated to infinite time (AUC[0-infinity]) of GSK2857916 following IV dose in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. Pharmacokinetic (PK) parameters of GSK2857916 were calculated using non-compartmental methods. Full Pharmacokinetic (PK) Population comprised of all participants in the Full Safety Population who had atleast 1 non-missing PK assessment. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, end of infusion (EOI), 2 hours and 24 hours post start of infusion (SOI) on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[114]	99[115]	24[116]	
Units: Hours*microgram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1,n=26,18,18	5644 (± 39.6)	6495 (± 54.3)	6962 (± 51.4)	
Cycle 3, n=19,21,9	7848 (± 42.7)	9199 (± 45.1)	9694 (± 49.9)	

Notes:

[114] - Full PK Population

[115] - Full PK Population

[116] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration-time curve over the dosing interval (AUC[0-tau]) of GSK2857916 following IV dose in participants With RRMM

End point title	Area under the concentration-time curve over the dosing interval (AUC[0-tau]) of GSK2857916 following IV dose in participants With RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of GSK2857916 were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[117]	99[118]	24[119]	
Units: Hours*microgram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=30,20,22	4666 (± 45.7)	5678 (± 40.1)	5946 (± 37.2)	
Cycle 3, n=26,24,11	6399 (± 31.6)	6941 (± 34.2)	7593 (± 34.5)	

Notes:

[117] - Full PK Population

[118] - Full PK Population

[119] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration-time curve from zero to time of last quantifiable concentration (AUC[0-tlast]) of GSK2857916 following IV dose in participants with RRMM

End point title	Area under the concentration-time curve from zero to time of last quantifiable concentration (AUC[0-tlast]) of GSK2857916 following IV dose in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of GSK2857916 were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[120]	99[121]	24[122]	
Units: Hours*microgram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=32,21,22	4607 (± 54.4)	5567 (± 51.0)	6293 (± 45.7)	
Cycle 3, n=28,28,11	6033 (± 44.7)	6084 (± 73.8)	8388 (± 46.1)	

Notes:

[120] - Full PK Population

[121] - Full PK Population

[122] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum observed concentration (Cmax) of GSK2857916 following IV dose in participants with RRMM

End point title	Maximum observed concentration (Cmax) of GSK2857916 following IV dose in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of GSK2857916 were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[123]	99[124]	24[125]	
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=32,21,22	42.51 (± 26.3)	52.03 (± 19.8)	51.32 (± 18.3)	
Cycle 3, n=29,28,11	42.35 (± 25.6)	45.5 (± 25.3)	48.06 (± 17.1)	

Notes:

[123] - Full PK Population

[124] - Full PK Population

[125] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Time to reach maximum observed concentration (Tmax) of GSK2857916

following IV dose in participants with RRMM

End point title	Time to reach maximum observed concentration (Tmax) of GSK2857916 following IV dose in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of GSK2857916 were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[126]	99[127]	24[128]	
Units: Hours				
median (full range (min-max))				
Cycle 1, n=32,21,22	0.780 (0.42 to 2.50)	0.700 (0.43 to 2.15)	0.750 (0.48 to 2.88)	
Cycle 3, n=29,28,11	0.580 (0.47 to 2.03)	0.715 (0.42 to 2.90)	0.870 (0.50 to 2.02)	

Notes:

[126] - Full PK Population

[127] - Full PK Population

[128] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal half-life (t1/2) of GSK2857916 following IV dose in participants with RRMM

End point title	Terminal half-life (t1/2) of GSK2857916 following IV dose in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of GSK2857916 were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[129]	99[130]	24[131]	
Units: Hours				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=29,19,22	164.4 (± 46.2)	165.8 (± 55.0)	196.2 (± 40.9)	
Cycle 3, n=26,23,11	193.7 (± 48.4)	214.4 (± 45.9)	279.5 (± 40.3)	

Notes:

[129] - Full PK Population

[130] - Full PK Population

[131] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-infinity) of GSK2857916 total antibody following IV dose in participants with RRMM

End point title	AUC(0-infinity) of GSK2857916 total antibody following IV dose in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of GSK2857916 total antibody were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[132]	99[133]	24[134]	
Units: Hours*microgram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=16,10,9	10268 (± 65.8)	10209 (± 64.9)	10170 (± 75.0)	
Cycle 3, n=10,11,3	20526 (± 45.1)	18637 (± 69.4)	22782 (± 161.1)	

Notes:

[132] - Full PK Population.

[133] - Full PK Population.

[134] - Full PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-tau) of GSK2857916 total antibody following IV dose in participants with RRMM

End point title	AUC(0-tau) of GSK2857916 total antibody following IV dose in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of GSK2857916 total antibody were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[135]	99[136]	24[137]	
Units: Hours*microgram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=29,18,19	7305 (± 41.9)	9566 (± 42.2)	9029 (± 40.2)	
Cycle 3, n=23,24,11	11243 (± 34.6)	11646 (± 38.0)	15311 (± 43.9)	

Notes:

[135] - Full PK Population

[136] - Full PK Population

[137] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-tlast) of GSK2857916 total antibody following IV dose in participants with RRMM

End point title	AUC(0-tlast) of GSK2857916 total antibody following IV dose in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of GSK2857916 total antibody were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[138]	99[139]	24[140]	
Units: Hours*microgram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=30,19,20	7417 (± 58.5)	9628 (± 52.8)	9017 (± 55.4)	
Cycle 3, n=27,26,11	10725 (± 59.4)	11295 (± 80.0)	17715 (± 61.0)	

Notes:

[138] - Full PK Population

[139] - Full PK Population

[140] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of GSK2857916 total antibody following IV dose in participants with RRMM

End point title	Cmax of GSK2857916 total antibody following IV dose in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of GSK2857916 total antibody were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[141]	99[142]	24[143]	
Units: Microgram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=30,19,20	48.94 (± 30.0)	61.06 (± 26.9)	60.08 (± 18.3)	
Cycle 3, n=29,28,11	49.34 (± 32.9)	55.60 (± 26.5)	65.07 (± 17.4)	

Notes:

[141] - Full PK Population

[142] - Full PK Population

[143] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax of GSK2857916 total antibody following IV dose in participants

with RRMM

End point title	Tmax of GSK2857916 total antibody following IV dose in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of GSK2857916 total antibody were calculated using non-compartmental methods.All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[144]	99[145]	24[146]	
Units: Hours				
median (full range (min-max))				
Cycle 1, n=30,19,20	1.750 (0.42 to 2.50)	1.870 (0.50 to 24.50)	0.650 (0.48 to 2.17)	
Cycle 3, n=29,28,11	0.830 (0.47 to 46.05)	1.150 (0.42 to 2.90)	1.750 (0.50 to 2.02)	

Notes:

[144] - Full PK Population

[145] - Full PK Population

[146] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: t1/2 of GSK2857916 total antibody following IV dose in participants with RRMM

End point title	t1/2 of GSK2857916 total antibody following IV dose in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of GSK2857916 total antibody were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[147]	99[148]	24[149]	
Units: Hours				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=29,17,19	241.8 (± 49.3)	250.8 (± 70.3)	299.8 (± 61.0)	
Cycle 3, n=23,23,11	352.4 (± 52.6)	372.0 (± 49.6)	557.3 (± 91.7)	

Notes:

[147] - Full PK Population

[148] - Full PK Population

[149] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-infinity) of Cysteine-maleimidocaproyl monomethyl auristatin F (Cys-mcMMAF) following IV dose of GSK2857916 in participants with RRMM

End point title	AUC(0-infinity) of Cysteine-maleimidocaproyl monomethyl auristatin F (Cys-mcMMAF) following IV dose of GSK2857916 in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of Cys-mcMMAF were calculated using non-compartmental methods.All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles). 66666 indicates Cys-mcMMAF was not detectable throughout the elimination phase; therefore, AUC(0-infinity) could not be estimated.

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[150]	99[151]	24[152]	
Units: Hours*nanogram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=27,20,19	66666 (± 66666)	66666 (± 66666)	66666 (± 66666)	
Cycle 3, n=26,29,11	66666 (± 66666)	66666 (± 66666)	66666 (± 66666)	

Notes:

[150] - Full PK Population

[151] - Full PK Population

[152] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-tlast) of Cysteine-maleimidocaproyl monomethyl auristatin F (Cys-mcMMAF) following IV dose of GSK2857916 in participants with RRMM

End point title	AUC(0-tlast) of Cysteine-maleimidocaproyl monomethyl auristatin F (Cys-mcMMAF) following IV dose of GSK2857916 in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of Cys-mcMMAF were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[153]	99[154]	24[155]	
Units: Hours*nanogram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=27,20,19	79.26 (± 61.0)	113.57 (± 58.3)	100.35 (± 51.8)	
Cycle 3, n=26,29,11	70.84 (± 46.9)	74.04 (± 73.0)	69.83 (± 36.6)	

Notes:

[153] - Full PK Population

[154] - Full PK Population

[155] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-tau) of Cys-mcMMAF following IV dose of GSK2857916 in participants with RRMM

End point title	AUC(0-tau) of Cys-mcMMAF following IV dose of GSK2857916 in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of Cys-mcMMAF were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles). 66666 indicates Cys-mcMMAF was not detectable throughout the dosing interval; therefore, AUC(0-tau) could not be estimated.

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[156]	99[157]	24[158]	
Units: Hours*nanogram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=27,20,19	66666 (± 66666)	66666 (± 66666)	66666 (± 66666)	
Cycle 3, n=26,29,11	66666 (± 66666)	66666 (± 66666)	66666 (± 66666)	

Notes:

[156] - Full PK Population

[157] - Full PK Population

[158] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of Cys-mcMMAF following IV dose of GSK2857916 in participants with RRMM

End point title	Cmax of Cys-mcMMAF following IV dose of GSK2857916 in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of Cys-mcMMAF were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[159]	99[160]	24[161]	
Units: Nanogram per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=27,20,19	0.903 (± 63.9)	1.148 (± 64.7)	1.017 (± 61.4)	
Cycle 3, n=26,29,11	0.660 (± 52.3)	0.749 (± 66.2)	0.656 (± 47.6)	

Notes:

[159] - Full PK Population

[160] - Full PK Population

[161] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax of Cys-mcMMAF following IV dose of GSK2857916 in participants with RRMM

End point title	Tmax of Cys-mcMMAF following IV dose of GSK2857916 in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of Cys-mcMMAF were calculated using non-compartmental methods. All the participants in the study were included in the analysis (95, 99 and 24 Participants), but only those participants with data available at the specified data points were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[162]	99[163]	24[164]	
Units: Hours				
median (full range (min-max))				
Cycle 1, n=27,20,19	22.830 (1.92 to 65.63)	23.835 (17.38 to 72.65)	24.080 (0.97 to 69.47)	
Cycle 3, n=26,29,11	23.235 (0.58 to 46.08)	22.570 (0.55 to 70.98)	22.780 (0.50 to 71.93)	

Notes:

[162] - Full PK Population

[163] - Full PK Population

[164] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: t1/2 of Cys-mcMMAF following IV dose of GSK2857916 in participants with RRMM

End point title	t1/2 of Cys-mcMMAF following IV dose of GSK2857916 in participants with RRMM

End point description:

Blood samples were collected at designated timepoints. PK parameters of Cys-mcMMAF were calculated using non-compartmental methods.

End point type	Secondary

End point timeframe:

Cycle 1 and Cycle 3: Pre-dose, EOI, 2 hours and 24 hours post SOI on Day 1, anytime on Day 4, and anytime on Day 8 to Day 15 (each cycle of 21 days)

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	95[165]	99[166]	24[167]	
Units: Hours				
geometric mean (geometric coefficient of variation)				
Cycle 1, n=27,20,19	66666 (± 66666)	66666 (± 66666)	66666 (± 66666)	
Cycle 3, n=26,29,11	66666 (± 66666)	66666 (± 66666)	66666 (± 66666)	

Notes:

[165] - Full PK Population

[166] - Full PK Population

[167] - Full PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with at least one confirmed positive post-Baseline anti-drug antibody (ADA) result

End point title	Number of participants with at least one confirmed positive post-Baseline anti-drug antibody (ADA) result

End point description:

Serum samples were collected for the determination of anti-GSK2857916 antibodies (ADA) using a validated electrochemiluminescent (ECL) immunoassay. The assay involved screening, confirmation and titration steps. If serum samples tested positive in the screening assay, they were considered 'potentially positive' and were further analyzed for the specificity using the confirmation assay. Samples that confirmed positive in the confirmation assay were reported as 'positive'. Confirmed positive ADA samples were further characterized in the titration assay to quasi-quantitate the amount of ADA in the sample. Additionally, confirmed positive ADA samples were also tested in a validated neutralizing antibody assay to determine the potential neutralizing activity of the ADA. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	89[168]	92[169]	24[170]	
Units: Participants	2	0	0	

Notes:

[168] - Full Safety Population.

[169] - Full Safety Population.

[170] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Titers of anti-drug antibodies against GSK2857916

End point title	Titers of anti-drug antibodies against GSK2857916[171]

End point description:

Serum samples were collected for the determination of ADA using a validated ECL immunoassay. The assay involved screening, confirmation and titration steps. If serum samples contained ADA, they were further analyzed for the specificity of antibodies by a confirmation assay. Confirmed positive samples were titrated to obtain the titers of antibodies. Titers of anti-drug antibodies against GSK2857916 is presented. No participant was found with positive results for ADA test in arm GSK2857916 3.4 mg/kg (Lyophilized). Hence, titer values was not presented for the arm. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Up to 186 weeks

Notes:

[171] - 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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4[172]	2[173]		
Units: Titers				
arithmetic mean (standard deviation)	125.0 (± 50.00)	100.0 (± 0.00)		

Notes:

[172] - Full Safety Population.

[173] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with symptomatic AEs measured by patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE)

End point title	Number of participants with symptomatic AEs measured by patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE)

End point description:

The PRO-CTCAE is a patient-reported outcome measure developed to evaluate symptomatic toxicity in participants on cancer clinical trials. It included symptomatic toxicities drawn from the CTCAE like blurred vision, chills, constipation, decreased appetite, fatigue, general pain, heart palpitations,

mouth/throat sores, nausea, nosebleed, shortness of breath, vomiting and watery eyes. Items were scored individually on a 0 to 4 scale for severity, frequency and interference. Number of participants with symptomatic AEs (those who had a maximum post-Baseline rating greater than 0, example; 1, 2, 3, or 4) measured by PRO-CTCAE are presented. Full Safety Population.

End point type	Secondary

End point timeframe:

Up to 186 weeks

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	84[174]	92[175]	22[176]	
Units: Participants				
Blurred Vision , n= 84,92,22	59	67	19	
Chills, n=43,42,13	39	36	12	
Constipation,n=84,92, 22	42	47	17	
Decreased Appetite, n=84,92, 22	60	65	16	
Fatigue, n=84,92, 22	81	87	21	
General Pain, n= 79, 80, 20	78	80	19	
Heart Palpitations,n=37, 37, 14	35	33	14	
Mouth/Throat Sores,n=84,92, 22	28	25	8	
Nausea,n=48, 52, 11	47	50	11	
Nosebleed,n=23, 33, 6	22	33	6	
Shortness Of Breath, n=84,92, 22	60	58	17	
Vomiting,n=21, 28, 6	20	28	5	
Watery Eyes,n=84,92, 22	50	59	19	

Notes:

[174] - Full Safety Population.

[175] - Full Safety Population.

[176] - Full Safety Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Worst change from Baseline in Ocular Surface Disease Index (OSDI) total score

End point title	Worst change from Baseline in Ocular Surface Disease Index (OSDI) total score

End point description:

The OSDI is a 12-item questionnaire designed to assess both the frequency of dry eye symptoms and their impact on vision-related functioning. The total OSDI score was calculated as (sum of scores for all questions answered*100) divided by (total number of questions answered*4). Domain scores ranged from 0 to 100; lower scores are better. Therefore, decrease in score from Baseline means improvement. Baseline was defined as latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. Change from Baseline was calculated by subtracting Baseline value from the post-dose visit value. Data for worst-case post Baseline is presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to Week 186

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	83[177]	92[178]	22[179]	
Units: Scores on a scale				
arithmetic mean (standard deviation)	26.9 (± 29.61)	28.2 (± 28.49)	35.0 (± 29.02)	

Notes:

[177] - Full Safety Population

[178] - Full Safety Population

[179] - Full Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Worst change from Baseline in National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25) overall composite score

End point title	Worst change from Baseline in National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25) overall composite score

End point description:

The NEI-VFQ-25 consisted of a base set of 25 vision-targeted questions representing 11 vision-related constructs, plus an additional single-item general health rating question to assess the impact of ocular toxicity on visual function. Items were coded to a 0 to 100 scale and averaged to calculate domains. Domain scores ranged from 0 to 100; higher scores are better. Therefore, increase in score means improvement. Baseline was defined as latest pre-dose assessment (Day 1) with a non-missing value, including unscheduled visits. Change from Baseline was calculated by subtracting Baseline value from the post-dose visit value. Data for worst-case post Baseline is presented. 3 participants out of 221 participants did not receive any study treatment and thus, were excluded from the Full Safety Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to Week 186

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	83[180]	92[181]	22[182]	
Units: Scores on a scale				
arithmetic mean (standard deviation)	-20.0 (± 22.60)	-19.6 (± 21.66)	-23.1 (± 23.82)	

Notes:

[180] - Full Safety Population

[181] - Full Safety Population

[182] - Full Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire 30-item Core module (EORTC QLQ-C30) score

End point title	Change from Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire 30-item Core module (EORTC QLQ-C30) score

End point description:

The EORTC QLQ-C30(physicalfunctioning [PF],rolefunctioning [RF],cognitivefunctioning [CF],emotionalfunctioning [EF]&socialfunctioning [SF]),(fatigue,pain,nausea/vomiting [N/V]),global health status (GHS)/Quality-of-Life (QoL) scale,(constipation,diarrhoea,insomnia,dyspnoea,appetite loss [AL],financial difficulties [FD]).Response options:1 to 4.Scores were averaged & transformed to 0 to 100,high score for functional scales GHS/QoLbetter functioning ability or healthrelated quality-of-life(HRQoL),whereas high score for symptom scales/single items-significant symptomatology.Baseline was latest predose assessment with non-missing value,including unscheduled visits.Change from Baseline was post-dose visit minus Baseline value.Only those participants who were measured analyzed(i.e.contributed data reported in the table)were included in the Overall Number of Participants Analyzed field.99999 indicates data is not available.77777 indicates SD could not be calculated for single participant

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 07, Week 13, Week 19, Week 25, Week 31, Week 37, Week 43, Week 61, Week 79, Week 97, Week 115, Week 133, Week 151, Week 169, and Week 186

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97[183]	99[184]	25[185]	
Units: Scores on a scale				
arithmetic mean (standard deviation)				
GHS/QoL,Week 07,n=48,47,17	-0.7 (± 20.47)	-4.1 (± 18.54)	1.5 (± 23.80)	
GHS/QoL,Week 13,n=29,29,16	-3.2 (± 18.42)	6.0 (± 16.50)	1.0 (± 14.23)	
GHS/QoL,Week 19,n=19,27,10	-2.2 (± 13.84)	3.7 (± 20.19)	0 (± 12.42)	
GHS/QoL,Week 25,n=20,23,7	-4.6 (± 16.10)	-2.5 (± 20.94)	7.1 (± 8.91)	
GHS/QoL,Week 31,n=15,18,7	-2.2 (± 14.59)	5.1 (± 20.44)	2.4 (± 14.20)	
GHS/QoL,Week 37,n=15,13,5	-1.7 (± 14.50)	1.9 (± 21.29)	11.7 (± 4.56)	
GHS/QoL,Week 43,n=15,14,4	-4.4 (± 14.04)	10.7 (± 15.82)	12.5 (± 10.76)	
GHS/QoL,Week 61,n=11,11,3	-3.8 (± 17.23)	-5.3 (± 13.58)	0.0 (± 0.00)	
GHS/QoL,Week 79,n=3,2,1	2.8 (± 24.06)	16.7 (± 23.57)	16.7 (± 77777)	
GHS/QoL,Week 97,n=4,5,3	8.3 (± 11.79)	1.7 (± 25.28)	8.3 (± 0.00)	
GHS/QoL,Week 115,n=2,6,3	-4.2 (± 17.68)	1.4 (± 22.00)	2.8 (± 4.81)	
GHS/QoL,Week 133,n=2,1,2	-4.2 (± 17.68)	33.3 (± 77777)	-8.3 (± 11.79)	
GHS/QoL,Week 151,n=0,2,0	99999 (± 99999)	8.3 (± 35.36)	99999 (± 99999)	
GHS/QoL,Week 169,n=0,1,0	99999 (± 99999)	33.3 (± 77777)	99999 (± 99999)	
GHS/QoL,Week 186n=41,46,17	-8.1 (± 19.50)	-11.6 (± 22.46)	-3.9 (± 15.34)	
PF,,Week 07,n=48,47,17	4.4 (± 15.70)	-1.0 (± 21.93)	-5.5 (± 24.18)	
PF,Week 13, n=29,29,16	0.7 (± 14.62)	4.1 (± 11.19)	-12.5 (± 23.84)	
PF,,Week 19,n=19,27,10	0.4 (± 13.78)	6.2 (± 24.87)	-4.0 (± 14.81)	

PF,Week 25, n=20,23,7	1.3 (± 12.16)	5.5 (± 25.08)	-1.0 (± 14.62)	
PF,Week 31,n=15,18,7	-2.7 (± 8.66)	9.3 (± 22.88)	4.8 (± 10.69)	
PF, Week 37,n=15,13, 5	4.0 (± 11.76)	15.4 (± 25.15)	10.7 (± 18.62)	
PF, Week 43,n=15,14, 4	3.1 (± 11.23)	14.8 (± 26.04)	6.7 (± 27.22)	
PF, Week 61,n=11,11, 3	4.2 (± 12.39)	9.7 (± 22.18)	15.6 (± 3.85)	
PF, Week 79,n=3,2, 2	2.2 (± 3.85)	10.0 (± 4.71)	10.0 (± 4.71)	
PF, Week 97,n=4,5, 3	0.0 (± 9.43)	0.0 (± 9.43)	-2.2 (± 23.41)	
PF, Week 115,n=2,6, 3	3.3 (± 4.71)	4.4 (± 13.11)	4.4 (± 10.18)	
PF, Week 133,n=2,1, 2	3.3 (± 4.71)	13.3 (± 77777)	-6.7 (± 18.86)	
PF, Week 151,n=0,2,0	99999 (± 99999)	0.0 (± 18.86)	99999 (± 99999)	
PF, Week 169, n=0,1,0	4.7 (± 20.98)	13.3 (± 77777)	-1.0 (± 20.81)	
PF, Week 186,n=41,46,17	-0.8 (± 21.20)	-6.2 (± 21.29)	-13.3 (± 24.38)	
RF,Week 07,n=48,47,17	0.3 (± 33.24)	-6.0 (± 35.68)	-7.8 (± 25.08)	
RF,Week 13,n=29,29,16	2.3 (± 33.55)	-0.6 (± 32.88)	-6.3 (± 30.96)	
RF,Week 19,n=19,27,10	-4.4 (± 31.35)	1.9 (± 36.50)	-5.0 (± 23.64)	
RF,Week 25,n=20,23,7	2.5 (± 32.57)	0.0 (± 32.57)	11.9 (± 32.93)	
RF,Week 31,n=15,18,7	8.9 (± 24.29)	3.7 (± 34.09)	7.1 (± 21.21)	
RF,Week 37,n=15,13,5	8.9 (± 29.46)	3.8 (± 39.76)	20.0 (± 27.39)	
RF,Week 43,n=15,14,4	8.9 (± 30.12)	11.9 (± 32.31)	8.3 (± 21.52)	
RF,Week 61,n=11,11,3	12.1 (± 36.58)	-3.0 (± 29.64)	16.7 (± 16.67)	
RF,Week 79,n=3,2,2	5.6 (± 34.69)	8.3 (± 11.79)	8.3 (± 35.36)	
RF,Week 97,n=4,5,3	-4.2 (± 43.83)	-6.7 (± 19.00)	5.6 (± 34.69)	
RF,Week 115,n=2,6,3	0.0 (± 47.14)	-5.6 (± 17.21)	16.7 (± 44.10)	
RF,Week 133,n=2,1,2	8.3 (± 35.36)	16.7 (± 77777)	25.0 (± 11.79)	
RF,Week 151,n=0,2,0	99999 (± 99999)	-16.7 (± 23.57)	99999 (± 99999)	
RF,Week 169,n=0,1,0	-7.7 (± 23.78)	0.0 (± 77777)	-1.4 (± 24.97)	
RF,Week 186,n=41,46,17	-0.4 (± 30.84)	-8.3 (± 33.66)	-16.7 (± 30.62)	
EF,Week 07,n=48,47,17	1.4 (± 18.86)	1.4 (± 27.10)	-4.4 (± 21.27)	
EF,Week 13,n=29,29,16	-2.0 (± 23.00)	-0.0 (± 25.00)	-9.4 (± 23.35)	
EF,Week 19,n=19,27,10	0.4 (± 19.93)	3.1 (± 20.30)	-1.7 (± 21.08)	
EF,Week 25, n=20, 23, 7	-4.6 (± 21.20)	4.0 (± 20.39)	-2.4 (± 14.20)	
EF,Week 37, n=15,13, 5	1.7 (± 13.44)	9.6 (± 23.29)	13.3 (± 16.24)	
EF,Week 43, n=15,14, 4	0.0 (± 18.90)	8.3 (± 27.74)	4.2 (± 4.81)	
EF,Week 61, n=11,11, 3	6.8 (± 12.81)	-5.3 (± 16.36)	19.4 (± 12.73)	
EF,Week 79, n=3,2,2	2.8 (± 4.81)	8.3 (± 11.79)	16.7 (± 23.57)	
EF,Week 97, n=4,5,3	2.1 (± 10.49)	1.7 (± 25.95)	8.3 (± 16.67)	
EF,Week 115, n=2,6,3	0.0 (± 23.57)	-2.8 (± 11.39)	11.1 (± 12.73)	
EF,Week 133, n=2,1,2	-4.2 (± 29.46)	16.7 (± 77777)	8.3 (± 23.57)	
EF,Week 169, n=0,1,0	99999 (± 99999)	16.7 (± 77777)	99999 (± 99999)	
EF,Week 186, n=41,46,17	-6.7 (± 24.45)	-6.2 (± 21.04)	-10.8 (± 17.37)	
CF,Week 07,n=48,47,17	4.5 (± 20.55)	-2.1 (± 21.03)	-1.0 (± 20.81)	
CF,Week 13,n=29,29,16	2.3 (± 23.45)	-1.1 (± 15.39)	-15.6 (± 27.53)	
CF,Week 19,n=19,27,10	-1.8 (± 26.58)	-0.6 (± 22.87)	-6.7 (± 21.08)	
CF,Week 25, n=20, 23, 7	-1.7 (± 27.52)	1.4 (± 21.27)	-11.9 (± 18.54)	
CF,Week 31, n=15,18, 7	6.7 (± 23.40)	-3.7 (± 19.43)	-4.8 (± 12.60)	
CF,Week 37, n=15,13, 5	3.3 (± 22.00)	3.8 (± 13.87)	3.3 (± 13.94)	

CF,Week 43, n=15,14, 4	2.2 (± 24.29)	1.2 (± 10.26)	-4.2 (± 8.33)	
CF,Week 61, n=11,11, 3	10.6 (± 27.15)	-1.5 (± 15.73)	5.6 (± 9.62)	
CF,Week 79, n=3,2,2	11.1 (± 19.25)	-25.0 (± 35.36)	8.3 (± 11.79)	
CF,Week 97, n=4,5,3	-4.2 (± 25.00)	-16.7 (± 33.33)	0.0 (± 16.67)	
CF,Week 115, n=2,6,3	0.0 (± 23.57)	-0.0 (± 18.26)	11.1 (± 9.62)	
CF,Week 133, n=2,1,2	-8.3 (± 35.36)	0.0 (± 77777)	8.3 (± 11.79)	
CF,Week 151, n=0,2,0	99999 (± 99999)	-16.7 (± 23.57)	99999 (± 99999)	
CF,Week 169, n=0,1,0	99999 (± 99999)	0.0 (± 77777)	99999 (± 99999)	
CF,Week 186, n=41,46,17	-3.3 (± 25.88)	-11.2 (± 26.07)	-9.8 (± 13.25)	
SF,Week 07,n=48,47,17	3.8 (± 29.02)	1.1 (± 32.49)	-1.0 (± 33.58)	
SF,Week 13,n=29,29,16	-4.0 (± 28.75)	1.7 (± 28.64)	-7.3 (± 31.01)	
SF,Week 19,n=19,27,10	-6.1 (± 28.44)	5.6 (± 28.50)	-6.7 (± 28.54)	
SF,Week 25, n=20, 23, 7	-6.7 (± 26.71)	13.8 (± 22.84)	2.4 (± 32.53)	
SF,Week 31, n=15,18, 7	2.2 (± 16.51)	15.7 (± 31.56)	2.4 (± 24.40)	
SF,Week 37, n=15,13, 5	2.2 (± 21.70)	16.7 (± 29.66)	20.0 (± 21.73)	
SF,Week 43, n=15,14, 4	-1.1 (± 17.21)	20.2 (± 30.08)	16.7 (± 23.57)	
SF,Week 61, n=11,11, 3	7.6 (± 32.80)	-1.5 (± 17.41)	33.3 (± 16.67)	
SF,Week 79, n=3,2,2	5.6 (± 19.25)	8.3 (± 35.36)	25.0 (± 35.36)	
SF,Week 97, n=4,5,3	-4.2 (± 43.83)	16.7 (± 20.41)	33.3 (± 16.67)	
SF,Week 115, n=2,6,3	16.7 (± 23.57)	2.8 (± 24.53)	27.8 (± 25.46)	
SF,Week 133, n=2,1,2	16.7 (± 23.57)	33.3 (± 77777)	41.7 (± 11.79)	
SF,Week 151, n=0,2,0	99999 (± 99999)	16.7 (± 23.57)	99999 (± 99999)	
SF,Week 169, n=0,1,0	99999 (± 99999)	33.3 (± 77777)	99999 (± 99999)	
SF,Week 186, n=41,46,17	-4.1 (± 26.56)	-10.1 (± 25.93)	-8.8 (± 31.80)	
Fatigue,Week 07,n=48,47,17	-3.7 (± 21.90)	-0.5 (± 23.74)	-5.2 (± 20.83)	
Fatigue,Week 13,n=29,29,16	-7.7 (± 23.78)	-7.7 (± 19.27)	-1.4 (± 24.97)	
Fatigue,Week 19,n=19,27,10	-0.6 (± 22.67)	-2.9 (± 22.77)	-11.1 (± 15.71)	
Fatigue,Week 25, n=20, 23, 7	3.3 (± 23.67)	-2.4 (± 21.70)	-11.1 (± 16.97)	
Fatigue,Week 31, n=15,18, 7	-0.7 (± 21.61)	-11.7 (± 22.05)	-12.7 (± 18.62)	
Fatigue,Week 37, n=15,13, 5	-9.6 (± 18.24)	-13.7 (± 24.07)	-20.0 (± 14.49)	
Fatigue,Week 43, n=15,14, 4	-12.6 (± 17.25)	-10.3 (± 32.16)	-22.2 (± 12.83)	
Fatigue,Week 61, n=11,11, 3	-12.1 (± 24.07)	3.0 (± 22.82)	-11.1 (± 0.00)	
Fatigue,Week 79, n=3,2,2	-22.2 (± 11.11)	-16.7 (± 7.86)	5.6 (± 23.57)	
Fatigue,Week 97, n=4,5,3	-5.6 (± 26.45)	6.7 (± 20.18)	-25.9 (± 23.13)	
Fatigue,Week 115, n=2,6,3	-16.7 (± 23.57)	-3.7 (± 15.18)	-18.5 (± 23.13)	
Fatigue,Week 133, n=2,1,2	-5.6 (± 39.28)	-22.2 (± 77777)	-22.2 (± 15.71)	
Fatigue,Week 151, n=0,2,0	99999 (± 99999)	16.7 (± 23.57)	99999 (± 99999)	
Fatigue,Week 169, n=0,1,0	99999 (± 99999)	0.0 (± 77777)	99999 (± 99999)	

