Clinical trial results:
A Phase II Multicenter, Parallel-Group, Randomized, Dose-Ranging Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics Following 12 Weeks of Oral Administration of GSK2336805 With Pegylated Interferon and Ribavirin in Treatment-Naïve Subjects With Chronic Genotype 1 or 4 Hepatitis C Infection.

Summary

EudraCT number	2012-000523-40
Trial protocol	BE DE BG
Global end of trial date	16 July 2014

Results information

Result version number	v1
This version publication date	10 March 2016
First version publication date	21 May 2015

Trial information

Trial identification

Sponsor protocol code	HAI115879

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,

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	19 August 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 July 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this study are:
• To evaluate the 12-week safety and tolerability of 40 and 60 mg of GSK2336805 when given in combination with pegylated interferon alfa-2a (PEG) and ribavirin (RIBA).
• To evaluate 12-week antiviral activity of 40 and 60 mg of GSK2336805 when given in combination with PEG and RIBA as measured by eRVR (defined as undetectable plasma HCV RNA at Weeks 4 and 12)

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 August 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 9
Country: Number of subjects enrolled	Bulgaria: 48
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Germany: 10
Country: Number of subjects enrolled	United States: 172
Country: Number of subjects enrolled	Puerto Rico: 44
Worldwide total number of subjects	286
EEA total number of subjects	70

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)	280
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants (par.) with treatment-naïve (TN) chronic Genotype 1 (G1) hepatitis C virus (HCV) infection were randomly allocated on a 2:2:1 basis to 2 dose levels of GSK2336805 or telaprevir. In a nonrandomized single-arm cohort, par. with TN genotype 4 (G4) chronic HCV infection were enrolled in parallel at the dose level of 60 mg of GSK2336805.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK2336805 40 mg, Genotype 1 HCV

Arm description:

Participants with chronic G1 HCV infection received GSK2336805 40 milligrams (mg) orally (20 mg x 2 tablets) once daily (OD) in the morning with food in combination with antiviral therapy (Pegylated Interferon Alfa-2a [PEG] + Ribavirin [RIBA]) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on the extended rapid virologic response (eRVR) achievement. PEG dose was 180 micrograms (µg) once weekly subcutaneous (SC) injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kilogram [kg]) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken in 2 divided doses with food.

Arm type	Experimental
Investigational medicinal product name	GSK2336805
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

40 mg, 2 tablets per day in morning with food

Investigational medicinal product name	Peginterferon alfa-2a (PEGASYS)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms per week by subcutaneous injection in the abdomen or thigh

Investigational medicinal product name	Ribavirin (Ripasphere)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

1000 mg if < 75 kg, 5 capsules (2 in morning and 3 in evening), 1200 mg if > or equal to 75 kg, 6 capsules (3 in morning and 3 in evening)

Arm title	GSK2336805 60 mg, Genotype 1 HCV

Arm description:

Participants with chronic G1 HCV infection received GSK2336805 60 mg orally (30 mg x 2 tablets) OD in the morning with food in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.

Arm type	Experimental
Investigational medicinal product name	GSK2336805
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60 mg, 2 tablets per day in morning with food

Investigational medicinal product name	Peginterferon alfa-2a (PEGASYS)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms per week by subcutaneous injection in the abdomen or thigh

Investigational medicinal product name	Ribavirin (Ripasphere)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

1000 mg if < 75 kg, 5 capsules (2 in morning and 3 in evening), 1200 mg if > or equal to 75 kg, 6 capsules (3 in morning and 3 in evening)

Arm title	Telaprevir, Genotype 1 HCV

Arm description:

Participants with chronic G1 HCV infection received two telaprevir 375 mg tablets orally 3 times a day (7 to 9 hours apart) with food containing approximately 20 grams of fat in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.

Arm type	Experimental
Investigational medicinal product name	Telaprevir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 x 375 mg tablets taken orally 3 times a day (7-9 hours apart) with food

Investigational medicinal product name	Peginterferon alfa-2a (PEGASYS)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms per week by subcutaneous injection in the abdomen or thigh

Investigational medicinal product name	Ribavirin (Ripasphere)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

1000 mg if < 75 kg, 5 capsules (2 in morning and 3 in evening), 1200 mg if > or equal to 75 kg, 6 capsules (3 in morning and 3 in evening)

Arm title	GSK2336805 60 mg, Genotype 4 HCV

Arm description:

Participants with chronic G4 HCV infection received GSK2336805 60 mg orally (30 mg x 2 tablets) OD in the morning with food in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.

Arm type	Experimental
Investigational medicinal product name	GSK2336805
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60 mg, 2 tablets per day in morning with food

Investigational medicinal product name	Peginterferon alfa-2a (PEGASYS)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

180 micrograms per week by subcutaneous injection in the abdomen or thigh

Investigational medicinal product name	Ribavirin (Ripasphere)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

1000 mg if < 75 kg, 5 capsules (2 in morning and 3 in evening), 1200 mg if > or equal to 75 kg, 6 capsules (3 in morning and 3 in evening)

Number of subjects in period 1[1]	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV
Started	41	40	17
Completed	29	28	9
Not completed	12	12	8
Physician decision	1	-	-
Consent withdrawn by subject	2	3	3
Adverse event, non-fatal	3	1	2
Lost to follow-up	2	1	2

Lack of efficacy	4	7	1

Number of subjects in period 1[1]	GSK2336805 60 mg, Genotype 4 HCV
Started	13
Completed	11
Not completed	2
Physician decision	-
Consent withdrawn by subject	2
Adverse event, non-fatal	-
Lost to follow-up	-
Lack of efficacy	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: A total of 286 participants were screened for enrollment and the eligible subjects were randomly assigned to the treatment groups. Of the 118 randomly assigned participants, the analysis populations included 111 participants in the Safety Population, 111 participants in the ITT Population.

Baseline characteristics

Reporting groups	
Reporting group title	GSK2336805 40 mg, Genotype 1 HCV
Reporting group description:	
Participants with chronic G1 HCV infection received GSK2336805 40 milligrams (mg) orally (20 mg x 2 tablets) once daily (OD) in the morning with food in combination with antiviral therapy (Pegylated Interferon Alfa-2a [PEG] + Ribavirin [RIBA]) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on the extended rapid virologic response (eRVR) achievement. PEG dose was 180 micrograms (µg) once weekly subcutaneous (SC) injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kilogram [kg]) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken in 2 divided doses with food.	
Reporting group title	GSK2336805 60 mg, Genotype 1 HCV
Reporting group description:	
Participants with chronic G1 HCV infection received GSK2336805 60 mg orally (30 mg x 2 tablets) OD in the morning with food in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.	
Reporting group title	Telaprevir, Genotype 1 HCV
Reporting group description:	
Participants with chronic G1 HCV infection received two telaprevir 375 mg tablets orally 3 times a day (7 to 9 hours apart) with food containing approximately 20 grams of fat in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.	
Reporting group title	GSK2336805 60 mg, Genotype 4 HCV
Reporting group description:	
Participants with chronic G4 HCV infection received GSK2336805 60 mg orally (30 mg x 2 tablets) OD in the morning with food in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.	

Reporting group values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV
Number of subjects	41	40	17
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 43.7 ± 13.23	 40.8 ± 9.87	 39.4 ± 12.02
Gender categorical Units: Subjects			
Female	13	16	6
Male	28	24	11
Race Units: Subjects			
African American/African Heritage	6	6	2
Asian - South East Asian Heritage	0	0	0

White - Arabic/North African Heritage	1	0	0
White - White/Caucasian/European Heritage	33	33	15
Mixed Race	1	1	0

Reporting group values	GSK2336805 60 mg, Genotype 4 HCV	Total	
Number of subjects	13	111	
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	45.3		
standard deviation	± 11.46	-	
Gender categorical			
Units: Subjects			
Female	3	38	
Male	10	73	
Race			
Units: Subjects			
African American/African Heritage	3	17	
Asian - South East Asian Heritage	1	1	
White - Arabic/North African Heritage	5	6	
White - White/Caucasian/European Heritage	4	85	
Mixed Race	0	2	

End points

End points reporting groups

Reporting group title	GSK2336805 40 mg, Genotype 1 HCV

Reporting group description:

Participants with chronic G1 HCV infection received GSK2336805 40 milligrams (mg) orally (20 mg x 2 tablets) once daily (OD) in the morning with food in combination with antiviral therapy (Pegylated Interferon Alfa-2a [PEG] + Ribavirin [RIBA]) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on the extended rapid virologic response (eRVR) achievement. PEG dose was 180 micrograms (µg) once weekly subcutaneous (SC) injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kilogram [kg]) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken in 2 divided doses with food.

Reporting group title	GSK2336805 60 mg, Genotype 1 HCV

Reporting group description:

Participants with chronic G1 HCV infection received GSK2336805 60 mg orally (30 mg x 2 tablets) OD in the morning with food in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.

Reporting group title	Telaprevir, Genotype 1 HCV

Reporting group description:

Participants with chronic G1 HCV infection received two telaprevir 375 mg tablets orally 3 times a day (7 to 9 hours apart) with food containing approximately 20 grams of fat in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.

Reporting group title	GSK2336805 60 mg, Genotype 4 HCV

Reporting group description:

Participants with chronic G4 HCV infection received GSK2336805 60 mg orally (30 mg x 2 tablets) OD in the morning with food in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.

Subject analysis set title	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with chronic G1 and G4 HCV infection received GSK2336805 60 mg orally (30 mg x 2 tablets) OD in the morning with food in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.

Primary: Number of participants achieving extended rapid virologic response (eRVR)

End point title	Number of participants achieving extended rapid virologic response (eRVR)[1]

End point description:

Extended rapid virologic response (eRVR) is defined as plasma HCV ribonucleic acid (RNA) <lower limit of quantification (LLOQ) and target not detected at Weeks 4 and 12. Participants who discontinued prior to Week 12 assessments or had missing HCV RNA values at Weeks 4 and 12 were treated as non-responders. Intent-To-Treat (ITT) Population: comprised of all participants who met the study criteria and were randomly assigned to treatment in the study with documented evidence of having received at least 1 dose of randomized treatment and at least 1 post Baseline HCV RNA measurement.

End point type	Primary

End point timeframe:

Week 4 and Week 12

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: The primary comparison of eRVR was performed using a Bayesian probability model.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[2]	40[3]	17[4]	13[5]
Units: Participants	23	21	9	9

Notes:

[2] - ITT Population

[3] - ITT Population

[4] - ITT Population

[5] - ITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any adverse events (AEs) and any serious adverse events (SAEs) up to Week 12

End point title	Number of participants with any adverse events (AEs) and any serious adverse events (SAEs) up to Week 12[6]

End point description:

An AE is defined as any untoward medical occurrence in a participant temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An AE can therefore be any unfavorable and unintended sign(including an abnormal laboratory finding), symptom, or disease(new or exacerbated) temporally associated with the use of a medicinal product. A SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, a congenital anomaly/birth defect, important medical events that jeopardize the participants or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. Safety Population: comprised of all participants who received at least 1 dose of study medication (GSK2336805 or telaprevir).

End point type	Primary

End point timeframe:

From the start of study treatment up to Week 12

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[7]	40[8]	17[9]	13[10]
Units: Participants				
Any AE	39	37	17	13
Any SAE	0	2	3	1

Notes:

[7] - Safety Population

[8] - Safety Population

[9] - Safety Population

[10] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in systolic blood pressure and diastolic blood pressure at the indicated time points up to Week 12

End point title	Mean change from Baseline in systolic blood pressure and diastolic blood pressure at the indicated time points up to Week 12[11]

End point description:

Blood pressure measurements were taken to observe vital signs and included systolic blood pressure (SBP) and diastolic blood pressure (DBP) at the Baseline, Day 2, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and Post-treatment (PT) Follow Up (FU) Weeks 4, 12 and 24. Change from Baseline in SBP and DBP is summarized for each post-Baseline assessment up to Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Day 2, Weeks 1, 2, 4, 6, 8, and 12

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[12]	40[13]	17[14]	13[15]
Units: Millimeters of mercury (mmHg)				
arithmetic mean (standard deviation)				
DBP; Day2; n=41, 40, 17, 13	-1.2 (± 6.63)	-1 (± 7.03)	-3 (± 9.03)	-1.5 (± 10.45)
DBP; Week1; n=41, 39, 15, 13	-0.4 (± 7.98)	-2.2 (± 9.13)	1 (± 10.54)	-1 (± 7.99)
DBP; Week2; n=41, 39, 14, 13	-0.4 (± 10.41)	-1.7 (± 9.52)	-0.3 (± 8.8)	-2.8 (± 11.09)
DBP; Week4; n=41, 39, 14, 13	-1.2 (± 7.73)	-4.4 (± 9.78)	-3.9 (± 9.74)	0.8 (± 9.92)
DBP; Week6; n=41, 39, 13, 13	-1.2 (± 7.65)	-4.8 (± 9.86)	-5.9 (± 7.82)	-1.6 (± 10.1)
DBP; Week8; n=41, 39, 13, 13	-2.1 (± 10)	-2.9 (± 9.11)	-4.4 (± 7.63)	-2.4 (± 9.02)
DBP; Week12; n=38, 35, 12, 13	0.3 (± 8.48)	-4.4 (± 10.24)	-3.5 (± 9.2)	-1 (± 9.11)
SBP; Day2; n=41, 40, 17, 13	-1.4 (± 10.1)	-0.8 (± 12.85)	-3.3 (± 10.46)	-1.3 (± 13.95)
SBP; Week1; n=41, 39, 15, 13	0.9 (± 12.99)	-3 (± 11.24)	-4.5 (± 12.67)	-2.6 (± 11.84)
SBP; Week2; n=41, 39, 14, 13	-2 (± 10.57)	-0.7 (± 11.67)	-4.1 (± 12.67)	-4.2 (± 17.35)
SBP; Week4; n=41, 39, 14, 13	-3.6 (± 11.56)	-4.2 (± 16.2)	-3.8 (± 9.73)	-5.2 (± 15.3)
SBP; Week6; n=41, 39, 13, 13	-0.4 (± 14.47)	-3.8 (± 13.28)	-5.9 (± 11.39)	0.2 (± 14.47)
SBP; Week8; n=41, 39, 13, 13	-3.7 (± 12.15)	-1.5 (± 12.64)	-2.9 (± 10.36)	-4.2 (± 12.95)
SBP; Week12; n=38, 35, 12, 13	-1.9 (± 13.65)	-1.4 (± 11.72)	-5.2 (± 5.81)	-2.6 (± 19.16)

Notes:

[12] - Safety Population

[13] - Safety Population

[14] - Safety Population

[15] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in heart rate at the indicated time points up to Week 12

End point title	Mean change from Baseline in heart rate at the indicated time points up to Week 12[16]

End point description:

Vital sign monitoring included heart rate, measured at the Baseline, Day 2, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4, 12 and 24. Change from Baseline in heart rate is summarized for each post-Baseline assessment upto Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Day 2, Weeks 1, 2, 4, 6, 8, and 12

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[17]	40[18]	17[19]	13[20]
Units: Beats per minute				
arithmetic mean (standard deviation)				
Heart Rate; Day2; n=41, 40, 17, 13	6.5 (± 8.65)	5.4 (± 9.96)	9.3 (± 11.74)	3.8 (± 5.79)
Heart Rate; Week1; n=41, 39, 15, 13	1.5 (± 8.33)	3.1 (± 8.75)	8.1 (± 6.32)	7.7 (± 10.11)
Heart Rate; Week2; n=41, 39, 14, 13	3.8 (± 9.02)	4.2 (± 12.14)	8.7 (± 8.17)	7.8 (± 8.6)
Heart Rate; Week4; n=41, 39, 14, 13	6.8 (± 9.42)	4.2 (± 11.78)	10.7 (± 11.39)	5.5 (± 8.35)
Heart Rate; Week6; n=41, 39, 13, 13	8 (± 10.15)	5 (± 10.98)	13.8 (± 9.75)	10.2 (± 8.2)
Heart Rate; Week8; n=41, 39, 13, 13	4.7 (± 9.91)	6.8 (± 12.42)	14.2 (± 10.36)	12.8 (± 12.27)
Heart Rate; Week12; n=38, 35, 12, 13	7 (± 9.2)	5.3 (± 12.1)	11 (± 8.02)	8.4 (± 9.47)

Notes:

[17] - Safety Population

[18] - Safety Population

[19] - Safety Population

[20] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in basophils, eosinophils, lymphocytes, monocytes, total neutrophils, platelet count and white blood cell count at the indicated time points up to Week 12

End point title	Mean change from Baseline in basophils, eosinophils, lymphocytes, monocytes, total neutrophils, platelet count and white blood cell count at the indicated time points up to Week 12[21]

End point description:

Blood samples were collected for the measurement of basophils, eosinophils, lymphocytes, monocytes, total neutrophils, platelet count and white blood cell count at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4. Change from Baseline in the basophils, eosinophils, lymphocytes, total neutrophils platelet count and white blood cell count values are summarized for each post-Baseline assessment until Week 12. . Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6, 8 and 12

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[22]	40[23]	17[24]	13[25]
Units: Giga per liter				
arithmetic mean (standard deviation)				
Basophils; Week1; n=38, 38, 14, 11	-0.011 (± 0.0191)	-0.011 (± 0.0193)	-0.012 (± 0.0105)	-0.013 (± 0.0119)
Basophils; Week2; n=40, 38, 14, 10	-0.014 (± 0.0175)	-0.01 (± 0.0192)	-0.009 (± 0.0107)	-0.009 (± 0.0179)
Basophils; Week4; n=41, 38, 14, 13	-0.017 (± 0.0184)	-0.012 (± 0.0187)	-0.01 (± 0.0118)	-0.015 (± 0.0113)
Basophils; Week6; n=41, 37, 12, 12	-0.015 (± 0.021)	-0.013 (± 0.0205)	-0.013 (± 0.0114)	-0.013 (± 0.0106)
Basophils; Week8; n=38, 39, 13, 13	-0.019 (± 0.0155)	-0.016 (± 0.018)	-0.009 (± 0.0132)	-0.012 (± 0.0142)
Basophils; Week12; n=37, 36, 12, 12	-0.018 (± 0.0184)	-0.013 (± 0.0187)	-0.011 (± 0.0124)	-0.012 (± 0.0153)
Eosinophils; Week1; n=38, 38, 14, 11	-0.051 (± 0.0874)	-0.075 (± 0.106)	-0.059 (± 0.0578)	-0.085 (± 0.1052)
Eosinophils; Week2; n=40, 38, 14, 10	-0.08 (± 0.1004)	-0.111 (± 0.0912)	-0.059 (± 0.104)	-0.114 (± 0.1247)
Eosinophils; Week4; n=41, 38, 14, 13	-0.105 (± 0.0872)	-0.132 (± 0.1057)	-0.079 (± 0.1089)	-0.108 (± 0.0923)
Eosinophils; Week6; n=41, 37, 12, 12	-0.117 (± 0.0929)	-0.134 (± 0.1182)	-0.113 (± 0.0607)	-0.109 (± 0.1208)
Eosinophils; Week8; n=38, 39, 13, 13	-0.121 (± 0.0897)	-0.134 (± 0.1061)	-0.13 (± 0.0965)	-0.104 (± 0.0916)
Eosinophils; Week12; n=37, 36, 12, 12	-0.118 (± 0.0916)	-0.112 (± 0.1594)	-0.106 (± 0.1152)	-0.102 (± 0.1428)
Lymphocytes; Week1; n=38, 38, 14, 11	-0.319 (± 0.5006)	-0.282 (± 0.5698)	-0.608 (± 0.5466)	-0.371 (± 0.4332)
Lymphocytes; Week2; n=40, 38, 14, 10	-0.448 (± 0.5385)	-0.603 (± 0.5921)	-0.675 (± 0.5639)	-0.553 (± 0.4346)

Lymphocytes; Week4; n=41, 38, 14, 13	-0.787 (± 0.5055)	-0.854 (± 0.5114)	-0.989 (± 0.5293)	-0.773 (± 0.4104)
Lymphocytes; Week6; n=41, 37, 12, 12	-0.963 (± 0.5313)	-1.043 (± 0.5928)	-1.334 (± 0.4906)	-0.93 (± 0.4955)
Lymphocytes; Week8; n=38, 39, 13, 13	-0.953 (± 0.4624)	-1.061 (± 0.6021)	-1.256 (± 0.3509)	-0.964 (± 0.5098)
Lymphocytes; Week12; n=37, 36, 12, 12	-1.118 (± 0.5139)	-1.074 (± 0.5883)	-1.438 (± 0.4773)	-1.048 (± 0.6612)
Monocytes; Week1; n=38, 38, 14, 11	-0.103 (± 0.1418)	-0.056 (± 0.145)	0.034 (± 0.1502)	-0.025 (± 0.0808)
Monocytes; Week2; n=40, 38, 14, 10	-0.122 (± 0.227)	-0.061 (± 0.1785)	-0.091 (± 0.1562)	-0.034 (± 0.1687)
Monocytes; Week4; n=41, 38, 14, 13	-0.151 (± 0.1771)	-0.129 (± 0.158)	-0.126 (± 0.1471)	-0.055 (± 0.2103)
Monocytes; Week6; n=41, 37, 12, 12	-0.182 (± 0.1664)	-0.171 (± 0.1326)	-0.245 (± 0.1786)	-0.135 (± 0.1088)
Monocytes; Week8; n=38, 39, 13, 13	-0.229 (± 0.167)	-0.165 (± 0.1779)	-0.185 (± 0.1344)	-0.124 (± 0.2164)
Monocytes; Week12; n=37, 36, 12, 12	-0.185 (± 0.1715)	-0.183 (± 0.1438)	-0.219 (± 0.1493)	-0.133 (± 0.2048)
Total Neutrophils; Week1; n=38, 38, 14, 11	-2.338 (± 1.4959)	-1.871 (± 1.5089)	-1.158 (± 1.2688)	-1.378 (± 0.598)
Total Neutrophils; Week 2; n=40, 38, 14, 10	-2.114 (± 1.9189)	-2.121 (± 1.6445)	-1.186 (± 1.3343)	-1.468 (± 0.584)
Total Neutrophils; Week4; n=41, 38, 14, 13	-2.487 (± 1.9145)	-2.333 (± 1.5497)	-1.412 (± 1.5704)	-1.603 (± 0.5953)
Total Neutrophils; Week6; n=41, 37, 12, 12	-2.51 (± 1.8144)	-2.247 (± 1.5132)	-1.413 (± 1.4303)	-1.683 (± 0.661)
Total Neutrophils; Week8; n=38, 39, 13, 13	-2.706 (± 1.7553)	-2.168 (± 1.6902)	-1.222 (± 1.3481)	-1.613 (± 0.6882)
Total Neutrophils; Week12; n=37, 36, 12, 12	-2.894 (± 1.8124)	-2.188 (± 1.7297)	-1.649 (± 0.8749)	-1.483 (± 0.5873)
Platelet Count; Week1; n=38, 39, 14, 11	-58.5 (± 36.23)	-51.4 (± 36.42)	-59.5 (± 36.29)	-33.1 (± 33.32)
Platelet Count; Week2; n=41, 38, 14, 11	-58 (± 43.92)	-57.8 (± 44.02)	-41.4 (± 37.44)	-34.4 (± 41.74)
Platelet Count; Week4; n=41, 38, 14, 13	-54.4 (± 49.18)	-55.9 (± 47.19)	-56.2 (± 50.99)	-33.8 (± 61.79)
Platelet Count; Week6; n=41, 38, 12, 13	-66.8 (± 50.43)	-71.9 (± 38.6)	-71.3 (± 47.07)	-46 (± 46.05)
Platelet Count; Week8; n=39, 39, 13, 13	-74.9 (± 42.31)	-75.7 (± 45.82)	-60.1 (± 43.26)	-52.6 (± 43.54)
Platelet Count; Week12; n=38, 34, 12, 12	-73.4 (± 45.3)	-85.3 (± 40.42)	-58.8 (± 58.77)	-53 (± 39.49)
White Blood Cell count; Week1; n=38, 38, 14, 11	-2.83 (± 1.705)	-2.3 (± 1.872)	-1.81 (± 1.516)	-1.87 (± 0.508)
White Blood Cell count; Week2; n=40, 38, 14, 10	-2.77 (± 2.178)	-2.92 (± 1.81)	-2.01 (± 1.869)	-2.17 (± 0.886)
White Blood Cell count; Week4; n=41, 38, 14, 13	-3.55 (± 2.183)	-3.47 (± 1.712)	-2.61 (± 2.055)	-2.55 (± 0.919)
White Blood Cell count; Week6; n=41, 37, 12, 12	-3.78 (± 2.051)	-3.62 (± 1.682)	-3.09 (± 1.69)	-2.85 (± 0.923)
White Blood Cell count; Week8; n=38, 39, 13, 13	-4.03 (± 2.028)	-3.55 (± 1.896)	-2.8 (± 1.477)	-2.8 (± 1.04)
White Blood Cell count; Week12; n=37, 36, 12, 12	-4.33 (± 2.149)	-3.58 (± 1.934)	-3.42 (± 1.104)	-2.77 (± 0.963)

Notes:

[22] - Safety Population

[23] - Safety Population

[24] - Safety Population

[25] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in red blood cell count at the indicated time points up to Week 12

End point title	Mean change from Baseline in red blood cell count at the indicated time points up to Week 12[26]

End point description:

Blood samples were collected for the measurement of red blood cell count at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4. Change from Baseline in the red blood cell count values are summarized for each post-Baseline assessment until Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6, 8 and 12

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[27]	40[28]	17[29]	13[30]
Units: Trillion per liter				
arithmetic mean (standard deviation)				
Red Blood Cell count; Week1; n=38, 39, 14, 12	-0.15 (± 0.226)	-0.04 (± 0.279)	-0.18 (± 0.212)	-0.13 (± 0.303)
Red Blood Cell count; Week2; n=41, 38, 14, 12	-0.48 (± 0.376)	-0.44 (± 0.508)	-0.57 (± 0.312)	-0.28 (± 0.361)
Red Blood Cell count; Week4; n=41, 38, 14, 13	-0.88 (± 0.507)	-0.64 (± 0.623)	-1.03 (± 0.441)	-0.72 (± 0.559)
Red Blood Cell count; Week6; n=41, 38, 12, 13	-0.97 (± 0.504)	-0.78 (± 0.563)	-1.28 (± 0.49)	-0.86 (± 0.52)
Red Blood Cell count; Week8; n=39, 39, 13, 13	-1.01 (± 0.506)	-0.82 (± 0.534)	-1.45 (± 0.357)	-0.85 (± 0.412)
Red Blood Cell count; Week12; n=38, 36, 12, 12	-1.08 (± 0.48)	-0.79 (± 0.56)	-1.61 (± 0.464)	-0.92 (± 0.459)

Notes:

[27] - Safety Population

[28] - Safety Population

[29] - Safety Population

[30] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in hemoglobin at the indicated time points up to Week 12

End point title	Mean change from Baseline in hemoglobin at the indicated time points up to Week 12[31]

End point description:

Blood samples were collected for the measurement of hemoglobin at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Week 4. Change from Baseline in the hemoglobin values are summarized for each post-Baseline assessment until Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6, 8 and 12

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[32]	40[33]	17[34]	13[35]
Units: Grams per liter				
arithmetic mean (standard deviation)				
Hemoglobin; Week1; n=38, 39, 14, 12	-5.2 (± 6.98)	-2.3 (± 9.38)	-6.6 (± 5.83)	-5.3 (± 8.85)
Hemoglobin; Week2; n=41, 38, 14, 12	-16.7 (± 12.54)	-14.9 (± 16.21)	-20.5 (± 10.66)	-9.9 (± 11.5)
Hemoglobin; Week4; n=41, 38, 14, 13	-28.6 (± 15.38)	-22.1 (± 18.98)	-34.4 (± 13.55)	-22.5 (± 14.89)
Hemoglobin; Week6; n=41, 38, 12, 13	-30.1 (± 14.54)	-24.7 (± 16)	-40.8 (± 14.11)	-25.2 (± 12.28)
Hemoglobin; Week8; n=39, 39, 13, 13	-30.5 (± 13.29)	-25.5 (± 14.22)	-44.9 (± 11.73)	-25.2 (± 8.66)
Hemoglobin; Week12; n=38, 36, 12, 12	-33 (± 12.88)	-24.1 (± 13.41)	-47.4 (± 14.12)	-27.6 (± 12.05)

Notes:

[32] - Safety Population

[33] - Safety Population

[34] - Safety Population

[35] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in hematocrit at the indicated time points up to Week 12

End point title	Mean change from Baseline in hematocrit at the indicated time points up to Week 12[36]

End point description:

Blood samples were collected for the measurement of hematocrit at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Week 4. Change from Baseline in the hematocrit values are summarized for each post-Baseline assessment until Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6, 8 and 12

Notes:

[36] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[37]	40[38]	17[39]	13[40]
Units: Percentage of RBC in blood				
arithmetic mean (standard deviation)				
Hematocrit; Week1; n=38, 39, 14, 12	-0.0196 (± 0.02345)	-0.0069 (± 0.02751)	-0.0201 (± 0.01921)	-0.0166 (± 0.0298)
Hematocrit; Week2; n=41, 38, 14, 12	-0.0539 (± 0.03653)	-0.0465 (± 0.04738)	-0.0609 (± 0.03007)	-0.0335 (± 0.03625)
Hematocrit; Week4; n=41, 38, 14, 13	-0.0848 (± 0.04576)	-0.0621 (± 0.05468)	-0.0999 (± 0.03967)	-0.0668 (± 0.04445)
Hematocrit; Week6; n=41, 38, 12, 13	-0.0859 (± 0.0411)	-0.0685 (± 0.04487)	-0.1203 (± 0.04463)	-0.074 (± 0.03316)
Hematocrit; Week8; n=39, 39, 13, 13	-0.0838 (± 0.03955)	-0.0663 (± 0.04144)	-0.1235 (± 0.03288)	-0.07 (± 0.02758)
Hematocrit; Week12; n=38, 36, 12, 12	-0.0843 (± 0.04038)	-0.0589 (± 0.03648)	-0.1318 (± 0.03847)	-0.0688 (± 0.03298)

Notes:

[37] - Safety Population

[38] - Safety Population

[39] - Safety Population

[40] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in mean corpuscle volume at the indicated time points up to Week 12

End point title	Mean change from Baseline in mean corpuscle volume at the indicated time points up to Week 12[41]

End point description:

Blood samples were collected for the measurement of mean corpuscle volume at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4. Change from Baseline in the mean corpuscle volume values are summarized for each post-Baseline assessment until Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the

safety population.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6, 8 and 12

Notes:

[41] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[42]	40[43]	17[44]	13[45]
Units: Femtoliters				
arithmetic mean (standard deviation)				
Mean corpuscle volume; Week1; n=38, 39, 14, 12	-1.1 (± 1.21)	-0.8 (± 1.37)	-0.4 (± 1.15)	-0.7 (± 1.37)
Mean corpuscle volume; Week2; n=41, 38, 14, 12	-2 (± 1.84)	-1.4 (± 1.59)	-1.4 (± 1.09)	-1.5 (± 1.45)
Mean corpuscle volume; Week4; n=41, 38, 14, 13	0.3 (± 3.33)	0.2 (± 3.4)	-0.8 (± 1.58)	-0.2 (± 2.94)
Mean corpuscle volume; Week6; n=41, 38, 12, 13	2.3 (± 4.76)	1.8 (± 4.67)	-0.2 (± 2.37)	1.4 (± 4.63)
Mean corpuscle volume; Week8; n=39, 39, 13, 13	3.8 (± 5.39)	3 (± 5.2)	3.1 (± 2.78)	2.2 (± 3.75)
Mean corpuscle volume; Week12; n=38, 34, 12, 12	5.7 (± 6)	4.2 (± 6.3)	5.3 (± 4.14)	3.8 (± 4.28)

Notes:

[42] - Safety Population

[43] - Safety Population

[44] - Safety Population

[45] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in albumin at the indicated time points up to Week 12

End point title	Mean change from Baseline in albumin at the indicated time points up to Week 12[46]

End point description:

Blood samples were collected for the measurement of albumin at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4. Change from Baseline in the albumin values are summarized for each post-Baseline assessment until Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6, 8 and 12

Notes:

[46] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[47]	40[48]	17[49]	13[50]
Units: Grams per liter				
arithmetic mean (standard deviation)				
Albumin; Week1; n=40, 39, 15, 13	-0.6 (± 2.67)	-0.3 (± 2.46)	-1.1 (± 1.6)	-1 (± 1.87)
Albumin; Week2; n=41, 38, 14, 13	-1.3 (± 2.98)	-1.5 (± 2.68)	-2 (± 2.6)	-0.2 (± 2.39)
Albumin; Week4; n=41, 39, 14, 13	-1.9 (± 2.48)	-1.5 (± 2.52)	-3 (± 3.21)	-1.2 (± 1.46)
Albumin; Week6; n=41, 38, 13, 13	-2.2 (± 2.65)	-1.5 (± 2.27)	-3.5 (± 3.36)	-2.1 (± 2.22)
Albumin; Week8; n=40, 39, 13, 13	-2.6 (± 2.99)	-1.7 (± 2)	-3.7 (± 4.71)	-1.5 (± 1.94)
Albumin; Week12; n=37, 35, 12, 13	-2.1 (± 3.03)	-1.3 (± 2.84)	-3.3 (± 3.02)	-1.6 (± 2.1)

Notes:

[47] - Safety Population

[48] - Safety Population

[49] - Safety Population

[50] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in alkaline phosphatase, alanine amino transferase, aspartate amino transferase, creatine kinase and gamma glutamyl transferase at the indicated time points up to Week 12

End point title	Mean change from Baseline in alkaline phosphatase, alanine amino transferase, aspartate amino transferase, creatine kinase and gamma glutamyl transferase at the indicated time points up to Week 12[51]

End point description:

Blood samples were collected for the measurement of alkaline phosphatase (ALP), alanine amino transferase (ALT), aspartate amino transferase (AST), creatine kinase (CK) and gamma glutamyl transferase (GGT) at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4 Change from Baseline in the ALP, ALT, AST, CK and GGT values are summarized for each post-Baseline assessment until Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6, 8 and 12

Notes:

[51] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[52]	40[53]	17[54]	13[55]
Units: International units per liter				
arithmetic mean (standard deviation)				
ALP; Week1; n=40, 39, 15, 13	0 (± 7.73)	1.5 (± 10.21)	3.9 (± 19.36)	-0.2 (± 17.45)
ALP; Week2; n=41, 38, 14, 13	4.6 (± 9.26)	3.8 (± 16.22)	9.4 (± 21.15)	3.8 (± 12.43)
ALP; Week4; n=41, 39, 14, 13	8.6 (± 11.12)	7.1 (± 13.76)	11.7 (± 26.61)	7.2 (± 15.3)
ALP; Week6; n=41, 38, 13, 13	9.1 (± 13.73)	7.2 (± 17.1)	16.6 (± 31.03)	6.6 (± 16.38)
ALP; Week8; n=40, 39, 13, 13	6.9 (± 15.59)	6.5 (± 15.91)	15.5 (± 25.83)	5.6 (± 14.72)
ALP; Week12; n=37, 35, 12, 13	6.7 (± 15.56)	6.4 (± 20.78)	11.7 (± 25.09)	7.3 (± 18.33)
ALT; Week1; n=40, 39, 15, 13	-26.8 (± 31.64)	-24.4 (± 32.39)	-30.7 (± 30.1)	-25.6 (± 20.74)
ALT; Week2; n=41, 38, 14, 13	-28.2 (± 40.33)	-24.9 (± 47.49)	-35.4 (± 36.38)	-26.8 (± 24.25)
ALT; Week4; n=41, 39, 14, 13	-32.5 (± 44.5)	-25.3 (± 50.87)	-40.4 (± 38.73)	-33 (± 28.79)
ALT; Week6; n=41, 38, 13, 13	-36 (± 49.77)	-30.3 (± 50.74)	-40.8 (± 41.51)	-38.4 (± 29.11)
ALT; Week8; n=40, 39, 13, 13	-36.8 (± 55.75)	-25.4 (± 55.92)	-39.9 (± 40.27)	-39.5 (± 29.92)
ALT; Week12; n=37, 35, 12, 13	-38.9 (± 59.7)	-23.5 (± 59.69)	-43.7 (± 40.45)	-36.8 (± 24.75)
AST; Week1; n=40, 39, 15, 13	-12.3 (± 16.28)	-15.2 (± 21.55)	-18.1 (± 21.77)	-13.9 (± 10.52)
AST; Week2; n=41, 38, 14, 13	-10 (± 20.84)	-11.6 (± 26.3)	-18.4 (± 23.52)	-10.2 (± 12.56)
AST; Week4; n=41, 39, 14, 13	-12.8 (± 21.45)	-10.6 (± 27.4)	-20.9 (± 25.86)	-15.8 (± 11.92)
AST; Week6; n=41, 38, 13, 13	-13.8 (± 21.56)	-13.8 (± 25.01)	-21.6 (± 28.43)	-19.5 (± 12.99)
AST; Week8; n=40, 39, 13, 13	-13.1 (± 26.01)	-7.6 (± 38.38)	-21.8 (± 26.38)	-18.6 (± 12.38)
AST; Week12; n=37, 35, 12, 13	-14.4 (± 25.58)	-6.5 (± 36.17)	-25.7 (± 27.32)	-17.3 (± 12.68)
CK; Week1; n=40, 39, 15, 13	18.2 (± 82.13)	-10.9 (± 103.31)	-3.3 (± 32.1)	-43.5 (± 82.73)
CK; Week2; n=41, 38, 14, 13	-0.7 (± 53.87)	-22.6 (± 77.26)	-9.6 (± 36.26)	-28.5 (± 54.43)
CK; Week4; n=41, 39, 14, 13	4.5 (± 141.46)	-32.1 (± 59.61)	-14.4 (± 22.06)	-47.7 (± 59.52)
CK; Week6; n=41, 38, 13, 13	-26 (± 63.11)	56.1 (± 566.79)	-21.5 (± 48.49)	-64.5 (± 110.82)
CK; Week8; n=40, 39, 13, 13	-21.3 (± 95.03)	-33.2 (± 65.96)	-30.3 (± 51.17)	-66.8 (± 107.3)
CK; Week12; n=37, 35, 12, 13	-36.3 (± 75.56)	-33.9 (± 47.72)	-20.9 (± 59.82)	-48.5 (± 61.63)
GGT; Week1; n=40, 39, 15, 13	-3.7 (± 20.79)	-2 (± 16.83)	-10.3 (± 19.38)	-6.4 (± 23.77)
GGT; Week2; n=41, 38, 14, 13	-11.7 (± 33.78)	-17.1 (± 45.23)	-19.9 (± 29.59)	-7.2 (± 29.11)
GGT; Week4; n=41, 39, 14, 13	-24.5 (± 52.93)	-25.5 (± 59.64)	-27.7 (± 36.64)	-16.2 (± 36.59)
GGT; Week6; n=41, 38, 13, 13	-28.1 (± 67.33)	-30.5 (± 72.27)	-30.5 (± 44.3)	-23.8 (± 39.91)
GGT; Week8; n=40, 39, 13, 13	-32.1 (± 70.41)	-27.2 (± 80.33)	-30.5 (± 45.05)	-28.5 (± 45.5)

GGT; Week12; n=37, 35, 12, 13	-29.7 (± 80.2)	-20.7 (± 73.43)	-33.6 (± 49.61)	-30 (± 53.44)

Notes:

[52] - Safety Population

[53] - Safety Population

[54] - Safety Population

[55] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in direct bilirubin, total bilirubin and creatinine at the indicated time points up to Week 12

End point title	Mean change from Baseline in direct bilirubin, total bilirubin and creatinine at the indicated time points up to Week 12[56]

End point description:

Blood samples were collected for the measurement of direct bilirubin, total bilirubin and creatinine at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4. Change from Baseline in the direct bilirubin, total bilirubin and creatinine values are summarized for each post-Baseline assessment until Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.Note too few par. or no par. were analyzed at the indicated test/time point; therefore, the value of 99999 was entered which represents NA.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6, 8 and 12

Notes:

[56] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[57]	40[58]	17[59]	13[60]
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Total Bilirubin; Week1; n=40, 39, 15, 13	6.9 (± 8.74)	6.7 (± 8.93)	8.1 (± 11.81)	4.2 (± 8.36)
Total Bilirubin; Week2; n=41, 38, 14, 13	5.8 (± 6.62)	5.5 (± 6.84)	5.6 (± 9.8)	6.5 (± 9.34)
Total Bilirubin; Week4; n=41, 39, 14, 13	2.2 (± 5.03)	2.9 (± 3.52)	0.7 (± 8.94)	2.5 (± 5.97)
Total Bilirubin; Week6; n=41, 38, 13, 13	1.5 (± 4.14)	2.7 (± 3.97)	-0.5 (± 9.09)	2.1 (± 6.87)
Total Bilirubin; Week8; n=40, 39, 13, 13	1.4 (± 4.63)	2.3 (± 4.93)	-0.3 (± 9.83)	1.8 (± 6.39)
Total Bilirubin; Week12; n=37, 35, 12, 13	0.4 (± 4.46)	1.4 (± 5.61)	-2.8 (± 10.04)	1.2 (± 5.31)
Direct Bilirubin; Week1; n=1, 1, 1, 1	0 (± 99999)	2 (± 99999)	-8 (± 99999)	-1 (± 0)
Direct Bilirubin; Week2; n=1, 1, 1, 1	0 (± 99999)	0 (± 99999)	-14 (± 99999)	1 (± 0)
Direct Bilirubin; Week4; n=1, 1, 0, 0	0 (± 99999)	2 (± 99999)	99999 (± 99999)	99999 (± 99999)

Direct Bilirubin; Week6; n=1, 1, 0, 0	0 (± 99999)	0 (± 99999)	99999 (± 99999)	99999 (± 99999)
Creatinine; Week1; n=40, 39, 15, 13	-1.41 (± 5.983)	0.23 (± 5.446)	5.12 (± 7.883)	-3.85 (± 5.868)
Creatinine; Week2; n=41, 38, 14, 13	-2.47 (± 7.966)	-2.78 (± 5.725)	4.13 (± 6.518)	-1.17 (± 7.692)
Creatinine; Week4; n=41, 39, 14, 13	-3.4 (± 5.894)	-1.33 (± 6.403)	5.35 (± 10.16)	-3.57 (± 9.599)
Creatinine; Week6; n=41, 38, 13, 13	-2.15 (± 6.18)	-0.34 (± 7.667)	7.1 (± 7.905)	-2.05 (± 9.365)
Creatinine; Week8; n=40, 39, 13, 13	-1.88 (± 5.724)	-0.51 (± 5.425)	9.43 (± 10.839)	-0.08 (± 10.23)
Creatinine; Week12; n=38, 35, 12, 13	-1.49 (± 8.411)	-1.99 (± 8.704)	6.85 (± 10.363)	-2.41 (± 12.239)

Notes:

[57] - Safety Population

[58] - Safety Population

[59] - Safety Population

[60] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in chloride, bicarbonate, glucose, potassium, sodium, inorganic phosphorus and urea/BUN at the indicated time points up to Week 12

End point title	Mean change from Baseline in chloride, bicarbonate, glucose, potassium, sodium, inorganic phosphorus and urea/BUN at the indicated time points up to Week 12[61]

End point description:

Blood samples were collected for the measurement of Chloride, bicarbonate, glucose, potassium, sodium, inorganic phosphorus and urea/blood urea nitrogen (BUN) at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4. Change from Baseline in the Chloride, Bicarbonate, Glucose, Potassium, Sodium, Inorganic Phosphorus and Urea/Bun values are summarized for each post-Baseline assessment until Week 12. . Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6, 8 and 12

Notes:

[61] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[62]	40[63]	17[64]	13[65]
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Chloride; Week1; n=40, 39, 15, 13	0.5 (± 2.1)	-0.4 (± 2.03)	0.6 (± 2.61)	-0.2 (± 1.95)
Chloride; Week2; n=41, 38, 14, 13	0.7 (± 2.37)	0.1 (± 1.9)	0.5 (± 1.61)	-0.7 (± 2.21)
Chloride; Week4; n=41, 39, 14, 13	1.7 (± 2.31)	1 (± 2.46)	1.6 (± 2.21)	0.1 (± 2.5)

Chloride; Week6; n=41, 38, 13, 13	1.6 (± 2.62)	0.8 (± 2.57)	0.8 (± 2.73)	-0.1 (± 1.38)
Chloride; Week8; n=40, 39, 13, 13	2 (± 3.49)	0.7 (± 2.36)	2.2 (± 3)	-0.8 (± 2.77)
Chloride; Week12; n=37, 35, 12, 13	1.5 (± 2.36)	0.1 (± 3.35)	1.9 (± 2.61)	1.2 (± 2.95)
Bicarbonate; Week1; n=40, 39, 15, 13	0 (± 3.05)	-0.9 (± 2.57)	-1.2 (± 2.54)	-0.7 (± 2.56)
Bicarbonate; Week2; n=41, 38, 14, 13	-0.3 (± 2.2)	-0.8 (± 3.1)	-1.5 (± 2.98)	-0.2 (± 3.65)
Bicarbonate; Week4; n=41, 39, 14, 13	-0.9 (± 1.91)	-0.8 (± 2.55)	-1.4 (± 1.86)	-0.5 (± 2.67)
Bicarbonate; Week6; n=41, 38, 13, 13	-0.4 (± 2)	-0.7 (± 2.23)	-1.5 (± 2.18)	0.6 (± 2.6)
Bicarbonate; Week8; n=40, 39, 13, 13	-0.7 (± 2.41)	-0.8 (± 2.35)	-1.2 (± 2.19)	0 (± 2.2)
Bicarbonate; Week12; n=37, 35, 12, 13	-0.6 (± 2.42)	-0.9 (± 2.37)	-1.1 (± 2.23)	-0.5 (± 2.76)
Glucose; Week1; n=40, 39, 15, 13	-0.37 (± 1.485)	-0.34 (± 0.761)	-0.03 (± 0.616)	0.36 (± 1.619)
Glucose; Week2; n=41, 38, 14, 13	-0.22 (± 1.467)	-0.17 (± 0.791)	0.11 (± 0.52)	0.13 (± 1.765)
Glucose; Week4; n=41, 39, 14, 13	-0.03 (± 1.162)	0.02 (± 1.054)	-0.11 (± 0.601)	-0.48 (± 0.832)
Glucose; Week6; n=41, 38, 13, 13	-0.15 (± 1.315)	-0.18 (± 1.154)	0.18 (± 0.772)	-0.55 (± 0.755)
Glucose; Week8; n=40, 39, 13, 13	-0.05 (± 1.165)	-0.06 (± 0.835)	0.04 (± 0.675)	-0.36 (± 1.191)
Glucose; Week12; n=38, 35, 12, 13	-0.3 (± 1.877)	-0.39 (± 1.047)	-0.23 (± 0.757)	-0.45 (± 1.063)
Potassium; Week1; n=40, 39, 15, 13	-0.02 (± 0.392)	-0.06 (± 0.339)	-0.11 (± 0.376)	-0.02 (± 0.313)
Potassium; Week2; n=41, 38, 14, 13	-0.1 (± 0.428)	-0.12 (± 0.453)	-0.39 (± 0.417)	-0.02 (± 0.316)
Potassium; Week4; n=41, 39, 14, 13	-0.16 (± 0.411)	-0.11 (± 0.455)	-0.34 (± 0.497)	-0.05 (± 0.499)
Potassium; Week6; n=41, 38, 13, 13	-0.15 (± 0.483)	-0.16 (± 0.387)	-0.45 (± 0.355)	-0.21 (± 0.38)
Potassium; Week8; n=40, 39, 13, 13	-0.11 (± 0.49)	-0.19 (± 0.42)	-0.51 (± 0.348)	-0.14 (± 0.348)
Potassium; Week12; n=37, 35, 12, 13	-0.15 (± 0.394)	-0.21 (± 0.362)	-0.38 (± 0.447)	-0.1 (± 0.428)
Sodium; Week1; n=40, 39, 15, 13	-0.4 (± 1.85)	-0.8 (± 1.76)	-0.2 (± 2.46)	-0.8 (± 2.08)
Sodium; Week2; n=41, 38, 14, 13	-0.1 (± 2.15)	-0.6 (± 1.81)	0 (± 1.8)	-1.3 (± 2.25)
Sodium; Week4; n=41, 39, 14, 13	0.1 (± 2.16)	-0.1 (± 2.2)	0.4 (± 1.78)	-0.8 (± 1.95)
Sodium; Week6; n=41, 38, 13, 13	0.2 (± 2.39)	-0.3 (± 2.39)	0.2 (± 2.91)	0 (± 2)
Sodium; Week8; n=40, 39, 13, 13	0.3 (± 3.28)	-0.6 (± 2.24)	1.1 (± 2.18)	-0.6 (± 2.22)
Sodium; Week12; n=37, 35, 12, 13	0.1 (± 1.91)	-0.3 (± 2.36)	0.8 (± 2.66)	0.5 (± 2.18)
Inorganic Phosphorus; Week1; n=40, 39, 15, 13	-0.13 (± 0.1599)	-0.086 (± 0.1415)	-0.122 (± 0.1353)	-0.087 (± 0.1489)
Inorganic Phosphorus; Week2; n=41, 38, 14, 13	-0.141 (± 0.181)	-0.108 (± 0.1754)	-0.081 (± 0.1194)	-0.105 (± 0.1159)
Inorganic Phosphorus; Week4; n=41, 39, 14, 13	-0.151 (± 0.1666)	-0.125 (± 0.1421)	-0.077 (± 0.1669)	-0.078 (± 0.1871)
Inorganic Phosphorus; Week6; n=41, 38, 13, 13	-0.171 (± 0.1939)	-0.181 (± 0.1823)	-0.121 (± 0.1549)	-0.159 (± 0.121)
Inorganic Phosphorus; Week8; n=40, 39, 13, 13	-0.169 (± 0.2025)	-0.23 (± 0.1937)	-0.112 (± 0.1563)	-0.14 (± 0.167)
Inorganic Phosphorus; Week12; n=37, 35, 12, 13	-0.172 (± 0.1708)	-0.168 (± 0.2047)	-0.117 (± 0.1123)	-0.136 (± 0.1943)
Urea/BUN; Week1; n=40, 39, 15, 13	0.24 (± 0.996)	0.04 (± 1.002)	0.19 (± 1.287)	-0.01 (± 1.188)
Urea/BUN; Week2; n=41, 38, 14, 13	0.2 (± 1.012)	-0.13 (± 1.05)	0.08 (± 1.309)	-0.12 (± 1.244)
Urea/BUN; Week4; n=41, 39, 14, 13	0.03 (± 1.145)	-0.4 (± 1.047)	0.11 (± 1.436)	-0.88 (± 1.137)
Urea/BUN; Week6; n=41, 38, 13, 13	-0.04 (± 1.09)	-0.29 (± 1.13)	-0.39 (± 0.883)	-1.02 (± 0.667)

Urea/BUN; Week8; n=40, 39, 13, 13	-0.16 (± 1.088)	-0.46 (± 1.337)	-0.07 (± 1.206)	-0.85 (± 1.067)
Urea/BUN; Week12; n=37, 35, 12, 13	-0.08 (± 1.164)	-0.31 (± 1.276)	-0.11 (± 1.272)	-0.64 (± 1.81)

Notes:

[62] - Safety Population

[63] - Safety Population

[64] - Safety Population

[65] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in creatinine clearance at the indicated time points up to Week 12

End point title	Mean change from Baseline in creatinine clearance at the indicated time points up to Week 12[66]

End point description:

Blood samples were collected for the measurement of Creatinine Clearance at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4. Change from Baseline in the Creatinine Clearance values are summarized for each post-Baseline assessment until Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Weeks 1, 2, 4, 6, 8 and 12

Notes:

[66] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[67]	40[68]	17[69]	13[70]
Units: Milliliter per minute (mL/min)				
arithmetic mean (standard deviation)				
Creatinine Clearance; Week1; n=40, 39, 15, 13	1.5 (± 9.79)	-2.1 (± 19.51)	-9.5 (± 10.09)	5.7 (± 10.18)
Creatinine Clearance; Week2; n=41, 38, 14, 13	3.3 (± 13.48)	4.7 (± 11.33)	-9 (± 12.55)	-1.8 (± 15.27)
Creatinine Clearance; Week4; n=41, 39, 14, 13	5 (± 12.45)	1.9 (± 14.72)	-9.1 (± 13.42)	4.5 (± 16.19)
Creatinine Clearance; Week6; n=41, 38, 13, 13	2.7 (± 11.93)	-0.7 (± 16.25)	-19.1 (± 20.54)	1.5 (± 13.12)
Creatinine Clearance; Week8; n=40, 39, 13, 13	1.9 (± 10.49)	3.4 (± 19.94)	-17.8 (± 16.1)	-3 (± 14.54)
Creatinine Clearance; Week12; n=38, 35, 12, 13	-0.2 (± 15.06)	2.2 (± 17.27)	-14.3 (± 16.99)	1.2 (± 20.49)

Notes:

[67] - Safety Population

[68] - Safety Population

[69] - Safety Population

[70] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with shift from Baseline in urinalysis data up to Week 12

End point title	Number of participants with shift from Baseline in urinalysis data up to Week 12[71]

End point description:

Urine samples were collected for urinalysis at Baseline, Weeks 2, 12, 18, 24, 48 and PT FU Weeks 4. Number of participants with shift from Baseline in urinalysis to normal (NL), abnormal (ANL) and missing (MIS) data up to Week 12 are summarized. urine bilirubin (UBIL), urine glucose (UGLU), urine ketones (UKET), urine leukocyte esterase test (ULET) for detecting WBC, urine nitrite (UNIT), urine occult blood (UOB) were performed with dipstick method. Urine microscopy (UM) is performed to detect bacteria (BAC), red blood cells (RBC), white blood cells (WBC). Other urinalysis parameter included urine pH (UpH), urine specific gravity (USG). Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety populat

End point type	Primary

End point timeframe:

Baseline, Weeks 2 and 12

Notes:

[71] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[72]	40[73]	17[74]	13[75]
Units: Participants				
Week 2, UBIL, BL NL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UBIL, BL NL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UBIL, BL NL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UBIL, BL ANL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UBIL, BL ANL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UBIL, BL ANL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UBIL, BL MIS to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UBIL, BL MIS to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UBIL, BL MIS to PBL MIS, n=1, 0, 0, 0	0	0	0	0

Week 12, UBIL, BL NL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UBIL, BL NL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UBIL, BL NL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UBIL, BL ANL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UBIL, BL ANL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UBIL, BL ANL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UBIL, BL MIS to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UBIL, BL MIS to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UBIL, BL MIS to PBL MIS, n=37, 34, 12, 13	37	34	12	13
Week 2, UGLU, BL NL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UGLU, BL NL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UGLU, BL NL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UGLU, BL ANL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UGLU, BL ANL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UGLU, BL ANL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UGLU, BL MIS to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UGLU, BL MIS to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UGLU, BL MIS to PBL MIS, n=1, 0, 0, 0	1	0	0	0
Week 12, UGLU, BL NL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UGLU, BL NL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UGLU, BL NL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UGLU, BL ANL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UGLU, BL ANL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UGLU, BL ANL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UGLU, BL MIS to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UGLU, BL MIS to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UGLU, BL MIS to PBL MIS, n=37, 34, 12, 13	37	34	12	13
Week 2, UKET, BL NL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UKET, BL NL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UKET, BL NL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UKET, BL ANL to PBL NL, n=1, 0, 0, 0	0	0	0	0

Week 2, UKET, BL ANL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UKET, BL ANL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UKET, BL MIS to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UKET, BL MIS to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UKET, BL MIS to PBL MIS, n=1, 0, 0, 0	1	0	0	0
Week 12, UKET, BL NL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UKET, BL NL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UKET, BL NL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UKET, BL ANL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UKET, BL ANL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UKET, BL ANL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UKET, BL MIS to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UKET, BL MIS to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UKET, BL MIS to PBL MIS, n=37, 34, 12, 13	37	34	12	13
Week 2, ULET, BL NL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, ULET, BL NL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, ULET, BL NL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, ULET, BL ANL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, ULET, BL ANL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, ULET, BL ANL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, ULET, BL MIS to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, ULET, BL MIS to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, ULET, BL MIS to PBL MIS, n=1, 0, 0, 0	1	0	0	0
Week 12, ULET, BL NL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, ULET, BL NL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, ULET, BL NL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, ULET, BL ANL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, ULET, BL ANL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, ULET, BL ANL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, ULET, BL MIS to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, ULET, BL MIS to PBL ANL, n=37, 34, 12, 13	0	0	0	0

Week 12, ULET, BL MIS to PBL MIS, n=37, 34, 12, 13	37	34	12	13
Week 2, UMBT, BL NL to PBL NL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMBT, BL NL to PBL ANL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMBT, BL NL to PBL MIS, n=0, 0, 0, 0	0	0	0	0
Week 2, UMBT, BL ANL to PBL NL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMBT, BL ANL to PBL ANL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMBT, BL ANL to PBL MIS, n=0, 0, 0, 0	0	0	0	0
Week 2, UMBT, BL MIS to PBL NL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMBT, BL MIS to PBL ANL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMBT, BL MIS to PBL MIS, n=0, 0, 0, 0	0	0	0	0
Week 12, UMBT, BL NL to PBL NL, n=1, 1, 0, 0	0	0	0	0
Week 12, UMBT, BL NL to PBL ANL, n=1, 1, 0, 0	0	0	0	0
Week 12, UMBT, BL NL to PBL MIS, n=1, 1, 0, 0	0	0	0	0
Week 12, UMBT, BL ANL to PBL NL, n=1, 1, 0, 0	0	0	0	0
Week 12, UMBT, BL ANL to PBL ANL, n=1, 1, 0, 0	0	0	0	0
Week 12, UMBT, BL ANL to PBL MIS, n=1, 1, 0, 0	0	0	0	0
Week 12, UMBT, BL MIS to PBL NL, n=1, 1, 0, 0	0	0	0	0
Week 12, UMBT, BL MIS to PBL ANL, n=1, 1, 0, 0	0	0	0	0
Week 12, UMBT, BL MIS to PBL MIS, n=1, 1, 0, 0	1	1	0	0
Week 2, UMRBC, BL NL to PBL NL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMRBC, BL NL to PBL ANL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMRBC, BL NL to PBL MIS, n=0, 0, 0, 0	0	0	0	0
Week 2, UMRBC, BL ANL to PBL NL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMRBC, BL ANL to PBL ANL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMRBC, BL ANL to PBL MIS, n=0, 0, 0, 0	0	0	0	0
Week 2, UMRBC, BL MIS to PBL NL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMRBC, BL MIS to PBL ANL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMRBC, BL MIS to PBL MIS, n=0, 0, 0, 0	0	0	0	0
Week 12, UMRBC, BL NL to PBL NL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMRBC, BL NL to PBL ANL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMRBC, BL NL to PBL MIS, n=4, 5, 2, 2	0	0	0	0

Week 12, UMRBC, BL ANL to PBL NL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMRBC, BL ANL to PBL ANL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMRBC, BL ANL to PBL MIS, n=4, 5, 2, 2	0	0	0	0
Week 12, UMRBC, BL MIS to PBL NL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMRBC, BL MIS to PBL ANL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMRBC, BL MIS to PBL MIS, n=4, 5, 2, 2	4	5	2	2
Week 2, UMWBC, BL NL to PBL NL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMWBC, BL NL to PBL ANL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMWBC, BL NL to PBL MIS, n=0, 0, 0, 0	0	0	0	0
Week 2, UMWBC, BL ANL to PBL NL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMWBC, BL ANL to PBL ANL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMWBC, BL ANL to PBL MIS, n=0, 0, 0, 0	0	0	0	0
Week 2, UMWBC, BL MIS to PBL NL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMWBC, BL MIS to PBL ANL, n=0, 0, 0, 0	0	0	0	0
Week 2, UMWBC, BL MIS to PBL MIS, n=0, 0, 0, 0	0	0	0	0
Week 12, UMWBC, BL NL to PBL NL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMWBC, BL NL to PBL ANL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMWBC, BL NL to PBL MIS, n=4, 5, 2, 2	0	0	0	0
Week 12, UMWBC, BL ANL to PBL NL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMWBC, BL ANL to PBL ANL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMWBC, BL ANL to PBL MIS, n=4, 5, 2, 2	0	0	0	0
Week 12, UMWBC, BL MIS to PBL NL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMWBC, BL MIS to PBL ANL, n=4, 5, 2, 2	0	0	0	0
Week 12, UMWBC, BL MIS to PBL MIS, n=4, 5, 2, 2	4	5	2	2
Week 2, UNIT, BL NL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UNIT, BL NL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UNIT, BL NL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UNIT, BL ANL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UNIT, BL ANL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UNIT, BL ANL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UNIT, BL MIS to PBL NL, n=1, 0, 0, 0	0	0	0	0

Week 2, UNIT, BL MIS to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UNIT, BL MIS to PBL MIS, n=1, 0, 0, 0	1	0	0	0
Week 12, UNIT, BL NL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UNIT, BL NL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UNIT, BL NL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UNIT, BL ANL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UNIT, BL ANL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UNIT, BL ANL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UNIT, BL MIS to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UNIT, BL MIS to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UNIT, BL MIS to PBL MIS, n=37, 34, 12, 13	37	34	12	13
Week 2, UOB, BL NL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UOB, BL NL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UOB, BL NL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UOB, BL ANL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UOB, BL ANL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UOB, BL ANL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UOB, BL MIS to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UOB, BL MIS to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UOB, BL MIS to PBL MIS, n=1, 0, 0, 0	1	0	0	0
Week 12, UOB, BL NL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UOB, BL NL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UOB, BL NL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UOB, BL ANL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UOB, BL ANL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UOB, BL ANL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UOB, BL MIS to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UOB, BL MIS to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UOB, BL MIS to PBL MIS, n=37, 34, 12, 13	37	34	12	13
Week 2, UPH, BL NL to PBL NL, n=1, 0, 0, 0	1	0	0	0
Week 2, UPH, BL NL to PBL ANL, n=1, 0, 0, 0	0	0	0	0

Week 2, UPH, BL NL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UPH, BL ANL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UPH, BL ANL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UPH, BL ANL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, UPH, BL MIS to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, UPH, BL MIS to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, UPH, BL MIS to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 12, UPH, BL NL to PBL NL, n=37, 34, 12, 13	36	34	12	13
Week 12, UPH, BL NL to PBL ANL, n=37, 34, 12, 13	1	0	0	0
Week 12, UPH, BL NL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UPH, BL ANL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UPH, BL ANL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UPH, BL ANL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, UPH, BL MIS to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, UPH, BL MIS to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, UPH, BL MIS to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 2, USG, BL NL to PBL NL, n=1, 0, 0, 0	1	0	0	0
Week 2, USG, BL NL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, USG, BL NL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, USG, BL ANL to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, USG, BL ANL to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, USG, BL ANL to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 2, USG, BL MIS to PBL NL, n=1, 0, 0, 0	0	0	0	0
Week 2, USG, BL MIS to PBL ANL, n=1, 0, 0, 0	0	0	0	0
Week 2, USG, BL MIS to PBL MIS, n=1, 0, 0, 0	0	0	0	0
Week 12, USG, BL NL to PBL NL, n=37, 34, 12, 13	37	34	12	12
Week 12, USG, BL NL to PBL ANL, n=37, 34, 12, 13	0	0	0	1
Week 12, USG, BL NL to PBL MIS, n=37, 34, 12, 13	0	0	0	0
Week 12, USG, BL ANL to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, USG, BL ANL to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, USG, BL ANL to PBL MIS, n=37, 34, 12, 13	0	0	0	0

Week 12, USG, BL MIS to PBL NL, n=37, 34, 12, 13	0	0	0	0
Week 12, USG, BL MIS to PBL ANL, n=37, 34, 12, 13	0	0	0	0
Week 12, USG, BL MIS to PBL MIS, n=37, 34, 12, 13	0	0	0	0

Notes:

[72] - Safety Population

[73] - Safety Population

[74] - Safety Population

[75] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in ECG heart rate values at the indicated time points up to Week 12

End point title	Mean change from Baseline in ECG heart rate values at the indicated time points up to Week 12[76]

End point description:

The electrocardiographic (ECG) parameters heart rate was measured at Baseline, Weeks 1 and 12. Change from Baseline in ECG heart rate is summarized for each post-Baseline assessment up to Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Weeks 1 and 12

Notes:

[76] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[77]	40[78]	17[79]	13[80]
Units: Beats per minute				
arithmetic mean (standard deviation)				
Week 1, n=41, 40, 15, 12	3.3 (± 8.28)	0.8 (± 8.49)	4.1 (± 9.52)	4.8 (± 10.62)
Week 12, n=38, 35, 12, 13	8.3 (± 8.37)	5.1 (± 10.86)	9.3 (± 10.15)	8.5 (± 8)

Notes:

[77] - Safety Population

[78] - Safety Population

[79] - Safety Population

[80] - Safety Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean change from Baseline in PR interval, QRS duration, uncorrected QT interval, QTcB, QTcF values at the indicated time points up to Week 12

End point title	Mean change from Baseline in PR interval, QRS duration, uncorrected QT interval, QTcB, QTcF values at the indicated time points up to Week 12[81]

End point description:

The electrocardiographic (ECG) parameters including PR interval, QRS duration, uncorrected QT interval, QT interval corrected Bazett's formula (QTcB), QT interval corrected using Fridericia's formula (QTcF) were measured at Baseline, Weeks 1 and 12. Change from Baseline in ECG parameters are summarized for each post-Baseline assessment up to Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.

End point type	Primary

End point timeframe:

Baseline, Weeks 1 and 12

Notes:

[81] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[82]	40[83]	17[84]	13[85]
Units: Milliseconds				
arithmetic mean (standard deviation)				
PR interval, Week 1, n=41, 40, 15, 12	0.5 (± 19.43)	1.2 (± 13.57)	2.7 (± 7.27)	-1.6 (± 20.92)
PR interval, Week 12, n=38, 35, 12, 13	2.9 (± 13.36)	3.2 (± 12.07)	5.5 (± 8.73)	0.2 (± 14.68)
QRS duration, Week 1, n=41, 40, 15, 12	-6.6 (± 50.28)	0.4 (± 7.69)	2.9 (± 6.61)	0.4 (± 4.03)
QRS duration, Week 12, n=38, 35, 12, 13	-8.2 (± 51.69)	-1.8 (± 6.44)	0.4 (± 7.54)	-2 (± 4.4)
Uncorrected QT Interval, Week 1, n=41, 40, 15, 12	-2.3 (± 27.29)	-2.6 (± 22.29)	-2.1 (± 22.39)	5.9 (± 25.68)
Uncorrected QT interval, Week 12, n=38, 35, 12, 13	-11.8 (± 31.28)	-12 (± 25.22)	-17 (± 18.01)	-4.6 (± 23.36)
Corrected QTcB interval, Week 1, n=41, 40, 15, 12	7.7087 (± 25.63001)	0.2491 (± 22.90285)	9.8112 (± 20.6771)	19.8879 (± 40.13504)
Corrected QTcB interval, Week 12, n=38, 35, 12, 13	11.5512 (± 26.5644)	1.7615 (± 20.3859)	11.2801 (± 25.54652)	18.9943 (± 16.76576)
Corrected QTcF interval, Week 1, n=41, 40, 15, 12	4.1995 (± 23.18239)	-0.7151 (± 19.69091)	5.7676 (± 17.06472)	14.9187 (± 32.2737)
Corrected QTcF interval, Week 12, n=38, 35, 12, 13	3.3516 (± 26.34546)	-3.1442 (± 17.38368)	1.6147 (± 18.38188)	10.7637 (± 17.07259)

Notes:

[82] - Safety Population

[83] - Safety Population

[84] - Safety Population

[85] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any adverse events (AEs) and any serious adverse events (SAEs) after Week 12

End point title	Number of participants with any adverse events (AEs) and any serious adverse events (SAEs) after Week 12

End point description:

An AE is defined as any untoward medical occurrence in a participant temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An AE can therefore be any unfavorable and unintended sign(including an abnormal laboratory finding), symptom, or disease(new or exacerbated) temporally associated with the use of a medicinal product. An SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, a congenital anomaly/birth defect, important medical events that jeopardize the participants or may require medical or surgical intervention to prevent one of the other outcomes listed in the above

End point type	Secondary

End point timeframe:

From Week 12 up to Post-Treatment (PT) Week 24 Follow-up (FU)

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[86]	40[87]	17[88]	13[89]
Units: Participants				
Any AE	21	22	8	9
Any SAE	0	2	3	1

Notes:

[86] - Safety Population

[87] - Safety Population

[88] - Safety Population

[89] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants achieving very rapid virologic response (vRVR), rapid virologic response (RVR), complete early virologic response (cEVR), sustained virologic response 12 and 24 (SVR12 and SVR24) with response guided treatment (RGT)

End point title	Number of participants achieving very rapid virologic response (vRVR), rapid virologic response (RVR), complete early virologic response (cEVR), sustained virologic response 12 and 24 (SVR12 and SVR24) with response guided treatment (RGT)

End point description:

Blood samples for the determination of HCV RNA levels were collected at Screening and Baseline, every study visit during the Treatment Period, and at PT FU Weeks 4, 12, and 24. Very rapid virologic response (vRVR) is defined as plasma HCV RNA <LLOQ and target not detected 2 weeks after initiation of therapy. Rapid virologic response (RVR) is defined as plasma HCV RNA <LLOQ and target not detected 4 weeks after initiation of therapy. Complete early virologic response (cEVR) is defined as plasma HCV RNA <LLOQ and target not detected 12 weeks after initiation of therapy. Sustained virologic response 12 (SVR12) is defined as plasma HCV RNA <LLOQ and target not detected 12 weeks after completion of all therapy. Sustained virologic response 24 (SVR24) is defined as plasma HCV RNA <LLOQ and target not detected 24 weeks after completion of all therapy. SVR24 with RGT are participants who achieved both SVR24 and eRVR.

End point type	Secondary

End point timeframe:

From the start of the treatment up to PT FU Week 24

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[90]	40[91]	17[92]	13[93]
Units: Participants				
vRVR	8	12	8	6
RVR	23	23	10	9
cEVR	33	30	11	13
SVR12	30	26	10	11
SVR24	27	25	10	12
SVR24 with RGT	17	17	9	9

Notes:

[90] - ITT Population

[91] - ITT Population

[92] - ITT Population

[93] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean GSK2336805 plasma concentrations on Day 1, Day 2, Week 4, and Week 12

End point title	Mean GSK2336805 plasma concentrations on Day 1, Day 2, Week 4, and Week 12[94]

End point description:

Plasma pharmacokinetic (PK) samples were collected for all participants on Day 1 (0 hour [h]-1h, 1h-4h, 4h-8h, 8h-20h), Day 2 (Predose [20-28h]), Week 4 (Predose [20-28h], 0h-1h, 1h-4h, 4h-8h, 8h-20h, 20h-28h) and Week 12 (Predose [20-28h]). PK Population is comprised of all participants who received GSK2336805 and underwent plasma PK sampling (intensive or sparse) during the study. Only participants for whom plasma PK samples were obtained were assessed (represented by n=X, X in category titles).The mean and standard deviation could not be determined (not reached) because too few participants experienced the event (system value of 99999 indicates NA for the mean and the standard deviation).

End point type	Secondary

End point timeframe:

Day 1, Day 2, Week 4, and Week 12

Notes:

[94] - 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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	41[95]	53[96]		
Units: nanogram per milliliter (ng/mL)				
arithmetic mean (standard deviation)				
Day 1 (0h-1h), n=1, 3	99999 (± 99999)	604 (± 392.763)		
Day 1 (1h-4h), n=35, 42	290.39 (± 241.05)	445.18 (± 314.624)		
Day 1 (4h-8h), n=0, 3	99999 (± 99999)	221.33 (± 191.996)		
Day 1 (8h-20h), n=0, 1	99999 (± 99999)	99999 (± 99999)		
Day 2 Predose (20-28h), n=36, 43	53.79 (± 52.629)	123.89 (± 257.575)		
Week 4 Predose (20-28h), n=33, 42	81.18 (± 153.462)	146.85 (± 243.331)		
Week 4 (0h-1h), n=2, 6	198.4 (± 242.679)	553 (± 536.451)		
Week 4 (1h-4h), n=46, 52	392.78 (± 275.504)	591.07 (± 402.442)		
Week 4 (4h-8h), n=22, 19	215.55 (± 127.737)	411.68 (± 251.604)		
Week 4 (8h-20h), n=1, 2	99999 (± 99999)	192.5 (± 94.045)		
Week 4 (20h-28h), n=11, 10	51.24 (± 57.261)	66.29 (± 53.604)		
Week 12 (Predose [20-28h]), n=26, 35	45.99 (± 42.034)	142.59 (± 178.252)		

Notes:

[95] - PK Population

[96] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum plasma concentration (Cmax) and concentration at the end of the dosing interval (Ctau) of GSK2336805 at Week 4

End point title	Maximum plasma concentration (Cmax) and concentration at the end of the dosing interval (Ctau) of GSK2336805 at Week 4[97]

End point description:

Blood samples for PK analysis of GSK2336805 was obtained on Week 4+1 day at predose and at 1, 2, 4, 7, 24 hours post-dose. : Intensive PK Summary Population is comprised of participants with evaluable GSK2336805 PK parameters at Week 4. Only participants available at the indicated time point were assessed (represented by n=X, X in category titles).

End point type	Secondary

End point timeframe:

Week 4

Notes:

[97] - 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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	11[98]	10[99]		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cmax, n=11, 10	335.35 (± 69.4)	618.75 (± 46.1)		
Ctau, n=11, 10	31.37 (± 135.9)	49.31 (± 97.6)		

Notes:

[98] - Intensive PK Summary Population

[99] - Intensive PK Summary Population

Statistical analyses

No statistical analyses for this end point

Secondary: Time of maximal plasma concentration (tmax) of GSK2336805 at Week 4

End point title	Time of maximal plasma concentration (tmax) of GSK2336805 at Week 4[100]

End point description:

Blood samples for PK analysis of GSK2336805 was obtained on Week 4+1 day at predose and at 1, 2, 4, 7, 24 hours postdose.

End point type	Secondary

End point timeframe:

Week 4

Notes:

[100] - 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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	11[101]	10[102]		
Units: hour				
median (full range (min-max))	2 (1 to 4)	2 (1 to 7)		

Notes:

[101] - Intensive PK Summary Population

[102] - Intensive PK Summary Population

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration-time curve over the dosing interval (AUC[0-tau]) at Week 12

End point title	Area under the concentration-time curve over the dosing interval (AUC[0-tau]) at Week 12[103]

End point description:

Blood samples for PK analysis of GSK2336805 was obtained on Week 4+1 day at predose and at 1, 2, 4, 7 and 24 hours postdose.

End point type	Secondary

End point timeframe:

Week 12

Notes:

[103] - 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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	11[104]	10[105]		
Units: hour*nanogram per milliliter(hr*ng/mL)				
geometric mean (geometric coefficient of variation)	2733.34 (± 82)	4948.23 (± 66.3)		

Notes:

[104] - Intensive PK Summary Population

[105] - Intensive PK Summary Population

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent clearance (CL/F) at Week 12

End point title	Apparent clearance (CL/F) at Week 12[106]

End point description:

Blood samples for PK analysis of GSK2336805 was obtained on Week 4+1 day at predose and at 1, 2, 4, 7 and 24 hours postdose. Apparent clearance is calculated as dose divided by AUC(0-tau).

End point type	Secondary

End point timeframe:

Week 12

Notes:

[106] - 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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	11[107]	10[108]		
Units: Liter per hour (L/hr)				
geometric mean (geometric coefficient of variation)	14.63 (± 82)	12.13 (± 66.3)		

Notes:

[107] - Intensive PK Summary Population

[108] - Intensive PK Summary Population

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent volume of distribution (Vz/F) at Week 12

End point title	Apparent volume of distribution (Vz/F) at Week 12[109]

End point description:

Blood samples for PK analysis of GSK2336805 was obtained on Week 4+1 day at predose and at 1, 2, 4, 7 and 24 hours postdose. Apparent volume of distribution is calculated as dose divided by (AUC[0-tau] lambda z) where lambda z is the terminal phase rate constant.

End point type	Secondary

End point timeframe:

Week 12

Notes:

[109] - 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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	11[110]	10[111]		
Units: Liter per hour (L/hr)				
geometric mean (geometric coefficient of variation)	172.81 (± 76.6)	125.09 (± 67.9)		

Notes:

[110] - Intensive PK Summary Population

[111] - Intensive PK Summary Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in basophils, eosinophils, lymphocytes, monocytes, total neutrophils, platelet count and white blood cell count at the indicated time points after Week 12

End point title	Mean change from Baseline in basophils, eosinophils, lymphocytes, monocytes, total neutrophils, platelet count and white blood cell count at the indicated time points after Week 12

End point description:

Blood samples were collected for the measurement of basophils, eosinophils, lymphocytes, monocytes, total neutrophils, platelet count and white blood cell count at the Baseline, Day 2, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT Week 4. Change from Baseline in the basophils, eosinophils, lymphocytes, total neutrophils platelet count and white blood cell count values are summarized for each post-Baseline assessment after Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value

observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population. System value of 99999 indicates NA (too few participants).

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[112]	40[113]	17[114]	13[115]
Units: Giga per liter				
arithmetic mean (standard deviation)				
Basophils; Week18; n=37, 33, 13, 12	-0.019 (± 0.0178)	-0.01 (± 0.0194)	-0.014 (± 0.0112)	-0.012 (± 0.0119)
Basophils; Week24; n=34, 32, 12, 11	-0.018 (± 0.0177)	-0.01 (± 0.0166)	-0.013 (± 0.0129)	-0.013 (± 0.011)
Basophils; Week30; n=13, 10, 2, 2	-0.018 (± 0.0142)	-0.012 (± 0.0148)	-0.02 (± 0)	-0.02 (± 0)
Basophils; Week36; n=12, 7, 1, 2	-0.02 (± 0.0165)	-0.006 (± 0.019)	-0.02 (± 99999)	-0.01 (± 0.0141)
Basophils; Week42; n=10, 6, 2, 2	-0.015 (± 0.0242)	-0.005 (± 0.0187)	0 (± 0.0424)	-0.015 (± 0.0071)
Basophils; Week48; n=7, 6, 1, 2	-0.007 (± 0.0214)	-0.007 (± 0.0197)	0.02 (± 99999)	0.005 (± 0.0119)
Basophils; PT Week4; n=32, 34, 11, 11	-0.007 (± 0.0162)	-0.003 (± 0.0189)	-0.001 (± 0.0181)	-0.003 (± 0.0189)
Eosinophils; Week18; n=37, 33, 13, 12	-0.119 (± 0.1006)	-0.127 (± 0.1207)	-0.087 (± 0.0507)	-0.068 (± 0.0746)
Eosinophils; Week24; n=34, 32, 12, 11	-0.128 (± 0.101)	-0.131 (± 0.1103)	-0.118 (± 0.0612)	-0.041 (± 0.1003)
Eosinophils; Week30; n=13, 10, 2, 2	-0.124 (± 0.0982)	-0.116 (± 0.1117)	-0.13 (± 0.0849)	-0.04 (± 0.0141)
Eosinophils; Week36; n=12, 7, 1, 2	-0.081 (± 0.1459)	-0.123 (± 0.1003)	-0.06 (± 99999)	-0.05 (± 0.0141)
Eosinophils; Week42; n=10, 6, 2, 2	-0.105 (± 0.074)	-0.1 (± 0.12)	-0.02 (± 0.0424)	-0.04 (± 0)
Eosinophils; Week48; n=8, 6, 1, 2	-0.071 (± 0.0889)	-0.11 (± 0.1223)	0.13 (± 99999)	-0.05 (± 0.0141)
Eosinophils; PT Week4; n=32, 34, 11, 11	-0.069 (± 0.0925)	-0.085 (± 0.1208)	-0.07 (± 0.0694)	-0.018 (± 0.0808)
Lymphocytes; Week18; n=37, 33, 13, 12	-1.081 (± 0.5533)	-1.157 (± 0.5373)	-0.999 (± 0.4672)	-0.973 (± 0.5328)
Lymphocytes; Week24; n=34, 32, 12, 11	-1.181 (± 0.4795)	-1.092 (± 0.5598)	-1.405 (± 0.5912)	-1.057 (± 0.4832)
Lymphocytes; Week30; n=13, 10, 2, 2	-1.225 (± 0.7588)	-1.085 (± 0.798)	-1.905 (± 0.1768)	-1.845 (± 0.2899)
Lymphocytes; Week36; n=12, 7, 1, 2	-1.267 (± 0.6828)	-1.286 (± 0.8983)	-1.97 (± 99999)	-1.92 (± 0.4808)
Lymphocytes; Week42; n=10, 6, 2, 2	-1.135 (± 0.8657)	-1.22 (± 0.9909)	-1.125 (± 1.0253)	-1.93 (± 0.1414)
Lymphocytes; Week48; n=7, 6, 1, 2	-0.779 (± 1.0639)	-1.4 (± 1.0384)	0.09 (± 99999)	-2.2 (± 0.0424)

Lymphocytes; PT Week4; n=32, 34, 11, 11	-0.681 (± 0.4594)	-0.7 (± 0.6163)	-0.756 (± 0.5874)	-0.737 (± 0.5666)
Monocytes; Week18; n=37, 33, 13, 12	-0.186 (± 0.1588)	-0.141 (± 0.1339)	-0.088 (± 0.1663)	-0.143 (± 0.1776)
Monocytes; Week24; n=34, 32, 12, 11	-0.206 (± 0.1692)	-0.156 (± 0.1574)	-0.151 (± 0.1474)	-0.121 (± 0.1902)
Monocytes; Week30; n=13, 10, 2, 2	-0.151 (± 0.1655)	-0.135 (± 0.091)	-0.4 (± 0.3111)	-0.06 (± 0.0141)
Monocytes; Week36; n=12, 7, 1, 2	-0.255 (± 0.1474)	-0.18 (± 0.0987)	-0.2 (± 99999)	0.015 (± 0.1061)
Monocytes; Week42; n=10, 6, 2, 2	-0.184 (± 0.234)	-0.093 (± 0.1743)	-0.025 (± 0.2192)	-0.01 (± 0.099)
Monocytes; Week48; n=7, 6, 1, 2	-0.066 (± 0.1744)	-0.147 (± 0.088)	0.02 (± 99999)	-0.085 (± 0.1909)
Monocytes; PT Week4; n=32, 34, 11, 11	-0.047 (± 0.1773)	-0.031 (± 0.165)	0.032 (± 0.1543)	-0.053 (± 0.1536)
Total Neutrophils; Week18; n=37, 33, 13, 12	-2.702 (± 1.9136)	-2.378 (± 1.6735)	-1.652 (± 0.852)	-1.463 (± 0.7174)
Total Neutrophils; Week24; n=34, 32, 12, 11	-2.527 (± 1.9492)	-2.187 (± 1.7758)	-1.308 (± 0.7148)	-1.3 (± 0.9956)
Total Neutrophils; Week30; n=13, 10, 2, 2	-2.402 (± 1.7954)	-2.252 (± 2.3658)	-2.24 (± 1.2869)	-2.085 (± 0.1909)
Total Neutrophils; Week36; n=12, 7, 1, 2	-2.503 (± 1.6709)	-2.777 (± 2.4215)	-1.61 (± 99999)	-1.63 (± 0.297)
Total Neutrophils; Week42; n=10, 6, 2, 2	-2.23 (± 2.0311)	-3.085 (± 2.7313)	-0.565 (± 0.7849)	-1.815 (± 0.4455)
Total Neutrophils; Week48; n=7, 6, 1, 2	-1.129 (± 2.2597)	-2.488 (± 3.397)	0.02 (± 99999)	-1.445 (± 0.4596)
Total Neutrophils; PT Week4; n=32, 34, 11, 11	-1.158 (± 1.8855)	-0.808 (± 1.6104)	-0.744 (± 1.1276)	-0.671 (± 0.8001)
Platelet Count; Week18; n=38, 34, 13, 12	-73.7 (± 43.93)	-87.5 (± 38.4)	-55.7 (± 56.96)	-52.1 (± 39.87)
Platelet Count; Week24; n=35, 33, 12, 11	-67.5 (± 43.22)	-78.8 (± 44.15)	-60.3 (± 56.5)	-51.9 (± 44.19)
Platelet Count; Week30; n=13, 10, 1, 2	-70 (± 60.5)	-71.9 (± 59.35)	-112 (± 99999)	-36.5 (± 47.38)
Platelet Count; Week36; n=12, 7, 1, 2	-64.1 (± 41.52)	-75.7 (± 65.89)	-115 (± 99999)	-34 (± 52.33)
Platelet Count; Week42; n=10, 6, 2, 2	-56.1 (± 53.01)	-67.3 (± 62.09)	-112 (± 0)	-22 (± 52.33)
Platelet Count; Week48; n=9, 6, 1, 2	-37.7 (± 66.18)	-68.8 (± 65.74)	33 (± 99999)	-14 (± 22.63)
Platelet Count; PT Week4; n=32, 34, 11, 11	-20.4 (± 44.37)	-28.9 (± 45.92)	-12.4 (± 34.3)	-12.9 (± 42.3)
White Blood Cell count; Week18; n=37, 33, 13, 12	-4.1 (± 2.258)	-3.81 (± 1.884)	-2.84 (± 0.961)	-2.65 (± 0.923)
White Blood Cell count ; Week24; n=34, 32, 12, 11	-4.06 (± 2.251)	-3.58 (± 1.977)	-3 (± 1.047)	-2.52 (± 1.272)
White Blood Cell count ; Week30; n=13, 10, 2, 2	-3.92 (± 2.258)	-3.59 (± 3.051)	-4.7 (± 1.838)	-4.05 (± 0.495)
White Blood Cell count ; Week36; n=12, 7, 1, 2	-4.13 (± 2.188)	-4.39 (± 3.168)	-3.9 (± 99999)	-3.55 (± 0.919)
White Blood Cell count ; Week42; n=10, 6, 2, 2	-3.67 (± 2.807)	-4.52 (± 3.68)	-1.75 (± 2.051)	-3.8 (± 0.707)
White Blood Cell count; Week48; n=7, 6, 1, 2	-2.09 (± 3.304)	-4.17 (± 4.172)	0.2 (± 99999)	-3.8 (± 0.141)
White Blood Cell count; PT Week4; n=32, 34, 11, 11	-1.97 (± 1.938)	-1.64 (± 1.907)	-1.54 (± 1.638)	-1.45 (± 0.884)

Notes:

[112] - Safety Population

[113] - Safety Population

[114] - Safety Population

[115] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in red blood cell count at the indicated time points after Week 12

End point title	Mean change from Baseline in red blood cell count at the indicated time points after Week 12

End point description:

Blood samples were collected for the measurement of red blood cell count at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Week 4. Change from Baseline in the red blood cell count values are summarized for each post-Baseline assessment after Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population.The mean and standard deviation could not be determined (not reached) because too few participants experienced the event (system value of 99999 indicates NA for the mean and the standard deviation).

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[116]	40[117]	17[118]	13[119]
Units: Trillion per liter				
arithmetic mean (standard deviation)				
Red Blood Cell count; Week 18; n=38, 34, 13, 12	-1.13 (± 0.494)	-0.88 (± 0.591)	-1.19 (± 0.638)	-0.99 (± 0.498)
Red Blood Cell count; Week 24; n=35, 33, 12, 11	-1.13 (± 0.482)	-0.94 (± 0.513)	-1.19 (± 0.552)	-1.14 (± 0.528)
Red Blood Cell count; Week 30; n=13, 10, 2, 2	0.482 (± 0.511)	-0.75 (± 0.809)	-1.45 (± 0.071)	-1.45 (± 0.354)
Red Blood Cell count; Week 36; n=12, 7, 1, 2	-0.88 (± 0.67)	-1.06 (± 0.761)	-1 (± 99999)	-1.3 (± 0.283)
Red Blood Cell count; Week 42; n=10, 6, 2, 2	-0.91 (± 0.674)	-1.17 (± 0.769)	-0.55 (± 0.636)	-1.45 (± 0.354)
Red Blood Cell count; Week 48; n=9, 6, 1, 2	-0.83 (± 0.791)	-1.03 (± 0.794)	-0.4 (± 99999)	-1.5 (± 0.566)
Red Blood Cell count; PT Week 4; n=32, 34, 11, 11	-0.57 (± 0.435)	-0.37 (± 0.353)	-0.66 (± 0.437)	-0.65 (± 0.474)

Notes:

[116] - Safety Population

[117] - Safety Population

[118] - Safety Population

[119] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in hemoglobin at the indicated time points after Week 12

End point title	Mean change from Baseline in hemoglobin at the indicated time points after Week 12

End point description:

Blood samples were collected for the measurement of hemoglobin at the the Baseline, Day 2, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Week 4. Change from Baseline in the hemoglobin values are summarized for each post-Baseline assessment after Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population The mean and standard deviation could not be determined (not reached) because too few participants experienced the event (system value of 99999 indicates NA for the mean and the standard deviation).

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[120]	40[121]	17[122]	13[123]
Units: Grams per liter				
arithmetic mean (standard deviation)				
Hemoglobin; Week 18; n=38, 34, 13, 12	-33.6 (± 12.34)	-26.7 (± 14.65)	-35 (± 16.38)	-29 (± 10.61)
Hemoglobin; Week 24; n=35, 33, 12, 11	-33.4 (± 12.16)	-28 (± 12.44)	-35.6 (± 13.48)	-32.3 (± 14.98)
Hemoglobin; Week 30; n=13, 10, 2, 2	-30.2 (± 16.13)	-21 (± 20.02)	-40 (± 12.73)	-40 (± 1.41)
Hemoglobin; Week 36; n=12, 7, 1, 2	-26.7 (± 18.86)	-30 (± 16.37)	-37 (± 99999)	-35 (± 1.41)
Hemoglobin; Week 42; n=10, 6, 2, 2	-27.1 (± 18.51)	-31.7 (± 19.82)	-25 (± 22.63)	-40 (± 1.41)
Hemoglobin; Week 48; n=9, 6, 1, 2	-25.9 (± 21.47)	-29.3 (± 20.33)	-18 (± 99999)	-41 (± 8.49)
Hemoglobin; PT Week 4; n=32, 34, 11, 11	-16.5 (± 11.43)	-11.7 (± 9.57)	-21.4 (± 8.59)	-16.8 (± 11.99)

Notes:

[120] - Safety Population

[121] - Safety Population

[122] - Safety Population

[123] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in hematocrit at the indicated time points after Week 12

End point title	Mean change from Baseline in hematocrit at the indicated time points after Week 12

End point description:

Blood samples were collected for the measurement of hematocrit at the the Baseline, Day 2, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Week 4. Change from Baseline in the hematocrit values are summarized for each post-Baseline assessment after Week 12. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population. The mean and standard deviation could not be determined (not reached) because too few participants experienced the event (system value of 99999 indicates NA).

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[124]	40[125]	17[126]	13[127]
Units: Percentage of RBC in blood				
arithmetic mean (standard deviation)				
Hematocrit; Week 18; n=38, 34, 13, 12	-0.083 (± 0.03831)	-0.0622 (± 0.04289)	-0.0776 (± 0.04313)	-0.0699 (± 0.02801)
Hematocrit; Week 24; n=35, 33, 12, 11	-0.0782 (± 0.04021)	-0.0635 (± 0.03499)	-0.0808 (± 0.03543)	-0.0823 (± 0.03968)
Hematocrit; Week 30; n=13, 10, 2, 2	-0.0713 (± 0.0486)	-0.0397 (± 0.05793)	-0.0955 (± 0.03323)	-0.1125 (± 0.00636)
Hematocrit; Week 36; n=12, 7, 1, 2	-0.0567 (± 0.05031)	-0.069 (± 0.04724)	-0.087 (± 99999)	-0.0895 (± 0.00354)
Hematocrit; Week 42; n=10, 6, 2, 2	-0.0623 (± 0.05449)	-0.0802 (± 0.0562)	-0.0535 (± 0.07)	-0.111 (± 0.00566)
Hematocrit; Week 48; n=9, 6, 1, 2	-0.0624 (± 0.06203)	-0.0753 (± 0.05285)	-0.047 (± 99999)	-0.1095 (± 0.03041)
Hematocrit; PT Week 4; n=32, 34, 11, 11	-0.0293 (± 0.03575)	-0.0135 (± 0.03178)	-0.0362 (± 0.02907)	-0.0354 (± 0.0358)

Notes:

[124] - Safety Population

[125] - Safety Population

[126] - Safety Population

[127] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in mean corpuscle volume at the indicated time points after Week 12

End point title	Mean change from Baseline in mean corpuscle volume at the indicated time points after Week 12

End point description:

Blood samples were collected for the measurement of mean corpuscle volume at the the Baseline, Day 2, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Week 4. Change from Baseline in the mean corpuscle volume values are summarized for each post-Baseline assessment after Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population. The mean and standard deviation could not be determined (not reached) because too few participants experienced the event (system value of 99999 indicates NA for the mean and the standard deviation).

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[128]	40[129]	17[130]	13[131]
Units: Femtoliters				
arithmetic mean (standard deviation)				
Mean Corpuscle Volume ; Week 18; n=38, 34, 13, 12	7.5 (± 6.37)	6.2 (± 8.19)	8.5 (± 5.78)	5.3 (± 5.28)
Mean Corpuscle Volume ; Week 24; n=35, 33, 12, 11	8.5 (± 6.14)	7.5 (± 8.89)	7.6 (± 5.9)	5.8 (± 5.08)
Mean Corpuscle Volume ; Week 30; n=13, 10, 2, 2	7.8 (± 7.24)	9.5 (± 12.02)	11.5 (± 7.78)	3 (± 2.83)
Mean Corpuscle Volume ; Week 36; n=12, 7, 1, 2	8.1 (± 5.92)	11.4 (± 13.6)	2 (± 99999)	5.5 (± 2.12)
Mean Corpuscle Volume ; Week 42; n=10, 6, 2, 2	6.9 (± 5.7)	10.7 (± 14.47)	1 (± 2.83)	4 (± 2.83)
Mean Corpuscle Volume ; Week 48; n=9, 6, 1, 2	5.2 (± 5.76)	9 (± 14.04)	-1 (± 99999)	5 (± 1.41)
Mean Corpuscle Volume; PT Week 4; n=32, 34, 11, 11	6.1 (± 5.56)	5.1 (± 4.86)	5.8 (± 3.79)	5.3 (± 5.1)

Notes:

[128] - Safety Population

[129] - Safety Population

[130] - Safety Population

[131] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in albumin at the indicated time points after Week 12

End point title	Mean change from Baseline in albumin at the indicated time points after Week 12

End point description:

Blood samples were collected for the measurement of albumin at the the Baseline, Day 2, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Week 4. Change from Baseline in the albumin values are summarized for each post-Baseline assessment after Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population. The mean and standard deviation could not be determined (not reached) because too few participants experienced the event (system value of 99999 indicates NA for the mean and the standard deviation).

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[132]	40[133]	17[134]	13[135]
Units: Grams per liter				
arithmetic mean (standard deviation)				
Albumin; Week 18; n=38, 34, 13, 12	-2.3 (± 2.78)	-1.4 (± 2.65)	-1.8 (± 2.86)	-1 (± 2.89)
Albumin; Week 24; n=35, 33, 12, 11	-2.1 (± 3.08)	-1.6 (± 2.82)	-2.3 (± 2.81)	-1.1 (± 2.81)
Albumin; Week 30; n=13, 10, 3, 2	-1.8 (± 2.09)	-0.7 (± 4.22)	-3 (± 2.65)	-4.5 (± 0.71)
Albumin; Week 36; n=10, 7, 2, 2	-1.7 (± 3.92)	-1.1 (± 2.85)	2 (± 1.41)	-2 (± 0)
Albumin; Week 42; n=9, 6, 1, 2	-1.3 (± 2.5)	-1.3 (± 1.63)	-1 (± 99999)	-3 (± 0)
Albumin; Week 48; n=6, 6, 0, 2	-1.3 (± 3.61)	-0.3 (± 2.16)	99999 (± 99999)	-4 (± 1.41)
Albumin; PT Week 4; n=33, 34, 11, 11	-0.7 (± 3.93)	-0.2 (± 2.84)	0.5 (± 2.3)	-0.7 (± 1.79)

Notes:

[132] - Safety Population

[133] - Safety Population

[134] - Safety Population

[135] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in alkaline phosphatase, alanine amino transferase, aspartate amino transferase, creatine kinase and gamma glutamyl transferase at the indicated time points after Week 12

End point title	Mean change from Baseline in alkaline phosphatase, alanine amino transferase, aspartate amino transferase, creatine kinase and gamma glutamyl transferase at the indicated time points after Week 12

End point description:

Blood samples were collected for the measurement of Alkaline Phosphatase (ALP) , Alanine Amino Transferase (ALT) , Aspartate Amino Transferase (AST) , Creatine Kinase (CK) and Gamma Glutamyl Transferase (GGT) at the the Baseline, Day 2, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Week 4. Change from Baseline in the ALP, ALT, AST, CK and GGT values are summarized for each post-Baseline assessment after Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population. System value of 99999 indicates NA (too few participants).

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[136]	40[137]	17[138]	13[139]
Units: International units per liter				
arithmetic mean (standard deviation)				
ALP; Week 18; n=38, 34, 13, 12	2.5 (± 17.25)	1.1 (± 16.95)	2.2 (± 21.77)	6.4 (± 20.08)
ALP; Week 24; n=35, 33, 12, 11	0.8 (± 19.71)	3.3 (± 18.83)	2.1 (± 20.24)	4.5 (± 22.82)
ALP; Week 30; n=13, 10, 3, 2	1.8 (± 15.79)	-6.4 (± 18.62)	-8 (± 8.54)	22.5 (± 14.85)
ALP; Week 36; n=10, 7, 2, 2	2 (± 17.49)	2.7 (± 9.45)	2.5 (± 0.71)	18 (± 7.07)
ALP; Week 42; n=9, 6, 1, 2	5.3 (± 13.4)	3.3 (± 8.45)	-2 (± 99999)	17.5 (± 2.12)
ALP; Week 48; n=6, 6, 0, 2	9.8 (± 17.36)	4.2 (± 9.62)	99999 (± 99999)	30 (± 24.04)
ALP; PT Week 4; n=33, 34, 11, 11	-4.9 (± 19.71)	-6.3 (± 17.88)	-7 (± 17.93)	-3.9 (± 22.15)
ALT; Week 18; n=38, 34, 13, 12	-38.9 (± 61.39)	-22.9 (± 61.65)	-38.6 (± 40.89)	-38.4 (± 32.63)
ALT; Week 24; n=35, 33, 12, 11	-43.9 (± 62.25)	-31.3 (± 56.12)	-39.7 (± 38.19)	-41.7 (± 28.32)
ALT; Week 30; n=13, 10, 3, 2	-34.8 (± 30.82)	-45.1 (± 95.76)	-57.7 (± 58.31)	-26 (± 22.63)
ALT; Week 36; n=10, 7, 2, 2	-30.2 (± 28.15)	-16.6 (± 13.7)	-69 (± 74.95)	-20.5 (± 16.26)
ALT; Week 42; n=9, 6, 1, 2	-34.3 (± 35.15)	-14.3 (± 20.07)	-122 (± 99999)	-28 (± 25.46)
ALT; Week 48; n=6, 6, 0, 2	-38.8 (± 42.1)	-10.8 (± 27.11)	99999 (± 99999)	-26.5 (± 26.16)
ALT; PT Week 4; n=33, 34, 11, 11	-45.5 (± 62.76)	-33.3 (± 56.81)	-31.5 (± 22.68)	-43.9 (± 27.71)
AST; Week 18; n=38, 34, 13, 12	-13.1 (± 27.49)	-3.5 (± 37.25)	-18.8 (± 27.32)	-16.3 (± 15.11)

AST; Week 24; n=35, 33, 12, 11	-16.5 (± 26.86)	-11.8 (± 30.51)	-23.8 (± 26.91)	-15.7 (± 18.91)
AST; Week 30; n=13, 10, 3, 2	-15.1 (± 17.35)	-18.7 (± 43.89)	-27.7 (± 20.13)	-6.5 (± 7.78)
AST; Week 36; n=10, 7, 2, 2	-11.8 (± 13.81)	-7.3 (± 9.5)	-27.5 (± 31.82)	-2.5 (± 2.12)
AST; Week 42; n=9, 6, 1, 2	-14.2 (± 16.81)	-5.8 (± 10.03)	-54 (± 99999)	-9 (± 7.07)
AST; Week 48; n=6, 6, 0, 2	-12.8 (± 18.65)	-2.2 (± 13.61)	99999 (± 99999)	-6.5 (± 9.19)
AST; PT Week 4; n=33, 34, 11, 11	-19.5 (± 26.41)	-15.6 (± 34.38)	-17.7 (± 14.67)	-16 (± 31.8)
CK; Week 18; n=38, 34, 13, 12	-44 (± 55.77)	-28.3 (± 36.59)	-38.7 (± 45.46)	-60.7 (± 75.8)
CK; Week 24; n=35, 33, 12, 11	-34.5 (± 66.48)	-18.7 (± 77.24)	-39 (± 36.68)	60.1 (± 475.39)
CK; Week 30; n=13, 10, 3, 2	-33 (± 83.25)	-15.8 (± 51.92)	-30 (± 24.27)	-78.5 (± 55.86)
CK; Week 36; n=10, 7, 2, 2	-18.9 (± 34.18)	-26.7 (± 32.22)	-37.5 (± 6.36)	-69 (± 53.74)
CK; Week 42; n=9, 6, 1, 2	-0.2 (± 51.5)	-29.7 (± 43.42)	-32 (± 99999)	-81 (± 57.98)
CK; Week 48; n=6, 6, 0, 2	10.5 (± 71.39)	22.3 (± 77.32)	99999 (± 99999)	-82.5 (± 70)
CK; PT Week 4; n=33, 34, 11, 11	-17.9 (± 48.82)	-26.4 (± 49.42)	-21.7 (± 42.62)	258.7 (± 994.88)
GGT; Week 18; n=38, 34, 13, 12	-37.3 (± 71.19)	-12.3 (± 60.35)	-30.2 (± 42.04)	-34.2 (± 56.52)
GGT; Week 24; n=35, 33, 12, 11	-38.3 (± 72.79)	-12.5 (± 86.73)	-37.4 (± 45.44)	-35.7 (± 59.63)
GGT; Week 30; n=13, 10, 3, 2	-44.2 (± 41.3)	-32.8 (± 31.81)	-38.7 (± 36.02)	-12 (± 4.24)
GGT; Week 36; n=10, 7, 2, 2	-51.5 (± 45.03)	-19.7 (± 24.52)	-40.5 (± 33.23)	-10 (± 4.24)
GGT; Week 42; n=9, 6, 1, 2	-44.6 (± 46.61)	-19.7 (± 25.06)	-17 (± 99999)	-9 (± 1.41)
GGT; Week 48; n=6, 6, 0, 2	-37.8 (± 28.74)	-16.8 (± 24.38)	99999 (± 99999)	-9.5 (± 6.36)
GGT; PT Week 4; n=33, 34, 11, 11	-43.4 (± 78.29)	-17.7 (± 78.22)	-30.7 (± 41.91)	-41.4 (± 61.06)

Notes:

[136] - Safety Population

[137] - Safety Population

[138] - Safety Population

[139] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in total bilirubin and creatinine at the indicated time points after Week 12

End point title	Mean change from Baseline in total bilirubin and creatinine at the indicated time points after Week 12

End point description:

Blood samples were collected for the measurement of total bilirubin and creatinine at the the Baseline, Day 2, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Week 4. Change from Baseline in the direct bilirubin, total bilirubin and creatinine values are summarized for each post-Baseline assessment afterl Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those

participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the safety population. The mean and standard deviation could not be determined (not reached) because too few participants experienced the event (system value of 99999 indicates NA for the mean and the standard deviation).

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[140]	40[141]	17[142]	13[143]
Units: Micromoles per liter				
arithmetic mean (standard deviation)				
Total bilirubin; Week 18; n=38, 34, 13, 12	0.5 (± 5.01)	1.7 (± 5.32)	-1.4 (± 11.37)	0.6 (± 6.49)
Total bilirubin; Week 24; n=35, 33, 12, 11	-0.1 (± 5.73)	1 (± 4.08)	-1.3 (± 11.9)	1.3 (± 6.26)
Total bilirubin; Week 30; n=13, 10, 3, 2	-0.2 (± 5.99)	0.8 (± 4.76)	-2.3 (± 9.29)	-4 (± 5.66)
Total bilirubin; Week 36; n=10, 7, 2, 2	0 (± 4.29)	1.9 (± 4.95)	-3 (± 11.31)	-3 (± 7.07)
Total bilirubin; Week 42; n=9, 6, 1, 2	0.1 (± 5.11)	1.5 (± 5.79)	-14 (± 99999)	-4 (± 5.66)
Total bilirubin; Week 48; n=6, 6, 0, 2	-0.7 (± 4.72)	3.5 (± 7.2)	99999 (± 99999)	-4 (± 2.83)
Total bilirubin PT Week 4; n=33, 34, 11, 11	-4.6 (± 3.57)	-2.4 (± 3.3)	-0.4 (± 5.68)	-2.2 (± 2.71)
Creatinine; Week 18; n=38, 34, 13, 12	-2.24 (± 9.186)	-1.97 (± 9.65)	-1.75 (± 9.874)	0.09 (± 10.668)
Creatinine; Week 24; n=35, 33, 12, 11	-1.55 (± 9.507)	-2.4 (± 8.413)	-3.12 (± 9.408)	1.31 (± 10.377)
Creatinine; Week 30; n=13, 10, 3, 2	0.66 (± 4.603)	2.82 (± 8.123)	-8.47 (± 8.693)	-8.85 (± 3.748)
Creatinine; Week 36; n=10, 7, 2, 2	2.33 (± 11.096)	2.99 (± 8.179)	-5.5 (± 16.829)	-8 (± 1.273)
Creatinine; Week 42; n=9, 6, 1, 2	1.23 (± 10.32)	4.97 (± 11.697)	-14.3 (± 99999)	-7.55 (± 5.586)
Creatinine; Week 48; n=6, 6, 0, 2	-2.35 (± 4.222)	10.07 (± 17.173)	99999 (± 99999)	-7.1 (± 1.273)
Creatinine; PT Week 4; n=33, 34, 11, 11	1.23 (± 8.22)	-0.34 (± 7.624)	-1.7 (± 6.897)	-1.25 (± 6.228)

Notes:

[140] - Safety Population

[141] - Safety Population

[142] - Safety Population

[143] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in systolic blood pressure and diastolic blood pressure at the indicated time points after Week 12

End point title	Mean change from Baseline in systolic blood pressure and

	diastolic blood pressure at the indicated time points after Week 12

End point description:

Blood pressure measurements were taken to observe vital signs and included systolic blood pressure (SBP) and diastolic blood pressure (DBP) at the Baseline, Day 2, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4. As defined in the Reporting Analysis Plan (RAP) for this protocol, the supplemental final data package generated for this study after Week 12 only provided graphical displays of vital signs (e.g., change from baseline for heart rate and blood pressure) to facilitate clinical interpretation and data summarization. All abnormal values were also provided in separate by-subject data listings. Therefore, no statistical summary table is available after week 12.

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[144]	0[145]	0[146]	0[147]
Units: Millimeters of mercury (mmHg)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[144] - Safety Population

[145] - Safety Population

[146] - Safety Population

[147] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in heart rate at the indicated time points after Week 12

End point title	Mean change from Baseline in heart rate at the indicated time points after Week 12

End point description:

Vital sign monitoring included heart rate, measured at the Baseline, Day 2, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4. As defined in the Reporting Analysis Plan (RAP) for this protocol, the supplemental final data package generated for this study after Week 12 only provided graphical displays of vital signs (e.g., change from Baseline for heart rate and blood pressure) to facilitate clinical interpretation and data summarization. All abnormal values were also provided in separate by-subject data listings. Therefore, no statistical summary table is available after week 12.

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[148]	0[149]	0[150]	0[151]
Units: Beats per minute				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[148] - Safety Population

[149] - Safety Population

[150] - Safety Population

[151] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in ECG heart rate values at the indicated time points after Week 12

End point title	Mean change from Baseline in ECG heart rate values at the indicated time points after Week 12

End point description:

The electrocardiographic (ECG) data was only collected "Perform as needed", therefore, no such summary table was generated.

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[152]	0[153]	0[154]	0[155]
Units: Beats per minute				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[152] - Safety Population

[153] - Safety Population

[154] - Safety Population

[155] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in PR interval, QRS duration, uncorrected QT interval, QTcB, QTcF values at the indicated time points after Week 12

End point title	Mean change from Baseline in PR interval, QRS duration, uncorrected QT interval, QTcB, QTcF values at the indicated time points after Week 12

End point description:

The electrocardiographic (ECG) data was only collected "Perform as needed", therefore, no such summary table was generated.

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[156]	0[157]	0[158]	0[159]
Units: Milliseconds				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[156] - Safety Population

[157] - Safety Population

[158] - Safety Population

[159] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in chloride, bicarbonate, glucose, potassium, sodium, inorganic phosphorus and urea/Bun at the indicated time points after Week 12

End point title	Mean change from Baseline in chloride, bicarbonate, glucose, potassium, sodium, inorganic phosphorus and urea/Bun at the indicated time points after Week 12

End point description:

Blood samples were collected for the measurement of Chloride, bicarbonate, glucose, potassium, sodium, inorganic phosphorus and urea/bun at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4. Change from Baseline in the Chloride, Bicarbonate, Glucose, Potassium, Sodium, Inorganic Phosphorus and Urea/Bun values are summarized for each post-Baseline assessment after Week 12. . Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT population. System value of 99999 indicates NA (too few participants).

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[160]	40[161]	17[162]	13[163]
Units: Millimoles per liter				
arithmetic mean (standard deviation)				
Chloride; Week 18; n=38, 34, 13, 12	1.9 (± 2.75)	1 (± 2.5)	1.8 (± 2.41)	0.5 (± 2.94)
Chloride; Week 24; n=35, 33, 12, 11	2 (± 2.33)	0.7 (± 2.73)	2.9 (± 2.81)	-0.2 (± 3.52)
Chloride; Week 30; n=13, 10, 3, 2	1.9 (± 2.72)	0.3 (± 2.87)	5.3 (± 3.21)	3 (± 0)
Chloride; Week 36; n=10, 7, 2, 2	1.3 (± 2.11)	-0.1 (± 2.54)	4.5 (± 6.36)	1 (± 0)
Chloride; Week 42; n=9, 6, 1, 2	1.3 (± 2.78)	0 (± 2)	10 (± 99999)	0.5 (± 0.71)
Chloride; Week 48; n=6, 6, 0, 2	1.3 (± 2.34)	-1 (± 3.16)	99999 (± 99999)	0 (± 0)
Chloride; PT Week 4; n=33, 34, 11, 11	0.5 (± 2.69)	0.2 (± 2.54)	0.6 (± 2.29)	-1.5 (± 2.25)
Bicarbonate; Week 18; n=38, 34, 13, 12	-0.3 (± 2.18)	-1 (± 2.16)	-1.2 (± 2.27)	0 (± 2.95)
Bicarbonate; Week 24; n=35, 33, 12, 11	-1 (± 2.41)	-1.2 (± 2.21)	-1.8 (± 2.41)	-0.4 (± 3.35)
Bicarbonate; Week 30; n=13, 10, 3, 2	0.4 (± 2.33)	-2.2 (± 4.02)	-1.3 (± 1.53)	-2 (± 2.83)
Bicarbonate; Week 36; n=10, 7, 2, 2	-0.9 (± 2.92)	0.1 (± 1.86)	-2.5 (± 2.12)	-1.5 (± 2.12)
Bicarbonate; Week 42; n=9, 6, 1, 2	-0.7 (± 1.73)	-0.2 (± 2.04)	-4 (± 99999)	-1 (± 2.83)
Bicarbonate; Week 48; n=6, 6, 0, 2	-1 (± 1.67)	-1.3 (± 2.66)	99999 (± 99999)	-0.5 (± 3.54)
Bicarbonate; PT Week 4; n=33, 34, 11, 11	-0.7 (± 2.1)	-0.5 (± 2.46)	-0.9 (± 2.43)	1 (± 3.07)
Glucose; Week 18; n=38, 34, 13, 12	-0.28 (± 1.326)	-0.13 (± 1.188)	-0.06 (± 0.702)	-0.23 (± 2.134)
Glucose; Week 24; n=35, 33, 12, 11	-0.33 (± 1.552)	0.27 (± 2.986)	-0.23 (± 0.672)	-0.22 (± 1.349)
Glucose; Week 30; n=13, 10, 3, 2	0.03 (± 1.383)	-0.26 (± 0.587)	-0.13 (± 0.252)	0.9 (± 0.707)
Glucose; Week 36; n=10, 7, 2, 2	-0.38 (± 0.758)	-0.37 (± 1.09)	-0.1 (± 0.99)	-0.7 (± 0.283)
Glucose; Week 42; n=9, 6, 1, 2	-0.28 (± 1.663)	-0.12 (± 0.794)	0.4 (± 99999)	-0.15 (± 0.919)
Glucose; Week 48; n=6, 6, 0, 2	0.25 (± 1.358)	-0.3 (± 0.867)	99999 (± 99999)	4.55 (± 4.596)
Glucose; PT Week 4; n=33, 34, 11, 11	0.24 (± 3.122)	0.18 (± 0.684)	-0.12 (± 0.735)	-0.07 (± 1.234)
Potassium; Week 18; n=38, 34, 13, 12	-0.19 (± 0.399)	-0.24 (± 0.376)	-0.41 (± 0.236)	-0.2 (± 0.424)
Potassium; Week 24; n=35, 33, 12, 11	-0.13 (± 0.452)	-0.12 (± 0.459)	-0.34 (± 0.403)	-0.32 (± 0.494)
Potassium; Week 30; n=13, 10, 3, 2	-0.03 (± 0.48)	-0.23 (± 0.377)	-0.1 (± 0.2)	-0.1 (± 0.424)
Potassium; Week 36; n=10, 7, 2, 2	0.24 (± 0.599)	-0.1 (± 0.365)	0.15 (± 0.071)	0.2 (± 0.424)
Potassium; Week 42; n=9, 6, 1, 2	-0.1 (± 0.555)	-0.2 (± 0.415)	-0.1 (± 99999)	0.1 (± 0.566)
Potassium; Week 48; n=6, 6, 0, 2	0.1 (± 0.566)	-0.3 (± 0.322)	99999 (± 99999)	0.05 (± 0.495)
Potassium; PT Week 4; n=33, 34, 11, 11	-0.16 (± 0.382)	-0.13 (± 0.398)	-0.25 (± 0.532)	-0.1 (± 0.316)
Sodium; Week 18; n=38, 34, 13, 12	0.7 (± 2.04)	0.1 (± 2.27)	0.7 (± 2.32)	0.4 (± 3.37)
Sodium; Week 24; n=35, 33, 12, 11	0.4 (± 1.86)	-0.1 (± 2.61)	1.5 (± 2.24)	0.4 (± 3.53)
Sodium; Week 30; n=13, 10, 3, 2	1.1 (± 3.25)	-1.4 (± 2.72)	1.3 (± 1.53)	0 (± 1.41)
Sodium; Week 36; n=10, 7, 2, 2	0.4 (± 2.67)	-0.7 (± 1.98)	2 (± 2.83)	-0.5 (± 0.71)
Sodium; Week 42; n=9, 6, 1, 2	0.4 (± 2.07)	-0.5 (± 1.38)	3 (± 99999)	-1.5 (± 0.71)

Sodium; Week 48; n=6, 6, 0, 2	-0.2 (± 2.14)	-1.2 (± 2.79)	99999 (± 99999)	-2.5 (± 3.54)
Sodium; PT Week 4; n=33, 34, 11, 11	-0.1 (± 2.3)	0.1 (± 2.45)	1.1 (± 2.47)	-0.5 (± 2.7)
Inorganic phosphorus; Week 18; n=38, 34, 13, 12	-0.161 (± 0.1971)	-0.13 (± 0.1928)	-0.092 (± 0.1537)	-0.111 (± 0.2648)
Inorganic phosphorus; Week 24; n=35, 33, 12, 11	-0.139 (± 0.2268)	-0.13 (± 0.2354)	-0.119 (± 0.1991)	-0.107 (± 0.2205)
Inorganic phosphorus; Week 30; n=13, 10, 3, 2	-0.156 (± 0.1644)	-0.118 (± 0.2071)	-0.267 (± 0.2023)	-0.225 (± 0.1768)
Inorganic phosphorus; Week 36; n=10, 7, 2, 2	-0.121 (± 0.2564)	-0.167 (± 0.1906)	-0.195 (± 0.0495)	-0.125 (± 0.2475)
Inorganic phosphorus; Week 42; n=9, 6, 1, 2	-0.08 (± 0.2248)	-0.108 (± 0.0794)	-0.15 (± 99999)	-0.1 (± 0.3536)
Inorganic phosphorus; Week 48; n=6, 6, 0, 2	-0.167 (± 0.1715)	-0.108 (± 0.1665)	99999 (± 99999)	-0.35 (± 0.0707)
Inorganic phosphorus; PT Week 4; n=33, 34, 11, 11	-0.084 (± 0.2375)	-0.003 (± 0.2162)	0.009 (± 0.0798)	-0.085 (± 0.2247)
Urea/BUN; Week 18; n=38, 34, 13, 12	-0.19 (± 1.166)	-0.23 (± 1.403)	-0.49 (± 1.233)	-0.25 (± 1.688)
Urea/BUN; Week 24; n=35, 33, 12, 11	-0.22 (± 1.263)	-0.55 (± 1.252)	-0.43 (± 1.106)	0.02 (± 2.007)
Urea/BUN; Week 30; n=13, 10, 3, 2	0.69 (± 1.107)	-0.16 (± 1.027)	-0.5 (± 1.082)	-0.5 (± 0)
Urea/BUN; Week 36; n=10, 7, 2, 2	0.65 (± 1.775)	0.04 (± 1.172)	-0.15 (± 0.636)	-0.25 (± 1.061)
Urea/BUN; Week 42; n=9, 6, 1, 2	0.34 (± 1.65)	0.5 (± 1.239)	0.5 (± 99999)	-0.5 (± 1.414)
Urea/BUN; Week 48; n=6, 6, 0, 2	0.67 (± 1.353)	0.4 (± 1.607)	99999 (± 99999)	-0.5 (± 0.707)
Urea/BUN; PT Week 4; n=33, 34, 11, 11	0.35 (± 1.284)	-0.19 (± 1.311)	-0.62 (± 1.012)	-0.47 (± 0.969)

Notes:

[160] - Safety Population

[161] - Safety Population

[162] - Safety Population

[163] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in creatinine clearance at the indicated time points after Week 12

End point title	Mean change from Baseline in creatinine clearance at the indicated time points after Week 12

End point description:

Blood samples were collected for the measurement of estimated creatinine clearance by Cockcroft-Gault formula at the Baseline, Weeks 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42, 48 and PT FU Weeks 4. Change from Baseline in the estimated creatinine clearance values are summarized for each post-Baseline assessment after Week 12. Change from Baseline was calculated as the individual post-Baseline value minus the Baseline value. Baseline value is defined as the last Pre-treatment value observed. Only those participants available at the specified time points were analyzed (represented by n=X,X,X,X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT population. The mean and standard deviation could not be determined (not reached) because too few participants experienced the event (system value of 99999 indicates NA for the mean and the standard deviation).

End point type	Secondary

End point timeframe:

Baseline, Weeks 18, 24, 30, 36, 42, 48 and PT FU Week 4

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV	GSK2336805 60 mg, Genotype 4 HCV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41[164]	40[165]	17[166]	13[167]
Units: mL/min				
arithmetic mean (standard deviation)				
Creatinine clearance; Week 18; n=38, 34, 13, 12	-0.1 (± 17.36)	-1.1 (± 20.69)	-2.5 (± 16.25)	-4.3 (± 19.37)
Creatinine clearance; Week 24; n=35, 33, 12, 11	-1.9 (± 16.77)	-1 (± 18.53)	-4.1 (± 15.11)	-6.1 (± 19.05)
Creatinine clearance; Week 30; n=13, 10, 3, 2	-4.8 (± 13.91)	-10.4 (± 14.41)	-3.7 (± 13.58)	7 (± 0)
Creatinine clearance; Week 36; n=10, 7, 2, 2	-11 (± 23.3)	-8.1 (± 13.28)	-1 (± 29.7)	1.5 (± 9.19)
Creatinine clearance; Week 42; n=9, 6, 1, 2	-6.1 (± 16.86)	-13.3 (± 16.13)	9 (± 99999)	-1.5 (± 0.71)
Creatinine clearance; Week 48; n=6, 6, 0, 2	3.2 (± 10.23)	-15.8 (± 16.18)	99999 (± 99999)	-4 (± 11.31)
Creatinine clearance; PT Week 4; n=33, 34, 11, 11	-1.5 (± 34.53)	-1.3 (± 23.85)	-2.7 (± 11.38)	-5.3 (± 13.95)

Notes:

[164] - Safety Population

[165] - Safety Population

[166] - Safety Population

[167] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation of individual GSK2336805 dose with Week 4 Plasma AUC(0-tau) versus eRVR Status

End point title	Correlation of individual GSK2336805 dose with Week 4 Plasma AUC(0-tau) versus eRVR Status[168]

End point description:

Correlation of individual GSK2336805 40 mg and 60 mg with Week 4 plasma AUC(0-tau) versus eRVR Status (eRVR and no eRVE) was performed. eRVR is defined as plasma HCV RNA <LLOQ and target not detected at Weeks 4 and 12. AUC (0-tau) is area under the concentration-time curve over the dosing interval. As defined in the Reporting Analysis Plan (RAP) for this protocol, correlations between GSK2336805 dose, and selected pharmacokinetic parameters and virological outcomes was analyzed only with graphical presentations to facilitate clinical interpretation and data summarization. These data were also provided in by-subject data listings. Therefore, no statistical summary tables are available.

End point type	Secondary

End point timeframe:

Week 4 and Week 12

Notes:

[168] - 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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	0[169]	0[170]		
Units: hr*ng/mL				
arithmetic mean (standard deviation)	()	()		

Notes:

[169] - Intensive PK Population

[170] - Intensive PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation of Individual GSK2336805 dose with Week 4 Plasma Cmax, Ctau, C0 versus eRVR status

End point title	Correlation of Individual GSK2336805 dose with Week 4 Plasma Cmax, Ctau, C0 versus eRVR status[171]

End point description:

Correlation of Individual GSK2336805 40 mg and 60 mg dose with Week 4 maximum plasma concentration (Cmax), pre-dose concentration (C0), concentration at the end of the dosing interval (Ctau) versus eRVR status (eRVR and no eRVR) was performed. eRVR is defined as plasma HCV RNA <LLOQ and target not detected at Weeks 4 and 12. As defined in the Reporting Analysis Plan (RAP) for this protocol, correlations between GSK2336805 dose, and selected pharmacokinetic parameters and virological outcomes was analyzed only with graphical presentations to facilitate clinical interpretation and data summarization. These data were also provided in by-subject data listings. Therefore, no statistical summary tables are available.

End point type	Secondary

End point timeframe:

Week 4 and Week 12

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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	0[172]	0[173]		
Units: ng/mL				
arithmetic mean (standard deviation)	()	()		

Notes:

[172] - Intensive PK Population

[173] - Intensive PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation of individual GSK2336805 dose with Week 4 Plasma AUC(0-tau) versus RVR Status

End point title	Correlation of individual GSK2336805 dose with Week 4 Plasma AUC(0-tau) versus RVR Status[174]

End point description:

Correlation of individual GSK2336805 40 mg and 60 mg with Week 4 plasma AUC(0-tau) versus eRVR Status (RVR and no eVE) was performed. RVR is defined as plasma HCV RNA <LLOQ and target not detected 4 weeks after initiation of therapy. AUC (0-tau) is area under the concentration-time curve over the dosing interval. As defined in the Reporting Analysis Plan (RAP) for this protocol, correlations between GSK2336805 dose, and selected pharmacokinetic parameters and virological outcomes was analyzed only with graphical presentations to facilitate clinical interpretation and data summarization. These data were also provided in by-subject data listings. Therefore, no statistical summary tables are available..

End point type	Secondary

End point timeframe:

Week 4

Notes:

[174] - 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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	0[175]	0[176]		
Units: hr*ng/mL				
arithmetic mean (standard deviation)	()	()		

Notes:

[175] - Intensive PK Population

[176] - Intensive PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation of Individual GSK2336805 dose with Week 4 Plasma Cmax, Ctau, C0 versus RVR status

End point title	Correlation of Individual GSK2336805 dose with Week 4 Plasma Cmax, Ctau, C0 versus RVR status[177]

End point description:

Correlation of Individual GSK2336805 40 mg and 60 mg dose with Week 4 maximum plasma concentration (Cmax), pre-dose concentration (C0), concentration at the end of the dosing interval (Ctau) versus RVR status (RVR and no RVR) was performed. RVR is defined as plasma HCV RNA <LLOQ and target not detected 4 weeks after initiation of therapy. As defined in the Reporting Analysis Plan (RAP) for this protocol, correlations between GSK2336805 dose, and selected pharmacokinetic parameters and virological outcomes was analyzed only with graphical presentations to facilitate clinical interpretation and data summarization. These data were also provided in by-subject data listings. Therefore, no statistical summary tables are available.

End point type	Secondary

End point timeframe:

Week 4

Notes:

[177] - 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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	0[178]	0[179]		
Units: ng/mL				
arithmetic mean (standard deviation)	()	()		

Notes:

[178] - Intensive PK Population

[179] - Intensive PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation of Individual GSK2336805 dose with pre-dose plasma concentration at Week 4 and Week 12 versus eRVR status

End point title	Correlation of Individual GSK2336805 dose with pre-dose plasma concentration at Week 4 and Week 12 versus eRVR status[180]

End point description:

Correlation of individual GSK2336805 dose with pre-dose plasma concentration at Week 4 and Week 12 versus eRVR status was performed. eRVR is defined as plasma HCV RNA <LLOQ and target not detected at Weeks 4 and 12. The PK/Pharmacodynamic (PD) analysis population comprised of all participants with available PD measures (e.g., safety and/or efficacy data) and with evaluable GSK2336805 plasma concentration data considered suitable for investigation of relationship with the PD measures. As defined in the Reporting Analysis Plan (RAP) for this protocol, correlations between GSK2336805 dose, and selected pharmacokinetic parameters and virological outcomes was analyzed only with graphical presentations to facilitate clinical interpretation and data summarization. These data were also provided in by-subject data listings. Therefore, no statistical summary tables are available.

End point type	Secondary

End point timeframe:

Week 4 and Week 12

Notes:

[180] - 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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	0[181]	0[182]		
Units: ng/mL				
arithmetic mean (standard deviation)	()	()		

Notes:

[181] - PK/PD Analysis Population

[182] - PK/PD Analysis Population

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation GSK2336805 pre-dose plasma concentration on Day 2 versus reduction in HCV RNA on Day 2

End point title	Correlation GSK2336805 pre-dose plasma concentration on Day 2 versus reduction in HCV RNA on Day 2[183]

End point description:

Correlation GSK2336805 pre-dose plasma concentration (ng/mL) on Day 2 versus reduction in HCV RNA (log IU/mL) on Day 2 was performed. As defined in the Reporting Analysis Plan (RAP) for this protocol, correlations between GSK2336805 dose, and selected pharmacokinetic parameters and virological outcomes was analyzed only with graphical presentations to facilitate clinical interpretation and data summarization. These data were also provided in by-subject data listings. Therefore, no statistical summary tables are available.

End point type	Secondary

End point timeframe:

Day 2

Notes:

[183] - 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: Statistical Analysis is not applicable for this Outcome Measure.

End point values	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 and Genotype 4 HCV		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	0[184]	0[185]		
Units: ng/mL				
arithmetic mean (standard deviation)	()	()		

Notes:

[184] - PK/PD Analysis Population

[185] - PK/PD Analysis Population

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs) and non-SAEs were collected from the start of study treatment until the follow-up contact (up to 20 study weeks).

Adverse event reporting additional description:

SAEs and non-SAEs were collected in participants of the ATS Population, comprised of all participants who had received at least one dose of study medication (GSK2336805 or telaprevir).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	GSK2336805 40 mg, Genotype 1 HCV

Reporting group description:

Participants with chronic G1 HCV infection received GSK2336805 40 milligrams (mg) orally (20 mg x 2 tablets) once daily (OD) in the morning with food in combination with antiviral therapy (Pegylated Interferon Alfa-2a [PEG] + Ribavirin [RIBA]) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on the extended rapid virologic response (eRVR) achievement. PEG dose was 180 micrograms (µg) once weekly subcutaneous (SC) injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kilogram [kg]) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken in 2 divided doses with food.

Reporting group title	GSK2336805 60 mg, Genotype 1 HCV

Reporting group description:

Participants with chronic G1 HCV infection received GSK2336805 60 mg orally (30 mg x 2 tablets) OD in the morning with food in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.

Reporting group title	Telaprevir, Genotype 1 HCV

Reporting group description:

Participants with chronic G1 HCV infection received two telaprevir 375 mg tablets orally 3 times a day (7 to 9 hours apart) with food containing approximately 20 grams of fat in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.

Reporting group title	GSK2336805 60 mg, Genotype 4 HCV

Reporting group description:

Participants with chronic G4 HCV infection received GSK2336805 60 mg orally (30 mg x 2 tablets) OD in the morning with food in combination with antiviral therapy (PEG+RIBA) for 12 weeks followed by PEG and RIBA alone for either 12 or 36 weeks based on eRVR achievement. PEG dose was 180 µg once weekly SC injection and the RIBA dose was 1000 mg orally (200 mg x 5 capsules) (if body weight is <75 kg) or 1200 mg orally (200 mg x 6 capsules) (if body weight is >=75 kg) taken orally in 2 divided doses with food.

Serious adverse events	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 41 (4.88%)	2 / 40 (5.00%)	3 / 17 (17.65%)
number of deaths (all causes)	0	0	0
number of deaths resulting from			

adverse events			
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 17 (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
Gastrointestinal disorders			
Haemorrhoids			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (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
Injection site abscess			

subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 17 (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
Otitis externa			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 17 (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
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 17 (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

Serious adverse events	GSK2336805 60 mg, Genotype 4 HCV		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 13 (7.69%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Haemorrhoids			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			

Myalgia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Injection site abscess			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis externa			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	GSK2336805 40 mg, Genotype 1 HCV	GSK2336805 60 mg, Genotype 1 HCV	Telaprevir, Genotype 1 HCV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	41 / 41 (100.00%)	38 / 40 (95.00%)	17 / 17 (100.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 41 (7.32%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	3	1	0
Hypotension			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 41 (12.20%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	7	1	0
Chills			
subjects affected / exposed	5 / 41 (12.20%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	5	0	1
Drug withdrawal syndrome			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	9 / 41 (21.95%)	12 / 40 (30.00%)	7 / 17 (41.18%)
occurrences (all)	9	13	8
Feeling hot			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	8 / 41 (19.51%)	9 / 40 (22.50%)	3 / 17 (17.65%)
occurrences (all)	16	10	3
Injection site bruising			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Injection site erythema			
subjects affected / exposed	6 / 41 (14.63%)	3 / 40 (7.50%)	1 / 17 (5.88%)
occurrences (all)	7	5	2
Injection site pain			

subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Injection site pruritus			
subjects affected / exposed	0 / 41 (0.00%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Injection site reaction			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Injury associated with device			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	4 / 41 (9.76%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	5	0	0
Mucosal dryness			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	4 / 41 (9.76%)	0 / 40 (0.00%)	2 / 17 (11.76%)
occurrences (all)	4	0	2
Pyrexia			
subjects affected / exposed	11 / 41 (26.83%)	8 / 40 (20.00%)	5 / 17 (29.41%)
occurrences (all)	17	16	7
Temperature intolerance			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	5 / 41 (12.20%)	3 / 40 (7.50%)	2 / 17 (11.76%)
occurrences (all)	5	3	3
Dyspnoea			
subjects affected / exposed	1 / 41 (2.44%)	3 / 40 (7.50%)	1 / 17 (5.88%)
occurrences (all)	1	3	1
Dyspnoea exertional			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 41 (0.00%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Wheezing			
subjects affected / exposed	2 / 41 (4.88%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	2	2	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	5 / 41 (12.20%)	3 / 40 (7.50%)	1 / 17 (5.88%)
occurrences (all)	6	3	1
Depressed mood			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	4 / 41 (9.76%)	3 / 40 (7.50%)	1 / 17 (5.88%)
occurrences (all)	4	3	1
Insomnia			
subjects affected / exposed	7 / 41 (17.07%)	8 / 40 (20.00%)	0 / 17 (0.00%)
occurrences (all)	7	9	0
Libido decreased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Mood swings			

subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Nervousness			
subjects affected / exposed	3 / 41 (7.32%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	3	1	0
Nightmare			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Panic attack			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	0	1	2
Investigations			
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Body temperature increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
International normalised ratio decreased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	1 / 41 (2.44%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
White blood cell count increased			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Upper respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Gingival injury			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Laceration			

subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Post procedural complication			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Road traffic accident			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Tachycardia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	1 / 41 (2.44%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Dizziness			
subjects affected / exposed	1 / 41 (2.44%)	5 / 40 (12.50%)	2 / 17 (11.76%)
occurrences (all)	1	6	2
Dysgeusia			
subjects affected / exposed	2 / 41 (4.88%)	2 / 40 (5.00%)	1 / 17 (5.88%)
occurrences (all)	2	2	1
Headache			
subjects affected / exposed	15 / 41 (36.59%)	14 / 40 (35.00%)	5 / 17 (29.41%)
occurrences (all)	21	25	10
Hyperaesthesia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Restless legs syndrome			

subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	22 / 41 (53.66%)	14 / 40 (35.00%)	9 / 17 (52.94%)
occurrences (all)	29	17	13
Coagulopathy			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Eosinopenia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Leukopenia			
subjects affected / exposed	6 / 41 (14.63%)	10 / 40 (25.00%)	6 / 17 (35.29%)
occurrences (all)	10	19	6
Lymphadenopathy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	5 / 41 (12.20%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	8	2	0
Monocytopenia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	12 / 41 (29.27%)	12 / 40 (30.00%)	2 / 17 (11.76%)
occurrences (all)	16	27	2
Thrombocytopenia			
subjects affected / exposed	11 / 41 (26.83%)	5 / 40 (12.50%)	4 / 17 (23.53%)
occurrences (all)	13	5	4
Ear and labyrinth disorders			
Ear discomfort			

subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Ear pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Dry eye			
subjects affected / exposed	2 / 41 (4.88%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Eye pain			
subjects affected / exposed	1 / 41 (2.44%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	1	1	1
Eye pruritus			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 41 (0.00%)	3 / 40 (7.50%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 41 (4.88%)	3 / 40 (7.50%)	0 / 17 (0.00%)
occurrences (all)	2	4	0
Abdominal pain upper			
subjects affected / exposed	2 / 41 (4.88%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	2	0	1
Anal pruritus			

subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	3 / 41 (7.32%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	4	1	0
Diarrhoea			
subjects affected / exposed	6 / 41 (14.63%)	2 / 40 (5.00%)	4 / 17 (23.53%)
occurrences (all)	11	6	7
Dry mouth			
subjects affected / exposed	2 / 41 (4.88%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	2	0	1
Dyspepsia			
subjects affected / exposed	2 / 41 (4.88%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	2	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Gingival bleeding			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Lip swelling			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	7 / 41 (17.07%)	8 / 40 (20.00%)	7 / 17 (41.18%)
occurrences (all)	8	11	8
Stomatitis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 41 (2.44%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	1	2	0
Vomiting			
subjects affected / exposed	3 / 41 (7.32%)	4 / 40 (10.00%)	4 / 17 (23.53%)
occurrences (all)	4	7	6
Hepatobiliary disorders			

Hyperbilirubinaemia			
subjects affected / exposed	1 / 41 (2.44%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	1	1	2
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	2 / 41 (4.88%)	4 / 40 (10.00%)	3 / 17 (17.65%)
occurrences (all)	2	4	3
Dermal cyst			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Dermatitis allergic			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Dry skin			
subjects affected / exposed	2 / 41 (4.88%)	5 / 40 (12.50%)	1 / 17 (5.88%)
occurrences (all)	3	5	1
Erythema			
subjects affected / exposed	1 / 41 (2.44%)	1 / 40 (2.50%)	2 / 17 (11.76%)
occurrences (all)	1	1	3
Pruritus			
subjects affected / exposed	3 / 41 (7.32%)	5 / 40 (12.50%)	2 / 17 (11.76%)
occurrences (all)	4	7	3
Pruritus generalised			
subjects affected / exposed	6 / 41 (14.63%)	4 / 40 (10.00%)	7 / 17 (41.18%)
occurrences (all)	7	4	7
Rash			
subjects affected / exposed	8 / 41 (19.51%)	5 / 40 (12.50%)	7 / 17 (41.18%)
occurrences (all)	9	6	10
Rash generalised			
subjects affected / exposed	0 / 41 (0.00%)	4 / 40 (10.00%)	2 / 17 (11.76%)
occurrences (all)	0	4	2
Rash macular			

subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Rash maculo-papular			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Rash pruritic			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Hypothyroidism			
subjects affected / exposed	2 / 41 (4.88%)	2 / 40 (5.00%)	0 / 17 (0.00%)
occurrences (all)	2	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 41 (4.88%)	3 / 40 (7.50%)	2 / 17 (11.76%)
occurrences (all)	3	4	2
Arthritis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	3 / 41 (7.32%)	3 / 40 (7.50%)	0 / 17 (0.00%)
occurrences (all)	3	4	0
Costochondritis			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	5 / 41 (12.20%)	7 / 40 (17.50%)	2 / 17 (11.76%)
occurrences (all)	6	8	4
Pain in extremity			
subjects affected / exposed	2 / 41 (4.88%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	3	0	0
Infections and infestations			

Asymptomatic bacteriuria			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Body tinea			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Hordeolum			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	1 / 41 (2.44%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	2 / 41 (4.88%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Oral herpes			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Periodontitis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 40 (2.50%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Tooth abscess			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 41 (4.88%)	0 / 40 (0.00%)	2 / 17 (11.76%)
occurrences (all)	2	0	3
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	4 / 41 (9.76%)	3 / 40 (7.50%)	2 / 17 (11.76%)
occurrences (all)	4	3	2
Dehydration			
subjects affected / exposed	1 / 41 (2.44%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Hyperphosphataemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 41 (0.00%)	0 / 40 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	2 / 41 (4.88%)	2 / 40 (5.00%)	1 / 17 (5.88%)
occurrences (all)	3	2	1

Non-serious adverse events	GSK2336805 60 mg, Genotype 4 HCV		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	2		
Chills			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Drug withdrawal syndrome			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Fatigue			

subjects affected / exposed	4 / 13 (30.77%)			
occurrences (all)	4			
Feeling hot				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Influenza like illness				
subjects affected / exposed	8 / 13 (61.54%)			
occurrences (all)	8			
Injection site bruising				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Injection site erythema				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Injection site pain				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Injection site pruritus				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Injection site reaction				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Injury associated with device				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Irritability				
subjects affected / exposed	2 / 13 (15.38%)			
occurrences (all)	2			
Mucosal dryness				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Non-cardiac chest pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pain				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Temperature intolerance			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Dyspnoea			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	2		
Dyspnoea exertional			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Epistaxis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	2		
Oropharyngeal pain			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Wheezing			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	2		
Depressed mood			

subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	3		
Libido decreased			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Mood swings			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Nervousness			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Nightmare			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Panic attack			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Investigations			
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Body temperature increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
International normalised ratio decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Weight decreased			

subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
White blood cell count increased			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Upper respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gingival injury			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Laceration			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Post procedural complication			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Road traffic accident			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Dizziness			

subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Dysgeusia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	4 / 13 (30.77%)		
occurrences (all)	4		
Hyperaesthesia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Restless legs syndrome			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Syncope			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Coagulopathy			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Eosinopenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Leukopenia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Lymphadenopathy			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Lymphopenia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	2		

Monocytopenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	4		
Thrombocytopenia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Ear pain			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Tinnitus			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Vertigo			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	3		
Eye disorders			
Conjunctivitis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Dry eye			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Eye pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eye pruritus			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Vision blurred			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	3		
Anal pruritus			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	3		
Dry mouth			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Dyspepsia			
subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	3		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gingival bleeding			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Lip swelling			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	4 / 13 (30.77%)		
occurrences (all)	4		

Stomatitis			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Toothache			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Dermal cyst			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dermatitis allergic			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	3		
Pruritus generalised			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	4		
Rash generalised			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rash macular			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rash pruritic			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypothyroidism			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Arthritis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Costochondritis			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	3		
Pain in extremity			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Body tinea			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Herpes simplex			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hordeolum			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Nasopharyngitis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Periodontitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Tooth abscess subjects affected / exposed occurrences (all) Urinary tract infection subjects affected / exposed occurrences (all)	 1 / 13 (7.69%) 1 0 / 13 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all) Dehydration subjects affected / exposed occurrences (all) Hyperphosphataemia subjects affected / exposed occurrences (all) Hypokalaemia subjects affected / exposed occurrences (all) Hypophosphataemia subjects affected / exposed occurrences (all)	 3 / 13 (23.08%) 3 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported