



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 | v2 (current) |
| This version publication date | 25 March 2016 |
| First version publication date | 21 May 2015 |
| Version creation reason | • Correction of full data set Minor corrections required. |

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 | 43.7 | 40.8 | 39.4 |
| standard deviation | ± 13.23 | ± 9.87 | ± 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 standard deviation | 45.3 ± 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

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 population.

| | |
|----------------|---------|
| 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 | 1 | 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 (V_z/F) at Week 12

| | |
|-----------------|---|
| End point title | Apparent volume of distribution (V _z /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 | -1.05 (± 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

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

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 occurrences (all) | 0 / 41 (0.00%) 0 | 1 / 40 (2.50%) 1 | 0 / 17 (0.00%) 0 |
| Nervousness subjects affected / exposed occurrences (all) | 3 / 41 (7.32%) 3 | 1 / 40 (2.50%) 1 | 0 / 17 (0.00%) 0 |
| Nightmare subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 1 / 17 (5.88%) 1 |
| Panic attack subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 1 / 40 (2.50%) 1 | 1 / 17 (5.88%) 2 |
| Investigations Blood thyroid stimulating hormone increased subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 1 / 17 (5.88%) 1 |
| Body temperature increased subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 1 / 17 (5.88%) 1 |
| International normalised ratio decreased subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 1 / 17 (5.88%) 1 |
| Weight decreased subjects affected / exposed occurrences (all) | 1 / 41 (2.44%) 1 | 2 / 40 (5.00%) 2 | 0 / 17 (0.00%) 0 |
| White blood cell count increased subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 17 (0.00%) 0 |
| Injury, poisoning and procedural complications Gingival injury subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 17 (0.00%) 0 |
| Laceration subjects affected / exposed occurrences (all) | 1 / 41 (2.44%) 1 | 0 / 40 (0.00%) 0 | 1 / 17 (5.88%) 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 occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 17 (0.00%) 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 occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 17 (0.00%) 0 |
| Tinnitus subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 17 (0.00%) 0 |
| Vertigo subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 17 (0.00%) 0 |
| Eye disorders Conjunctivitis subjects affected / exposed occurrences (all) | 1 / 41 (2.44%) 1 | 0 / 40 (0.00%) 0 | 0 / 17 (0.00%) 0 |
| Dry eye subjects affected / exposed occurrences (all) | 2 / 41 (4.88%) 2 | 0 / 40 (0.00%) 0 | 0 / 17 (0.00%) 0 |
| Eye pain subjects affected / exposed occurrences (all) | 1 / 41 (2.44%) 1 | 1 / 40 (2.50%) 1 | 1 / 17 (5.88%) 1 |
| Eye pruritus subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 17 (0.00%) 0 |
| Vision blurred subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 3 / 40 (7.50%) 3 | 0 / 17 (0.00%) 0 |
| Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) | 2 / 41 (4.88%) 2 | 3 / 40 (7.50%) 4 | 0 / 17 (0.00%) 0 |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 2 / 41 (4.88%) 2 | 0 / 40 (0.00%) 0 | 1 / 17 (5.88%) 1 |
| Anal pruritus subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 1 / 17 (5.88%) 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 occurrences (all) | 1 / 41 (2.44%) 1 | 0 / 40 (0.00%) 0 | 1 / 17 (5.88%) 1 |
| Rash pruritic subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 1 / 40 (2.50%) 3 | 0 / 17 (0.00%) 0 |
| Endocrine disorders Hyperthyroidism subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 1 / 40 (2.50%) 1 | 1 / 17 (5.88%) 1 |
| Hypothyroidism subjects affected / exposed occurrences (all) | 2 / 41 (4.88%) 2 | 2 / 40 (5.00%) 2 | 0 / 17 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 2 / 41 (4.88%) 3 | 3 / 40 (7.50%) 4 | 2 / 17 (11.76%) 2 |
| Arthritis subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 0 / 17 (0.00%) 0 |
| Back pain subjects affected / exposed occurrences (all) | 3 / 41 (7.32%) 3 | 3 / 40 (7.50%) 4 | 0 / 17 (0.00%) 0 |
| Costochondritis subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 1 / 17 (5.88%) 1 |
| Myalgia subjects affected / exposed occurrences (all) | 5 / 41 (12.20%) 6 | 7 / 40 (17.50%) 8 | 2 / 17 (11.76%) 4 |
| Pain in extremity subjects affected / exposed occurrences (all) | 2 / 41 (4.88%) 3 | 0 / 40 (0.00%) 0 | 0 / 17 (0.00%) 0 |
| Infections and infestations Asymptomatic bacteriuria subjects affected / exposed occurrences (all) | 0 / 41 (0.00%) 0 | 0 / 40 (0.00%) 0 | 1 / 17 (5.88%) 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 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 41 (0.00%) | 0 / 40 (0.00%) | 1 / 17 (5.88%) |
| occurrences (all) | 0 | 0 | 1 |
| 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 occurrences (all) | 2 / 13 (15.38%) 2 | | |
| Temperature intolerance subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | | |
| Reproductive system and breast disorders Erectile dysfunction subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | | |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all) Dyspnoea exertional subjects affected / exposed occurrences (all) Epistaxis subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all) Wheezing subjects affected / exposed occurrences (all) | 2 / 13 (15.38%) 2 1 / 13 (7.69%) 2 1 / 13 (7.69%) 1 1 / 13 (7.69%) 2 1 / 13 (7.69%) 1 0 / 13 (0.00%) 0 | | |
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) Depressed mood subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 2 1 / 13 (7.69%) 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 occurrences (all) | 1 / 13 (7.69%) 1 | | |
| Injury, poisoning and procedural complications | | | |
| 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 occurrences (all) | 1 / 13 (7.69%) 1 | | |
| Ear and labyrinth disorders | | | |
| Ear discomfort subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | | |
| Ear pain subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | | |
| Tinnitus subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | | |
| Vertigo subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 3 | | |
| Eye disorders | | | |
| Conjunctivitis subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | | |
| Dry eye subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | | |
| Eye pain subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | | |
| Eye pruritus subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | | |
| Vision blurred subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal pain subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 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 | 1 / 13 (7.69%) | | |
| occurrences (all) | 1 | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 13 (0.00%) | | |
| occurrences (all) | 0 | | |

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