Fatigue,Week 186, n=41,46,17	-1.6 (± 23.12)	4.1 (± 23.35)	6.5 (± 22.93)	
N/V,Week 07,n=48,47,17	2.4 (± 14.17)	4.3 (± 17.88)	2.0 (± 14.29)	
N/V,Week 13,n=29,29,16	2.3 (± 13.16)	1.1 (± 9.89)	7.3 (± 25.80)	
N/V,Week 19,n=19,27,10	-1.8 (± 15.61)	-1.2 (± 15.96)	1.7 (± 5.27)	
N/V,Week 25,n=20,23,7	5.0 (± 12.21)	-0.7 (± 12.79)	-4.8 (± 12.60)	
N/V,Week 31,n=15,18,7	-3.3 (± 6.90)	1.9 (± 7.86)	-2.4 (± 15.00)	
N/V,Week 37,n=15,13, 5	-6.7 (± 16.43)	2.6 (± 11.48)	0.0 (± 0.00)	
N/V,Week 43,n=15,14,4	-7.8 (± 15.26)	1.2 (± 7.91)	-8.3 (± 16.67)	
N/V,Week 61, n=11,11,3	-4.5 (± 10.78)	4.5 (± 7.78)	0.0 (± 16.67)	
N/V,Week 79, n=3,2,2	0.0 (± 0.00)	0.0 (± 0.00)	0.0 (± 0.00)	
N/V,Week 97, n=4,5,3	0.0 (± 0.00)	0.0 (± 0.00)	-11.1 (± 19.25)	
N/V,Week 115, n=2,6,3	0.0 (± 0.00)	0.0 (± 0.00)	-16.7 (± 16.67)	
N/V,Week 133, n=2,1,2	0.0 (± 0.00)	0.0 (± 77777)	-25.0 (± 11.79)	
N/V, Week 151, n=0,2,0	99999 (± 99999)	0.0 (± 0.00)	99999 (± 99999)	
N/V, Week 169, n=0,1,0	99999 (± 99999)	0.0 (± 77777)	99999 (± 99999)	
N/V, Week 186, n=41,46,17	5.7 (± 24.04)	3.3 (± 18.47)	1.0 (± 21.63)	
Pain,Week 07,n=48,47,17	-3.1 (± 28.69)	-1.1 (± 28.32)	8.8 (± 28.33)	
Pain,Week 13,n=29,28,16	-4.0 (± 26.97)	-2.3 (± 25.48)	5.2 (± 27.02)	
Pain,Week 19,n=19,27,10	4.4 (± 19.12)	-8.6 (± 31.14)	1.7 (± 30.88)	
Pain,Week 25,n=20,23,7	2.5 (± 18.16)	-1.4 (± 24.57)	-0.0 (± 28.87)	
Pain,Week 31,n=15,18,7	4.4 (± 19.38)	-0.9 (± 23.90)	2.4 (± 35.26)	
Pain,Week 37,n=15,13,5	-2.2 (± 21.70)	-10.3 (± 24.09)	-3.3 (± 24.72)	
Pain,Week 43,n=15,14,4	-2.2 (± 15.26)	-8.3 (± 24.24)	4.2 (± 36.96)	
Pain,Week 61,n=11,11,3	-10.6 (± 18.67)	-0.0 (± 21.08)	-5.6 (± 34.69)	
Pain,Week 79,n=3,2,2	-16.7 (± 16.67)	0.0 (± 23.57)	8.3 (± 58.93)	
Pain,Week 97,n=4,5,3	-4.2 (± 20.97)	26.7 (± 22.36)	-0.0 (± 44.10)	
Pain,Week 115,n=2,6, 3	0.0 (± 0.00)	8.3 (± 27.39)	5.6 (± 53.58)	
Pain,Week 133,n=2,1, 2	0.0 (± 0.00)	16.7 (± 77777)	16.7 (± 70.71)	
Pain,Week 151,n=0,2, 0	99999 (± 99999)	33.3 (± 23.57)	99999 (± 99999)	
Pain,Week 169,n=0,1, 0	99999 (± 99999)	16.7 (± 77777)	99999 (± 99999)	
Pain,Week 186,n=41,46, 17	1.6 (± 27.59)	1.4 (± 25.29)	16.7 (± 31.73)	
Dyspnoea,Week 07,n=48,47,17	-2.1 (± 22.18)	2.1 (± 14.59)	-7.8 (± 18.74)	
Dyspnoea,Week 13,n=29,29,16	-1.1 (± 18.86)	1.1 (± 22.68)	2.1 (± 30.96)	
Dyspnoea,Week 19,n=19,27,10	-5.3 (± 20.07)	3.7 (± 25.04)	-16.7 (± 28.33)	
Dyspnoea,Week 25,n=20,23,7	-1.7 (± 20.16)	4.3 (± 18.27)	0.0 (± 27.22)	
Dyspnoea,Week 31,n=15, 18, 7	-6.7 (± 18.69)	0.0 (± 16.17)	-9.5 (± 16.27)	
Dyspnoea,Week 37,n=15, 13, 5	-8.9 (± 19.79)	12.8 (± 16.88)	-26.7 (± 27.89)	
Dyspnoea,Week 43,n=15, 14, 4	-6.7 (± 22.54)	2.4 (± 15.82)	-25.0 (± 31.91)	
Dyspnoea,Week 61,n=11,11,3	0.0 (± 21.08)	3.0 (± 17.98)	-33.3 (± 33.33)	
Dyspnoea,Week 79,n=3, 2,2	0.0 (± 0.00)	0.0 (± 0.00)	-33.3 (± 47.14)	
Dyspnoea,Week 97,n=4, 5,3	16.7 (± 19.25)	0.0 (± 23.57)	-22.2 (± 38.49)	

Dyspnoea,Week 115,n=2, 6,3	0.0 (± 0.00)	5.6 (± 13.61)	-33.3 (± 33.33)	
Dyspnoea,Week 133,n=2,1,2	0.0 (± 0.00)	0.0 (± 77777)	-16.7 (± 23.57)	
Dyspnoea,Week 151,n=0,2,0	99999 (± 99999)	0.0 (± 0.00)	99999 (± 99999)	
Dyspnoea,Week 169,n=0,1,0	99999 (± 99999)	0.0 (± 77777)	99999 (± 99999)	
Dyspnoea,Week 186,n=41, 46,17	0.0 (± 19.72)	12.3 (± 24.70)	-9.8 (± 25.72)	
Insomnia,Week 07,n=48, 47, 17	-6.2 (± 29.70)	-2.8 (± 26.77)	-0.0 (± 23.57)	
Insomnia,Week 13,n=29,29,16	0.0 (± 26.73)	-1.1 (± 25.95)	-0.0 (± 34.43)	
Insomnia,Week 19,n=19,27,10	-8.8 (± 24.45)	-4.9 (± 28.80)	-13.3 (± 35.83)	
Insomnia,Week 25,n=20,23,7	-5.0 (± 32.94)	-7.2 (± 22.38)	0.0 (± 33.33)	
Insomnia,Week 31,n=15,18,7	-17.8 (± 27.79)	-9.3 (± 33.93)	4.8 (± 40.50)	
Insomnia,Week 37,n=15,13,5	-15.6 (± 33.01)	-10.3 (± 16.01)	-13.3 (± 38.01)	
Insomnia,Week 43,n=15,14,4	-15.6 (± 30.52)	-4.8 (± 22.10)	-0.0 (± 47.14)	
Insomnia,Week 61,n=11,11,3	-9.1 (± 15.57)	-9.1 (± 21.56)	-11.1 (± 19.25)	
Insomnia,Week 79,n=3,2,2	0.0 (± 33.33)	16.7 (± 23.57)	-33.3 (± 47.14)	
Insomnia,Week 97,n=4,5,3	-25.0 (± 31.91)	-6.7 (± 14.91)	-44.4 (± 38.49)	
Insomnia,Week 115,n=2,6,3	-33.3 (± 47.14)	5.6 (± 25.09)	-33.3 (± 33.33)	
Insomnia,Week 133,n=2,1,2	-16.7 (± 70.71)	0.0 (± 77777)	-66.7 (± 0.00)	
Insomnia,Week 151,n=0,2,0	99999 (± 99999)	0.0 (± 0.00)	99999 (± 99999)	
Insomnia,Week 169,n=0,1,0	99999 (± 99999)	0.0 (± 77777)	99999 (± 99999)	
Insomnia,Week 186,n=41,46,17	2.4 (± 33.66)	-2.9 (± 32.07)	2.0 (± 29.98)	
AL,Week 07,n=48,47,17	4.9 (± 24.78)	2.1 (± 29.00)	2.0 (± 27.56)	
AL,Week 13,n=29,29,16	8.0 (± 29.08)	-2.3 (± 25.09)	12.5 (± 26.87)	
AL,Week 19,n=19,27,10	0.0 (± 24.85)	-0.0 (± 38.12)	-3.3 (± 10.54)	
AL,Week 25,n=20, 23, 7	6.7 (± 31.72)	-5.8 (± 21.68)	-9.5 (± 16.27)	
AL,Week 31,n=15,18, 7	-8.9 (± 15.26)	0.0 (± 19.80)	-4.8 (± 23.00)	
AL,Week 37,n=15,13,5	-4.4 (± 17.21)	-5.1 (± 22.96)	-20.0 (± 18.26)	
AL,Week 43,n=15,14,4	-4.4 (± 17.21)	-9.5 (± 24.21)	-25.0 (± 16.67)	
AL,Week 61,n=11,11,3	-6.1 (± 20.10)	0.0 (± 36.51)	11.1 (± 19.25)	
AL,Week 79,n=3,2,2	-33.3 (± 0.00)	16.7 (± 23.57)	16.7 (± 23.57)	
AL,Week 97,n=4,5,3	-8.3 (± 16.67)	13.3 (± 18.26)	0.0 (± 33.33)	
AL,Week 115,n=2,6,3	0.0 (± 0.00)	0.0 (± 21.08)	0.0 (± 33.33)	
AL,Week 133,n=2,1,2	0.0 (± 0.00)	0.0 (± 77777)	-16.7 (± 23.57)	
AL,Week 151,n=0,2,0	99999 (± 99999)	33.3 (± 47.14)	99999 (± 99999)	
AL,Week 169,n=0,1,0	99999 (± 99999)	0.0 (± 77777)	99999 (± 99999)	
AL,Week 186,n=41,46,17	5.7 (± 24.61)	-0.0 (± 32.96)	2.0 (± 21.96)	
Constipation,Week 07,n=48,47,17	1.4 (± 22.76)	-2.1 (± 17.59)	-7.8 (± 25.08)	
Constipation,Week 13,n=29,29,16	0.0 (± 25.20)	-5.7 (± 17.97)	8.3 (± 31.03)	
Constipation,Week 19,n=19,27,10	-7.0 (± 21.02)	1.2 (± 17.25)	-3.3 (± 18.92)	

Constipation,Week 25,n=20,23,7	-3.3 (± 14.91)	-1.4 (± 18.74)	-14.3 (± 32.53)	
Constipation,Week 31,n=15,18,7	-4.4 (± 11.73)	-3.7 (± 15.71)	-19.0 (± 26.23)	
Constipation,Week 37,n=15,13,5	2.2 (± 23.46)	-5.1 (± 22.96)	-20.0 (± 38.01)	
Constipation,Week 43,n=15,14,4	-4.4 (± 17.21)	-2.4 (± 20.52)	-16.7 (± 43.03)	
Constipation,Week 61,n=11,11,3	0.0 (± 14.91)	-9.1 (± 30.15)	-11.1 (± 38.49)	
Constipation,Week 79,n=3,2,2	0.0 (± 0.00)	0.0 (± 0.00)	0.0 (± 47.14)	
Constipation,Week 97,n=4,5,3	0.0 (± 0.00)	0.0 (± 0.00)	-22.2 (± 50.92)	
Constipation,Week 115,n=2,6,3	0.0 (± 0.00)	-5.6 (± 13.61)	-22.2 (± 50.92)	
Constipation,Week 133,n=2,1,2	0.0 (± 0.00)	0.0 (± 77777)	-50.0 (± 23.57)	
Constipation,Week 151,n=0,2,0	99999 (± 99999)	0.0 (± 0.00)	99999 (± 99999)	
Constipation,Week 169,n=0,1,0	99999 (± 99999)	0.0 (± 77777)	99999 (± 99999)	
Constipation,Week 186,n=41,46,17	5.7 (± 20.95)	3.6 (± 20.16)	3.9 (± 33.09)	
Diarrhoea,Week 07,n=48,47,17	-2.8 (± 26.48)	-0.0 (± 28.66)	-2.0 (± 24.92)	
Diarrhoea,Week 13,n=29,29,16	0.0 (± 25.20)	-6.9 (± 18.64)	4.2 (± 31.91)	
Diarrhoea,Week 19,n=19,27,10	1.8 (± 26.00)	-2.5 (± 24.33)	-3.3 (± 18.92)	
Diarrhoea,Week 25,n=20,23,7	3.3 (± 28.41)	-7.2 (± 33.27)	-19.0 (± 17.82)	
Diarrhoea,Week 31,n=15,18,7	-2.2 (± 23.46)	-3.7 (± 34.09)	-4.8 (± 29.99)	
Diarrhoea,Week 37,n=15,13,5	-2.2 (± 23.46)	2.6 (± 28.74)	-20.0 (± 18.26)	
Diarrhoea,Week 43,n=15,14,4	-4.4 (± 21.33)	14.3 (± 28.39)	-16.7 (± 19.25)	
Diarrhoea,Week 61,n=11,11,3	0.0 (± 21.08)	15.2 (± 31.14)	0.0 (± 33.33)	
Diarrhoea,Week 79,n=3,2,2	0.0 (± 0.00)	0.0 (± 0.00)	0.0 (± 47.14)	
Diarrhoea,Week 97,n=4,5,3	-8.3 (± 16.67)	0.0 (± 0.00)	-22.2 (± 19.25)	
Diarrhoea,Week 115,n=2,6,3	0.0 (± 0.00)	0.0 (± 0.00)	-22.2 (± 19.25)	
Diarrhoea,Week 133,n=2,1,2	0.0 (± 0.00)	0.0 (± 77777)	-33.3 (± 0.00)	
Diarrhoea,Week 151,n=0,2,0	99999 (± 99999)	0.0 (± 0.00)	99999 (± 99999)	
Diarrhoea,Week 169,n=0,1,0	99999 (± 99999)	0.0 (± 77777)	99999 (± 99999)	
Diarrhoea,Week 186,n=41,46,17	-0.8 (± 21.72)	-5.1 (± 28.08)	0.0 (± 35.36)	
FD,Week 07,n=48,47,17	-4.9 (± 25.72)	2.8 (± 24.90)	0.0 (± 16.67)	
FD,Week 13,n=29,29,16	-4.6 (± 23.10)	4.6 (± 19.36)	10.4 (± 20.07)	
FD,Week 19,n=19,27,10	-7.0 (± 21.02)	3.7 (± 26.69)	10.0 (± 22.50)	
FD,Week 25,n=20,23,7	-3.3 (± 26.27)	-1.4 (± 15.82)	0.0 (± 19.25)	
FD,Week 31,n=15,18, 7	-6.7 (± 22.54)	-1.9 (± 17.98)	4.8 (± 23.00)	
FD,Week 37,n=15,13,5	-2.2 (± 23.46)	-2.6 (± 16.45)	6.7 (± 14.91)	
FD,Week 43,n=15,14,4	-6.7 (± 18.69)	0.0 (± 22.65)	8.3 (± 31.91)	
FD,Week 61,n=11,11,3	-12.1 (± 37.34)	6.1 (± 29.13)	11.1 (± 19.25)	
FD,Week 79,n=3,2,1	0.0 (± 0.00)	-16.7 (± 23.57)	0.0 (± 77777)	
FD,Week 97,n=4,5,3	-25.0 (± 31.91)	0.0 (± 23.57)	-11.1 (± 19.25)	
FD,Week 115,n=2,6,3	0.0 (± 0.00)	22.2 (± 50.18)	-11.1 (± 19.25)	

FD,Week 133,n=2,1,2	-50.0 (± 23.57)	-33.3 (± 77777)	-16.7 (± 23.57)	
FD,Week 151,n=0,2,0	99999 (± 99999)	-33.3 (± 0.00)	99999 (± 99999)	
FD,Week 169,n=0,1,0	99999 (± 99999)	-33.3 (± 77777)	99999 (± 99999)	
FD,Week 186,n=41,46,17	-1.6 (± 24.67)	12.3 (± 25.68)	5.9 (± 21.20)	

Notes:

[183] - Full Analysis Population

[184] - Full Analysis Population

[185] - Full Analysis Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in EORTC QLQ 20-item multiple myeloma module (MY20) score

End point title	Change from Baseline in EORTC QLQ 20-item multiple myeloma module (MY20) score

End point description:

The EORTC QLQ-MY20 is supplement to QLQ-C30 instrument used in participants with multiple myeloma.The modulecomprised 20 questions that addressed four myeloma-specific HRQoL domains:disease symptoms(DS),side effects of treatment(SET),future perspective(FP),body image(BI).Responses are 1 to 4.Scores were averaged & scales were transformed to 0 to100 scale.A high score for disease symptoms & side effects of treatment represented high level of symptomatology or problems,whereas high score for future perspective& body image represented better outcomes Baseline was latest pre-dose assessment (Day 1) withnon-missing value, including unscheduled visits.Change from Baseline was subtracting Baseline value from post-dose visit value.99999 indicatesdata is not available.77777 indicates SD could not be calculated forsingle participant.Only those participants who were measured analyzed(i.e.,contributed data reported in the table)were included in the Overall Number of Participants Analyzed field.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 07, Week 13, Week 19, Week 25, Week 31, Week 37, Week 43, Week 61, Week 79, Week 97, Week 115, Week 133, Week 151, Week 169, and Week 186

End point values	GSK2857916 2.5 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Frozen liquid)	GSK2857916 3.4 mg/kg (Lyophilized)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97[186]	99[187]	25[188]	
Units: Scores on a scale				
arithmetic mean (standard deviation)				
FP,Week 07,n=47,45,16	2.8 (± 25.11)	4.2 (± 29.99)	8.3 (± 24.51)	
FP,Week 13,n=28,28,15	-2.0 (± 24.39)	8.3 (± 22.55)	-2.2 (± 27.28)	
FP,Week 19,n=18,25,10	3.7 (± 22.87)	10.7 (± 20.91)	3.3 (± 27.24)	
FP,Week 25,n=19,23,7	2.3 (± 27.11)	13.5 (± 29.39)	4.8 (± 31.98)	
FP,Week 31,n=14,18,7	7.1 (± 18.80)	19.1 (± 24.93)	7.9 (± 27.00)	
FP,Week 37,n=14,13,5	6.3 (± 17.28)	29.1 (± 22.47)	11.1 (± 31.43)	
FP,Week 43,n=15,13,4	8.1 (± 21.19)	29.9 (± 26.98)	8.3 (± 5.56)	
FP,Week 61,n=11,11,3	10.1 (± 18.89)	4.0 (± 20.65)	25.9 (± 54.81)	
FP,Week 79,n=3,2,2	-7.4 (± 6.42)	33.3 (± 31.43)	38.9 (± 39.28)	
FP,Week 97,n=4,5,3	5.6 (± 14.34)	17.8 (± 39.75)	22.2 (± 40.06)	

FP,Week 115,n=2,6,3	11.1 (± 15.71)	16.7 (± 25.09)	33.3 (± 58.79)	
FP,Week 133,n=2,1,2	27.8 (± 7.86)	55.6 (± 77777)	38.9 (± 55.00)	
FP,Week 151,n=0,2,0	99999 (± 99999)	44.4 (± 15.71)	99999 (± 99999)	
FP,Week 169,n=0,1,0	99999 (± 99999)	55.6 (± 77777)	99999 (± 99999)	
FP,Week 186,n=39,46,16	-9.4 (± 19.34)	-7.7 (± 26.69)	3.5 (± 24.59)	
BI,Week 07,n=47,45,16	2.8 (± 22.87)	9.6 (± 28.09)	4.2 (± 43.67)	
BI,Week 13,n=28,28,15	6.0 (± 25.75)	6.0 (± 35.20)	-4.4 (± 37.52)	
BI,Week 19,n=18,25,10	5.6 (± 23.57)	8.0 (± 25.96)	-3.3 (± 42.89)	
BI,Week 25,n=19,23,7	7.0 (± 23.78)	15.9 (± 31.57)	9.5 (± 53.45)	
BI,Week 31,n=14,18,7	2.4 (± 20.52)	14.8 (± 30.73)	9.5 (± 56.81)	
BI,Week 37,n=14,13,5	9.5 (± 27.51)	25.6 (± 30.89)	26.7 (± 54.77)	
BI,Week 43,n=15,13,4	4.4 (± 24.77)	28.2 (± 38.12)	8.3 (± 16.67)	
BI,Week 61,n=11,11,3	6.1 (± 25.03)	12.1 (± 26.97)	33.3 (± 57.74)	
BI,Week 79,n=3,2,2	0.0 (± 0.00)	0.0 (± 0.00)	33.3 (± 94.28)	
BI,Week 97,n=4,5,3	8.3 (± 31.91)	6.7 (± 27.89)	44.4 (± 69.39)	
BI,Week 115,n=2,6,3	-16.7 (± 70.71)	5.6 (± 25.09)	55.6 (± 50.92)	
BI,Week 133,n=2,1,2	16.7 (± 23.57)	0.0 (± 77777)	83.3 (± 23.57)	
BI,Week 151,n=0,2,0	99999 (± 99999)	16.7 (± 23.57)	99999 (± 99999)	
BI,Week 169,n=0,1,0	99999 (± 99999)	0.0 (± 77777)	99999 (± 99999)	
BI,Week 186,n=39,46,16	-4.3 (± 30.76)	-0.7 (± 35.48)	10.4 (± 41.67)	
DS,Week 07,n=47,45,16	-1.8 (± 19.73)	-1.0 (± 17.78)	-2.8 (± 12.17)	
DS,Week 13,n=28,28,15	-1.0 (± 16.22)	-3.2 (± 22.95)	1.1 (± 25.65)	
DS,Week 19,n=18,25,10	0.9 (± 14.91)	-6.4 (± 17.98)	-1.7 (± 20.63)	
DS,Week 25,n=19,23,7	-0.0 (± 16.25)	-3.6 (± 17.78)	-1.6 (± 25.20)	
DS,Week 31,n=14,18,7	-3.6 (± 10.59)	-10.5 (± 19.23)	-4.8 (± 23.88)	
DS,Week 37,n=14,13,5	-6.0 (± 12.22)	-9.8 (± 22.92)	-14.4 (± 16.01)	
DS,Week 43,n=15,13,4	-5.9 (± 12.51)	-14.5 (± 24.06)	-8.3 (± 26.64)	
DS,Week 61,n=11,11,3	-11.6 (± 12.29)	-7.6 (± 10.02)	-11.1 (± 16.67)	
DS,Week 79,n=3,2,2	-16.7 (± 11.11)	-2.8 (± 3.93)	-2.8 (± 27.50)	
DS,Week 97,n=4,5,3	-12.5 (± 15.30)	-3.3 (± 15.52)	-7.4 (± 25.05)	
DS,Week 115,n=2,6,3	-19.4 (± 3.93)	-7.4 (± 10.92)	-10.0 (± 16.59)	
DS,Week 133,n=2,1,2	-13.9 (± 11.79)	-5.6 (± 77777)	8.3 (± 51.07)	
DS,Week 151,n=0,2,0	99999 (± 99999)	5.6 (± 15.71)	99999 (± 99999)	
DS,Week 169,n=0,1,0	99999 (± 99999)	-5.6 (± 77777)	99999 (± 99999)	
DS,Week 186, n=39,46,16	-0.6 (± 17.28)	2.5 (± 18.36)	4.9 (± 24.50)	
SET,Week 07,n=47,45,16	1.5 (± 9.21)	0.4 (± 13.33)	0.2 (± 15.49)	
SET,Week 13,n=28,28,15	2.0 (± 10.44)	-1.7 (± 11.96)	6.8 (± 23.69)	
SET,Week 19,n=18,25,10	0.0 (± 10.40)	-1.2 (± 10.87)	0.9 (± 9.04)	
SET,Week 25,n=19,23,7	3.4 (± 8.41)	0.1 (± 13.10)	0.4 (± 6.45)	
SET,Week 31,n=14,18,7	2.0 (± 6.07)	-2.9 (± 13.87)	5.5 (± 11.12)	
SET,Week 37,n=14,13,5	2.2 (± 6.91)	-6.0 (± 17.82)	-1.8 (± 4.04)	
SET,Week 43,n=15,13,4	1.0 (± 8.81)	-5.6 (± 19.05)	-4.9 (± 5.76)	

SET,Week 61,n=11,11,3	-2.1 (± 12.32)	1.9 (± 12.82)	2.0 (± 9.84)	
SET,Week 79,n=3,2,2	5.9 (± 11.40)	9.1 (± 12.83)	-1.3 (± 4.45)	
SET,Week 97,n=4,5,3	-0.2 (± 5.42)	5.0 (± 13.80)	-4.7 (± 3.44)	
SET,Week 115,n=2,6,3	5.7 (± 13.36)	0.7 (± 7.21)	-1.0 (± 7.09)	
SET,Week 133,n=2,1,2	5.7 (± 13.36)	-7.4 (± 77777)	-8.1 (± 5.24)	
SET,Week 151,n=0,2,0	99999 (± 99999)	0.0 (± 15.71)	99999 (± 99999)	
SET,Week 169,n=0,1,0	99999 (± 99999)	-11.1 (± 77777)	99999 (± 99999)	
SET,Week 186,n=39,46,16	4.0 (± 10.98)	4.0 (± 12.61)	3.7 (± 10.75)	

Notes:

[186] - Full Analysis Population.

[187] - Full Analysis Population.

[188] - Full Analysis Population.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality, Serious adverse events (SAEs) and (>=5%) non-serious AEs (Non SAEs) were collected from the start of study treatment until maximum of 186 weeks for main study and up to approximately 325 weeks for PACT phase.

Adverse event reporting additional description:

SAEs & non-SAEs for Full Safety Population comprised all participants who received atleast 1 dose of treatment.3 out of 221 participants didn't receive treatment & excluded from reporting. All-cause mortality for Full Safety Population comprised all randomized participants whether or not randomized treatment was administered.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Main Study-GSK2857916 2.5 mg/kg (Frozen liquid)

Reporting group description:

Participants were administered frozen liquid (30 mg/vial solution in a single use vial) at a dose of 2.5 mg/kg GSK2857916 as IV solution once every three weeks for a maximum of up to 39 cycles (1 cycle= 21 days). Frozen liquid was diluted with 0.9 percent saline.

Reporting group title	PACT Phase: GSK2857916 3.4 mg/kg (Frozen liquid)

Reporting group description:

Participants were administered frozen liquid (30 mg/vial solution in a single use vial) at a dose of 3.4 mg/kg GSK2857916 as IV solution once every three weeks up to approximately 101 weeks. Frozen liquid was diluted with 0.9 percent saline.

Reporting group title	PACT Phase: GSK2857916 2.5 mg/kg (Frozen liquid)

Reporting group description:

Participants were administered frozen liquid (30 mg/vial solution in a single use vial) at a dose of 2.5 mg/kg GSK2857916 as IV solution once every three weeks up to approximately 101 weeks. Frozen liquid was diluted with 0.9 percent saline.

Reporting group title	Main Study-GSK2857916 3.4 mg/kg (Frozen liquid)

Reporting group description:

Participants were administered frozen liquid (30 mg/vial solution in a single use vial) at a dose of 3.4 mg/kg GSK2857916 as IV solution once every three weeks for a maximum of up to 32 cycles (1 cycle= 21 days). Frozen liquid was diluted with 0.9 percent saline.

Reporting group title	Main Study-GSK2857916 3.4 mg/kg (Lyophilized)

Reporting group description:

Participants were administered lyophilized powder (100 mg/vial in a single use vial) at a dose of 3.4 mg/kg GSK2857916 given IV for a maximum of up to 35 cycles (1 cycle= 21 days). Lyophilized powder was reconstituted using water for injection.

Serious adverse events	Main Study-GSK2857916 2.5 mg/kg (Frozen liquid)	PACT Phase: GSK2857916 3.4 mg/kg (Frozen liquid)	PACT Phase: GSK2857916 2.5 mg/kg (Frozen liquid)
Total subjects affected by serious adverse events			
subjects affected / exposed	43 / 95 (45.26%)	2 / 2 (100.00%)	1 / 1 (100.00%)
number of deaths (all causes)	70	0	0
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Basal cell carcinoma			
subjects affected / exposed	0 / 95 (0.00%)	1 / 2 (50.00%)	0 / 1 (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
Metastases to meninges			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Prostate cancer			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Squamous cell carcinoma			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Aortic stenosis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Hypertension			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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

General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	7 / 95 (7.37%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	2 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Chest pain			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Fatigue			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Influenza like illness			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Immune system disorders			
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Epistaxis			

subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Pleural effusion			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Dyspnoea			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Hypoxia			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Delirium			

subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Electrocardiogram T wave inversion			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	3 / 95 (3.16%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	4 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Clavicle fracture			

subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Fall			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Fracture			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Humerus fracture			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Tibia fracture			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Subdural haematoma			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Road traffic accident			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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			
Cardiac arrest			

subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Mitral valve disease			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Pericarditis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Tachycardia			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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 failure			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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 failure congestive			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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 failure acute			

subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Cognitive disorder			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Headache			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Lethargy			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Seizure			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Spinal cord compression			

subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Hyperviscosity syndrome			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Anaemia			
subjects affected / exposed	1 / 95 (1.05%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Eye disorders			
Keratopathy			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Ulcerative keratitis			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Gastrointestinal disorders			

Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 95 (2.11%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Ascites			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Colitis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Diarrhoea			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Gastric fibrosis			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Haematochezia			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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 haemorrhage			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Pancreatitis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Intestinal haemorrhage			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Cholestasis			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Cholecystitis			
subjects affected / exposed	0 / 95 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Renal impairment			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Urinary retention			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Muscular weakness			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Pathological fracture			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Osteolysis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Arthritis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Bone pain			

subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Haematoma muscle			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Lumbar spinal stenosis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Osteonecrosis of jaw			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Pain in extremity			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Spinal osteoarthritis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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			
Pneumonia			
subjects affected / exposed	7 / 95 (7.37%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	2 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Influenza			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Staphylococcal sepsis			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			

subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Escherichia sepsis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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 bacteraemia			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Enterocolitis infectious			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Herpes simplex pneumonia			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Nocardiosis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Otitis media			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			

subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Sinusitis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Staphylococcal infection			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Viral infection			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Epiglottitis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Gastroenteritis viral			

subjects affected / exposed	0 / 95 (0.00%)	1 / 2 (50.00%)	0 / 1 (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
Infective keratitis			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Urinary tract infection			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Bacterial sepsis			
subjects affected / exposed	0 / 95 (0.00%)	1 / 2 (50.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	4 / 95 (4.21%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Hypokalaemia			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Hyperglycaemia			

subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (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
Hypophosphataemia			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Hypocalcaemia			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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
Hypomagnesaemia			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (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

Serious adverse events	Main Study-GSK2857916 3.4 mg/kg (Frozen liquid)	Main Study-GSK2857916 3.4 mg/kg (Lyophilized)	
Total subjects affected by serious adverse events			
subjects affected / exposed	53 / 99 (53.54%)	15 / 24 (62.50%)	
number of deaths (all causes)	80	16	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	1 / 99 (1.01%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to meninges			

subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 99 (1.01%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (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			
Pyrexia			
subjects affected / exposed	5 / 99 (5.05%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	5 / 7	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Non-cardiac chest pain			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza like illness			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	1 / 99 (1.01%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			

subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Aspartate aminotransferase increased			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (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			
Infusion related reaction			
subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			

subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve disease			

subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac failure congestive			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral haemorrhage			

subjects affected / exposed	3 / 99 (3.03%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	1 / 3	0 / 0	
Cognitive disorder			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	3 / 99 (3.03%)	3 / 24 (12.50%)	
occurrences causally related to treatment / all	3 / 3	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			

subjects affected / exposed	3 / 99 (3.03%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperviscosity syndrome			
subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	3 / 99 (3.03%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Keratopathy			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative keratitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			

subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (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 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric fibrosis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal haemorrhage			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			

subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			

subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteolysis			
subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma muscle			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			

subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis of jaw			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	14 / 99 (14.14%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	6 / 16	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Sepsis			
subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			

subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	1 / 99 (1.01%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain abscess			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			

subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis infectious			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes simplex pneumonia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (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	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nocardiosis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia legionella			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			

subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Epiglottitis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related sepsis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective keratitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (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	1 / 99 (1.01%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	0 / 99 (0.00%)	2 / 24 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 99 (0.00%)	1 / 24 (4.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophosphataemia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			

subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 24 (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: 5 %

Non-serious adverse events	Main Study-GSK2857916 2.5 mg/kg (Frozen liquid)	PACT Phase: GSK2857916 3.4 mg/kg (Frozen liquid)	PACT Phase: GSK2857916 2.5 mg/kg (Frozen liquid)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	93 / 95 (97.89%)	0 / 2 (0.00%)	0 / 1 (0.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	9 / 95 (9.47%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	10	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	15 / 95 (15.79%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	19	0	0
Pyrexia			
subjects affected / exposed	18 / 95 (18.95%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	21	0	0
Asthenia			
subjects affected / exposed	3 / 95 (3.16%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Chills			
subjects affected / exposed	8 / 95 (8.42%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Oedema peripheral			
subjects affected / exposed	5 / 95 (5.26%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Pain			

subjects affected / exposed	5 / 95 (5.26%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Chest pain			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	10 / 95 (10.53%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	11	0	0
Epistaxis			
subjects affected / exposed	9 / 95 (9.47%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	11	0	0
Dyspnoea			
subjects affected / exposed	8 / 95 (8.42%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	6 / 95 (6.32%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Depression			
subjects affected / exposed	5 / 95 (5.26%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Confusional state			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	21 / 95 (22.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	26	0	0
Platelet count decreased			
subjects affected / exposed	15 / 95 (15.79%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	18	0	0
Lymphocyte count decreased			

subjects affected / exposed	13 / 95 (13.68%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	15	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	10 / 95 (10.53%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	10	0	0
Blood creatinine increased			
subjects affected / exposed	10 / 95 (10.53%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	11	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	9 / 95 (9.47%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	10	0	0
White blood cell count decreased			
subjects affected / exposed	7 / 95 (7.37%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Neutrophil count decreased			
subjects affected / exposed	7 / 95 (7.37%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	10	0	0
Intraocular pressure increased			
subjects affected / exposed	6 / 95 (6.32%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	10	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	4 / 95 (4.21%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	5 / 95 (5.26%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	13	0	0
Weight decreased			
subjects affected / exposed	8 / 95 (8.42%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Alanine aminotransferase increased			
subjects affected / exposed	6 / 95 (6.32%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
C-reactive protein increased			

subjects affected / exposed	3 / 95 (3.16%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Bacterial test positive			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	15 / 95 (15.79%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	16	0	0
Rib fracture			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 95 (0.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	3 / 95 (3.16%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	11 / 95 (11.58%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	12	0	0
Dizziness			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	22 / 95 (23.16%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	34	0	0
Anaemia			

subjects affected / exposed	25 / 95 (26.32%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	28	0	0
Neutropenia			
subjects affected / exposed	7 / 95 (7.37%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	17	0	0
Leukopenia			
subjects affected / exposed	9 / 95 (9.47%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	9	0	0
Lymphopenia			
subjects affected / exposed	6 / 95 (6.32%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Eye disorders			
Keratopathy			
subjects affected / exposed	67 / 95 (70.53%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	267	0	0
Vision blurred			
subjects affected / exposed	22 / 95 (23.16%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	37	0	0
Dry eye			
subjects affected / exposed	14 / 95 (14.74%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	18	0	0
Photophobia			
subjects affected / exposed	7 / 95 (7.37%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	12	0	0
Diplopia			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Eye pruritus			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Visual acuity reduced			
subjects affected / exposed	5 / 95 (5.26%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Blepharitis			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0

Gastrointestinal disorders			
Nausea			
subjects affected / exposed	24 / 95 (25.26%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	29	0	0
Diarrhoea			
subjects affected / exposed	11 / 95 (11.58%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	14	0	0
Vomiting			
subjects affected / exposed	8 / 95 (8.42%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	11	0	0
Constipation			
subjects affected / exposed	12 / 95 (12.63%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	13	0	0
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	3 / 95 (3.16%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	5 / 95 (5.26%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	11	0	0
Haematuria			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	12 / 95 (12.63%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	13	0	0
Arthralgia			
subjects affected / exposed	19 / 95 (20.00%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	24	0	0
Pain in extremity			
subjects affected / exposed	8 / 95 (8.42%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	8	0	0
Bone pain			

subjects affected / exposed	4 / 95 (4.21%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Musculoskeletal chest pain			
subjects affected / exposed	7 / 95 (7.37%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	7	0	0
Myalgia			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Muscular weakness			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	10 / 95 (10.53%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	12	0	0
Urinary tract infection			
subjects affected / exposed	6 / 95 (6.32%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	7	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 95 (1.05%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	6 / 95 (6.32%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Pneumonia			
subjects affected / exposed	2 / 95 (2.11%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	12 / 95 (12.63%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	16	0	0
Hypercalcaemia			
subjects affected / exposed	10 / 95 (10.53%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	11	0	0
Hypokalaemia			

subjects affected / exposed	5 / 95 (5.26%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Hyperuricaemia			
subjects affected / exposed	9 / 95 (9.47%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	23	0	0
Hyponatraemia			
subjects affected / exposed	5 / 95 (5.26%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	6	0	0
Hypoalbuminaemia			
subjects affected / exposed	4 / 95 (4.21%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Hypophosphataemia			
subjects affected / exposed	7 / 95 (7.37%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	10	0	0
Hypomagnesaemia			
subjects affected / exposed	5 / 95 (5.26%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	7	0	0
Hyperglycaemia			
subjects affected / exposed	5 / 95 (5.26%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	9	0	0
Hypocalcaemia			
subjects affected / exposed	4 / 95 (4.21%)	0 / 2 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0

Non-serious adverse events	Main Study-GSK2857916 3.4 mg/kg (Frozen liquid)	Main Study-GSK2857916 3.4 mg/kg (Lyophilized)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	96 / 99 (96.97%)	24 / 24 (100.00%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	10 / 99 (10.10%)	2 / 24 (8.33%)	
occurrences (all)	11	6	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	28 / 99 (28.28%)	12 / 24 (50.00%)	
occurrences (all)	37	13	

Pyrexia			
subjects affected / exposed	22 / 99 (22.22%)	4 / 24 (16.67%)	
occurrences (all)	29	6	
Asthenia			
subjects affected / exposed	11 / 99 (11.11%)	2 / 24 (8.33%)	
occurrences (all)	11	2	
Chills			
subjects affected / exposed	4 / 99 (4.04%)	2 / 24 (8.33%)	
occurrences (all)	4	2	
Oedema peripheral			
subjects affected / exposed	4 / 99 (4.04%)	3 / 24 (12.50%)	
occurrences (all)	10	5	
Pain			
subjects affected / exposed	4 / 99 (4.04%)	0 / 24 (0.00%)	
occurrences (all)	4	0	
Chest pain			
subjects affected / exposed	2 / 99 (2.02%)	3 / 24 (12.50%)	
occurrences (all)	2	3	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	19 / 99 (19.19%)	3 / 24 (12.50%)	
occurrences (all)	20	4	
Epistaxis			
subjects affected / exposed	17 / 99 (17.17%)	1 / 24 (4.17%)	
occurrences (all)	21	1	
Dyspnoea			
subjects affected / exposed	6 / 99 (6.06%)	3 / 24 (12.50%)	
occurrences (all)	7	3	
Oropharyngeal pain			
subjects affected / exposed	5 / 99 (5.05%)	1 / 24 (4.17%)	
occurrences (all)	5	1	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 99 (1.01%)	2 / 24 (8.33%)	
occurrences (all)	1	2	
Depression			

subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences (all)	3	0	
Confusional state			
subjects affected / exposed	5 / 99 (5.05%)	1 / 24 (4.17%)	
occurrences (all)	6	1	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	24 / 99 (24.24%)	6 / 24 (25.00%)	
occurrences (all)	30	8	
Platelet count decreased			
subjects affected / exposed	11 / 99 (11.11%)	3 / 24 (12.50%)	
occurrences (all)	26	3	
Lymphocyte count decreased			
subjects affected / exposed	10 / 99 (10.10%)	2 / 24 (8.33%)	
occurrences (all)	13	3	
Gamma-glutamyltransferase increased			
subjects affected / exposed	14 / 99 (14.14%)	2 / 24 (8.33%)	
occurrences (all)	14	2	
Blood creatinine increased			
subjects affected / exposed	11 / 99 (11.11%)	2 / 24 (8.33%)	
occurrences (all)	14	2	
Blood alkaline phosphatase increased			
subjects affected / exposed	11 / 99 (11.11%)	1 / 24 (4.17%)	
occurrences (all)	11	1	
White blood cell count decreased			
subjects affected / exposed	9 / 99 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	11	0	
Neutrophil count decreased			
subjects affected / exposed	11 / 99 (11.11%)	2 / 24 (8.33%)	
occurrences (all)	13	2	
Intraocular pressure increased			
subjects affected / exposed	8 / 99 (8.08%)	5 / 24 (20.83%)	
occurrences (all)	8	6	
Blood lactate dehydrogenase increased			

subjects affected / exposed	7 / 99 (7.07%)	4 / 24 (16.67%)	
occurrences (all)	8	4	
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 99 (3.03%)	0 / 24 (0.00%)	
occurrences (all)	3	0	
Weight decreased			
subjects affected / exposed	2 / 99 (2.02%)	1 / 24 (4.17%)	
occurrences (all)	2	1	
Alanine aminotransferase increased			
subjects affected / exposed	4 / 99 (4.04%)	0 / 24 (0.00%)	
occurrences (all)	5	0	
C-reactive protein increased			
subjects affected / exposed	5 / 99 (5.05%)	1 / 24 (4.17%)	
occurrences (all)	5	1	
Urine albumin/creatinine ratio increased			
subjects affected / exposed	8 / 99 (8.08%)	0 / 24 (0.00%)	
occurrences (all)	8	0	
Bacterial test positive			
subjects affected / exposed	0 / 99 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Blood bilirubin increased			
subjects affected / exposed	1 / 99 (1.01%)	2 / 24 (8.33%)	
occurrences (all)	2	2	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	9 / 99 (9.09%)	2 / 24 (8.33%)	
occurrences (all)	10	2	
Rib fracture			
subjects affected / exposed	2 / 99 (2.02%)	2 / 24 (8.33%)	
occurrences (all)	2	2	
Contusion			
subjects affected / exposed	8 / 99 (8.08%)	2 / 24 (8.33%)	
occurrences (all)	8	2	
Fall			

subjects affected / exposed	0 / 99 (0.00%)	2 / 24 (8.33%)	
occurrences (all)	0	2	
Nervous system disorders			
Headache			
subjects affected / exposed	17 / 99 (17.17%)	5 / 24 (20.83%)	
occurrences (all)	22	6	
Dizziness			
subjects affected / exposed	7 / 99 (7.07%)	1 / 24 (4.17%)	
occurrences (all)	8	1	
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	44 / 99 (44.44%)	8 / 24 (33.33%)	
occurrences (all)	73	12	
Anaemia			
subjects affected / exposed	36 / 99 (36.36%)	8 / 24 (33.33%)	
occurrences (all)	49	14	
Neutropenia			
subjects affected / exposed	18 / 99 (18.18%)	1 / 24 (4.17%)	
occurrences (all)	27	4	
Leukopenia			
subjects affected / exposed	7 / 99 (7.07%)	0 / 24 (0.00%)	
occurrences (all)	8	0	
Lymphopenia			
subjects affected / exposed	5 / 99 (5.05%)	1 / 24 (4.17%)	
occurrences (all)	5	1	
Eye disorders			
Keratopathy			
subjects affected / exposed	74 / 99 (74.75%)	23 / 24 (95.83%)	
occurrences (all)	320	100	
Vision blurred			
subjects affected / exposed	30 / 99 (30.30%)	8 / 24 (33.33%)	
occurrences (all)	50	13	
Dry eye			
subjects affected / exposed	19 / 99 (19.19%)	5 / 24 (20.83%)	
occurrences (all)	21	10	
Photophobia			

subjects affected / exposed	9 / 99 (9.09%)	3 / 24 (12.50%)	
occurrences (all)	16	3	
Diplopia			
subjects affected / exposed	4 / 99 (4.04%)	2 / 24 (8.33%)	
occurrences (all)	5	2	
Eye pruritus			
subjects affected / exposed	5 / 99 (5.05%)	1 / 24 (4.17%)	
occurrences (all)	10	1	
Visual acuity reduced			
subjects affected / exposed	5 / 99 (5.05%)	3 / 24 (12.50%)	
occurrences (all)	5	3	
Blepharitis			
subjects affected / exposed	6 / 99 (6.06%)	0 / 24 (0.00%)	
occurrences (all)	6	0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	32 / 99 (32.32%)	2 / 24 (8.33%)	
occurrences (all)	40	3	
Diarrhoea			
subjects affected / exposed	15 / 99 (15.15%)	4 / 24 (16.67%)	
occurrences (all)	15	4	
Vomiting			
subjects affected / exposed	21 / 99 (21.21%)	0 / 24 (0.00%)	
occurrences (all)	23	0	
Constipation			
subjects affected / exposed	9 / 99 (9.09%)	4 / 24 (16.67%)	
occurrences (all)	9	5	
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	2 / 99 (2.02%)	2 / 24 (8.33%)	
occurrences (all)	2	2	
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	3 / 99 (3.03%)	3 / 24 (12.50%)	
occurrences (all)	21	3	
Haematuria			

subjects affected / exposed	1 / 99 (1.01%)	2 / 24 (8.33%)	
occurrences (all)	1	2	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	12 / 99 (12.12%)	6 / 24 (25.00%)	
occurrences (all)	12	6	
Arthralgia			
subjects affected / exposed	16 / 99 (16.16%)	4 / 24 (16.67%)	
occurrences (all)	19	6	
Pain in extremity			
subjects affected / exposed	12 / 99 (12.12%)	1 / 24 (4.17%)	
occurrences (all)	16	1	
Bone pain			
subjects affected / exposed	9 / 99 (9.09%)	0 / 24 (0.00%)	
occurrences (all)	10	0	
Musculoskeletal chest pain			
subjects affected / exposed	7 / 99 (7.07%)	1 / 24 (4.17%)	
occurrences (all)	9	1	
Myalgia			
subjects affected / exposed	4 / 99 (4.04%)	2 / 24 (8.33%)	
occurrences (all)	5	2	
Muscular weakness			
subjects affected / exposed	6 / 99 (6.06%)	0 / 24 (0.00%)	
occurrences (all)	6	0	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	20 / 99 (20.20%)	4 / 24 (16.67%)	
occurrences (all)	24	4	
Urinary tract infection			
subjects affected / exposed	9 / 99 (9.09%)	1 / 24 (4.17%)	
occurrences (all)	16	1	
Nasopharyngitis			
subjects affected / exposed	5 / 99 (5.05%)	0 / 24 (0.00%)	
occurrences (all)	6	0	
Bronchitis			

subjects affected / exposed	2 / 99 (2.02%)	0 / 24 (0.00%)	
occurrences (all)	2	0	
Pneumonia			
subjects affected / exposed	5 / 99 (5.05%)	2 / 24 (8.33%)	
occurrences (all)	5	2	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	19 / 99 (19.19%)	5 / 24 (20.83%)	
occurrences (all)	21	5	
Hypercalcaemia			
subjects affected / exposed	15 / 99 (15.15%)	4 / 24 (16.67%)	
occurrences (all)	17	5	
Hypokalaemia			
subjects affected / exposed	12 / 99 (12.12%)	3 / 24 (12.50%)	
occurrences (all)	13	7	
Hyperuricaemia			
subjects affected / exposed	7 / 99 (7.07%)	1 / 24 (4.17%)	
occurrences (all)	7	1	
Hyponatraemia			
subjects affected / exposed	12 / 99 (12.12%)	4 / 24 (16.67%)	
occurrences (all)	14	4	
Hypoalbuminaemia			
subjects affected / exposed	8 / 99 (8.08%)	1 / 24 (4.17%)	
occurrences (all)	12	1	
Hypophosphataemia			
subjects affected / exposed	8 / 99 (8.08%)	3 / 24 (12.50%)	
occurrences (all)	11	3	
Hypomagnesaemia			
subjects affected / exposed	6 / 99 (6.06%)	1 / 24 (4.17%)	
occurrences (all)	8	1	
Hyperglycaemia			
subjects affected / exposed	7 / 99 (7.07%)	3 / 24 (12.50%)	
occurrences (all)	11	4	
Hypocalcaemia			
subjects affected / exposed	3 / 99 (3.03%)	2 / 24 (8.33%)	
occurrences (all)	3	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 April 2018	Amendment 01: Addressed regulatory agency advice. The original single-arm design with 1 dose level (3.4 milligram per kilogram [mg/kg] GSK2857916 once every 3 weeks [Q3W]) was amended to an open label, randomized, 2-arm study with 2 dose levels by including the 2.5 mg/kg Q3W dose. In addition, a new exploratory cohort of 25 participants, who will receive a lyophilized configuration of GSK2857916, was added to gain clinical experience with the lyophilized configuration. To accommodate these main changes, the overall sample size and related analytical methods were changed.
04 September 2018	Amendment 02: Addressed feedback from regulatory agencies, ethics commitee/institutional review board, and investigators. The updates included the addition of Exclusion Criteria defining the use of high dose steroids, clarification of specific timeframe from last treatment required for systemic anti-myeloma therapy, and increase of corrected QT interval Fridericia criteria. Additional pharmacokinetic sampling timepoints were added to capture the maximum observed concentration of the free cytotoxic drug (cysteine-maleimidocaproyl monomethyl auristatin F [cys-mcMMAF]) and to better define the kinetics of cys-mcMMAF and the elimination phase of antibody drug conjugate and cys-mcMMAF. Soluble B-cell maturation antigen (BCMA) collection timepoints were also added to capture the effect of GSK2857916 administration on soluble BCMA concentrations over time as a marker of pharmacodynamic effect. The dose modifications guidelines for GSK2857916 related Corneal Events clarified dose adjustments for GlaxoSmithKline Scale Grade 2 events.
17 December 2018	Amendment 03: Addressed over-enrolment in the frozen liquid solution portion of the study. Due to the over-enrolment, the primary analysis will be based on all randomized participants (anticipated approximately 200) enroled into the frozen liquid solution arms. In addition, a sensitivity analysis based on the first 130 participants will be performed to account for the original design.
21 October 2019	Amendment 04: Updated schedule of activities to include the footnotes. Updated risk assessment, modified dose justification, modified treatments administered, updated dose reductions for toxicity, modified corneal supportive care guidelines and schedule of activities, updated guidance on prohibited medications, updated requirements for efficacy assessments, modified timeframes for contraception usage in males and females, modified monocular prophylaxis and treatment, updated immunogenicity, updated timeframe of minimal residual disease testing, updated GlaxoSmithKline corneal event severity scale and mitigation strategy for treatment related corneal events.
08 October 2020	Amendment 05:The protocol has been amended to provide updates based on analyses of data from the DREAMM-1, DREAMM-2 and the exposure Corrected QT interval. The updates include the removal of ECG collection, unless clinically indicated, and updated contraception timeframe. The dose modification guidelines for belantamab mafodotin related corneal events was updated to align with the approved label and an appendix on Home Healthcare and Telemedicine Approaches was introduced as a result of the COVID-19 pandemic to ensure sites and participants had alternate approaches to assist participants to continue receiving care while maintaining protocol adherence.
19 November 2021	Amendment 06: The protocol has been amended to provide updates including the addition of the end of study definition and continued access to study intervention after the end of the study section (Post Analysis Continued Treatment [PACT])

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported