



Clinical trial results:

A Randomized, Double-Blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Adults with Chronic Hepatitis C Virus Genotype 2 Infection (ENDURANCE-2)

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2015-002348-14 |
| Trial protocol | BE PT LT IT |
| Global end of trial date | 23 February 2017 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 02 February 2018 |
| First version publication date | 02 February 2018 |

Trial information

Trial identification

| | |
|-----------------------|---------|
| Sponsor protocol code | M15-464 |
|-----------------------|---------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02640482 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | AbbVie Deutschland GmbH & Co. KG |
| Sponsor organisation address | AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6-4UB |
| Public contact | Global Medical Services, AbbVie, 001 800-633-9110, |
| Scientific contact | Neddie Zadeikis, AbbVie, neddie.zadeikis@abbvie.com |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 23 February 2017 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 23 February 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the safety and efficacy of ABT-493/ABT-530 in adults with genotype 2 chronic hepatitis C virus (HCV) infection.

Protection of trial subjects:

Subject read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 27 November 2015 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Italy: 54 |
| Country: Number of subjects enrolled | Korea, Republic of: 65 |
| Country: Number of subjects enrolled | Taiwan: 41 |
| Country: Number of subjects enrolled | United States: 53 |
| Country: Number of subjects enrolled | Portugal: 7 |
| Country: Number of subjects enrolled | Belgium: 21 |
| Country: Number of subjects enrolled | France: 45 |
| Country: Number of subjects enrolled | Lithuania: 18 |
| Worldwide total number of subjects | 304 |
| EEA total number of subjects | 145 |

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) | 203 |
| From 65 to 84 years | 101 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Safety population: All participants who received at least one dose of study drug.

Pre-assignment

Screening details:

A total of 304 subjects were enrolled of which 302 received at least 1 dose of study drug and were included in the intent-to-treat (ITT) population (N=302; 202 in Arm A and 100 in Arm B). Most efficacy analyses were performed on Arm A only (N=202) and excluded prior sofosbuvir (SOF) + ribavirin (RBV) ± pegylated-interferon (pegIFN) failures (N=6).

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 | Investigator, Subject |

Arms

| | |
|------------------------------|----------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Arm A DB Active Drug |

Arm description:

ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks (double-blind [DB] treatment period)

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | ABT-493/ABT-530 |
| Investigational medicinal product code | |
| Other name | ABT-493 also known as glecaprevir, ABT-530 also known as pibrentasvir, MAVIRET |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Tablet; ABT-493 coformulated with ABT-530 administered orally

| | |
|------------------|---------------------------------|
| Arm title | Arm B DB Placebo Then OL Active |
|------------------|---------------------------------|

Arm description:

Placebo for ABT-493/ABT-530 QD for 12 weeks (DB treatment period) followed by ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks (open-label [OL] treatment period)

| | |
|--|----------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Placebo tablet administered orally

| | |
|--|--|
| Investigational medicinal product name | ABT-493/ABT-530 |
| Investigational medicinal product code | |
| Other name | ABT-493 also known as glecaprevir, ABT-530 also known as pibrentasvir, MAVIRET |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Tablet; ABT-493 coformulated with ABT-530 administered orally.

| Number of subjects in period 1^[1] | Arm A DB Active Drug | Arm B DB Placebo Then OL Active |
|---|----------------------|---------------------------------|
| Started | 202 | 100 |
| Completed | 199 | 100 |
| Not completed | 3 | 0 |
| Lost to follow-up | 3 | - |

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 304 subjects were enrolled of which 302 received at least 1 dose of study drug and were included in the intent-to-treat (ITT) population (N = 302; 202 subjects in Arm A and 100 subjects in Arm B). Most efficacy analyses were performed on Arm A only (N = 202) and excluded prior SOF + RBV ± pegIFN failures (N = 6).

Baseline characteristics

Reporting groups

| | |
|-----------------------|----------------------|
| Reporting group title | Arm A DB Active Drug |
|-----------------------|----------------------|

Reporting group description:

ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks (double-blind [DB] treatment period)

| | |
|-----------------------|---------------------------------|
| Reporting group title | Arm B DB Placebo Then OL Active |
|-----------------------|---------------------------------|

Reporting group description:

Placebo for ABT-493/ABT-530 QD for 12 weeks (DB treatment period) followed by ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks (open-label [OL] treatment period)

| Reporting group values | Arm A DB Active Drug | Arm B DB Placebo Then OL Active | Total |
|------------------------|----------------------|---------------------------------|-------|
| Number of subjects | 202 | 100 | 302 |
| Age categorical | | | |
| Units: Subjects | | | |

| | | | |
|--------------------|---------|---------|-----|
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 56.77 | 57.60 | |
| standard deviation | ± 12.79 | ± 12.04 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 104 | 55 | 159 |
| Male | 98 | 45 | 143 |

End points

End points reporting groups

| | |
|--|---------------------------------|
| Reporting group title | Arm A DB Active Drug |
| Reporting group description: ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks (double-blind [DB] treatment period) | |
| Reporting group title | Arm B DB Placebo Then OL Active |
| Reporting group description: Placebo for ABT-493/ABT-530 QD for 12 weeks (DB treatment period) followed by ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks (open-label [OL] treatment period) | |

Primary: Percentage of Participants With Sustained Virologic Response 12 Weeks Post-treatment (SVR12) in Arm A DB Active Drug Excluding Prior SOF + Ribavirin (RBV) ± pegIFN Failures: Noninferiority Analysis

| | |
|---|---|
| End point title | Percentage of Participants With Sustained Virologic Response 12 Weeks Post-treatment (SVR12) in Arm A DB Active Drug Excluding Prior SOF + Ribavirin (RBV) ± pegIFN Failures: Noninferiority Analysis ^{[1][2]} |
| End point description: SVR12 was defined as plasma HCV RNA level <LLOQ 12 weeks after the last dose of study drug. The primary efficacy endpoint was the noninferiority of the percentage of participants who achieved SVR12 in Arm A Double Blind (DB) Active Drug excluding prior SOF + RBV ± pegIFN failures compared with the historical control rate for patients treated with the current standard of care (SOC) (SOF + RBV for 12 weeks). The lower confidence bound of the 2-sided 95% confidence interval (95% CI) for the percentage of participants with SVR12 must exceed 89% to achieve noninferiority. | |
| End point type | Primary |
| End point timeframe: 12 weeks after the last actual dose of active study drug | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The noninferiority of the rate of sustained virologic response at 12 weeks after treatment for Arm A as compared with the historical rate for patients treated with the current standard of care (SOF + RBV for 12 weeks) was analyzed; the lower confidence bound of the 2-sided 95% CI for the percentage of participants with sustained virologic response at 12 weeks after treatment must exceed 89% to achieve noninferiority.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The primary endpoint included Arm A.

| End point values | Arm A DB Active Drug | | | |
|-----------------------------------|----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 196 ^[3] | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 99.5 (98.5 to 100) | | | |

Notes:

[3] - ITT participants in Arm A excluding participants with prior SOF + RBV ± pegIFN failures.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With SVR12 in Arm A DB Active Drug Excluding Prior SOF + RBV ± pegIFN Failures: Superiority Analysis

| | |
|-----------------|--|
| End point title | Percentage of Participants With SVR12 in Arm A DB Active Drug Excluding Prior SOF + RBV ± pegIFN Failures: Superiority Analysis ^[4] |
|-----------------|--|

End point description:

SVR12 was defined as plasma HCV RNA level <LLOQ 12 weeks after the last dose of study drug. The secondary efficacy endpoint was the superiority of the percentage of participants who achieved SVR12 in Arm A Double Blind (DB) Active Drug excluding prior SOF + RBV ± pegIFN failures compared with the historical control rate for patients treated with the current standard of care (SOC) (SOF + RBV for 12 weeks). The lower confidence bound of the 2-sided 95% CI for the percentage of participants with SVR12 must exceed 95% to achieve superiority.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

12 weeks after the last actual dose of active study drug

Notes:

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

Justification: The secondary endpoint included Arm A.

| | | | | |
|-----------------------------------|----------------------|--|--|--|
| End point values | Arm A DB Active Drug | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 196 ^[5] | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 99.5 (98.5 to 100) | | | |

Notes:

[5] - ITT participants in Arm A excluding participants with prior SOF + RBV ± pegIFN failures.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With On-treatment Virologic Failure in Arm A DB Active Drug Excluding Prior SOF + RBV ± pegIFN Failures

| | |
|-----------------|---|
| End point title | Percentage of Participants With On-treatment Virologic Failure in Arm A DB Active Drug Excluding Prior SOF + RBV ± pegIFN Failures ^[6] |
|-----------------|---|

End point description:

On-treatment virologic failure was defined as confirmed increase of > 1 log(subscript)10(subscript) IU/mL above the lowest value of post-baseline HCV RNA during treatment; confirmed HCV RNA ≥ 100 IU/mL after HCV RNA < LLOQ during treatment, or HCV RNA ≥ LLOQ at end of treatment with at least 6 weeks of treatment.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Week 12 post baseline

Notes:

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

Justification: The secondary endpoint included Arm A.

| | | | | |
|-----------------------------------|----------------------|--|--|--|
| End point values | Arm A DB Active Drug | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 196 ^[7] | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0 to 1.9) | | | |

Notes:

[7] - ITT participants in Arm A excluding participants with prior SOF + RBV ± pegIFN failures.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Post-treatment Relapse in Arm A DB Active Drug Excluding Prior SOF + RBV ± pegIFN Failures

| | |
|-----------------|---|
| End point title | Percentage of Participants With Post-treatment Relapse in Arm A DB Active Drug Excluding Prior SOF + RBV ± pegIFN Failures ^[8] |
|-----------------|---|

End point description:

Post-treatment relapse was defined as confirmed HCV RNA \geq LLOQ between the end of DB treatment and 12 weeks after the last dose of active study drug among participants who completed treatment with HCV RNA levels $<$ LLOQ at the end of treatment, excluding reinfection.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Between End of Treatment (Week 12) and 12 weeks after the last dose of Arm A DB active drug (up to Week 24)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The secondary endpoint included Arm A.

| | | | | |
|-----------------------------------|----------------------|--|--|--|
| End point values | Arm A DB Active Drug | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 195 ^[9] | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0 to 1.9) | | | |

Notes:

[9] - ITT: Arm A, HCV RNA $<$ LLOQ at final treatment, completed DB, excluding prior SOF+RBV±pegIFN failures

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With SVR12 in Arm A DB Active Drug With Prior SOF + RBV ± pegIFN Failure

| | |
|-----------------|---|
| End point title | Percentage of Participants With SVR12 in Arm A DB Active Drug With Prior SOF + RBV ± pegIFN Failure ^[10] |
|-----------------|---|

End point description:

SVR12 was defined as HCV RNA level $<$ LLOQ 12 weeks after the last dose of active study drug.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

12 weeks after the last actual dose of active study drug

Notes:

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

Justification: The secondary endpoint included Arm A.

| End point values | Arm A DB Active Drug | | | |
|-----------------------------------|-------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 6 ^[11] | | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 100 | | | |

Notes:

[11] - ITT participants in Arm A DB with prior SOF + RBV ± pegIFN failures.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events (TEAEs) and serious adverse events (TESAEs) were collected from initial study drug administration until 30 days after the last dose of study drug (up to 16 weeks) in both the double-blind (DB) open-label (OL) periods.

Adverse event reporting additional description:

TEAEs and TESAEs are defined as any AE or SAE with an onset date after the first dose of study drug until 30 days after the last dose of study drug (or until prior to the first dose of open-label active drug for subjects who received DB placebo then OL active study drug) and collected whether elicited or spontaneously reported by the participant.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 19.0 |

Reporting groups

| | |
|-----------------------|----------------------|
| Reporting group title | Arm A DB Active Drug |
|-----------------------|----------------------|

Reporting group description:

ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks (double-blind [DB] treatment period)

| | |
|-----------------------|------------------|
| Reporting group title | Arm B DB Placebo |
|-----------------------|------------------|

Reporting group description:

Placebo for ABT-493/ABT-530 QD for 12 weeks (DB treatment period)

| | |
|-----------------------|----------------------|
| Reporting group title | Arm B OL Active Drug |
|-----------------------|----------------------|

Reporting group description:

ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks (open-label [OL] treatment period)

| Serious adverse events | Arm A DB Active Drug | Arm B DB Placebo | Arm B OL Active Drug |
|---|----------------------|------------------|----------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 202 (1.49%) | 1 / 100 (1.00%) | 1 / 100 (1.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Ankle fracture | | | |
| subjects affected / exposed | 1 / 202 (0.50%) | 0 / 100 (0.00%) | 0 / 100 (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 |
| Joint dislocation | | | |
| subjects affected / exposed | 1 / 202 (0.50%) | 0 / 100 (0.00%) | 0 / 100 (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 | 1 / 202 (0.50%) | 0 / 100 (0.00%) | 0 / 100 (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 |
| Hepatobiliary disorders | | | |
| Bile duct stone | | | |
| subjects affected / exposed | 1 / 202 (0.50%) | 0 / 100 (0.00%) | 0 / 100 (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 |
| Musculoskeletal and connective tissue disorders | | | |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 0 / 202 (0.00%) | 1 / 100 (1.00%) | 1 / 100 (1.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | Arm A DB Active Drug | Arm B DB Placebo | Arm B OL Active Drug |
|---|----------------------|-------------------|----------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 75 / 202 (37.13%) | 38 / 100 (38.00%) | 31 / 100 (31.00%) |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 2 / 202 (0.99%) | 5 / 100 (5.00%) | 2 / 100 (2.00%) |
| occurrences (all) | 2 | 5 | 2 |
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 6 / 202 (2.97%) | 5 / 100 (5.00%) | 1 / 100 (1.00%) |
| occurrences (all) | 6 | 6 | 1 |
| Headache | | | |
| subjects affected / exposed | 24 / 202 (11.88%) | 12 / 100 (12.00%) | 8 / 100 (8.00%) |
| occurrences (all) | 32 | 12 | 8 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |

| | | | |
|--|-------------------------|-------------------------|----------------------|
| subjects affected / exposed occurrences (all) | 19 / 202 (9.41%) 21 | 8 / 100 (8.00%) 8 | 5 / 100 (5.00%) 5 |
| Fatigue subjects affected / exposed occurrences (all) | 23 / 202 (11.39%) 24 | 10 / 100 (10.00%) 10 | 5 / 100 (5.00%) 5 |
| Gastrointestinal disorders | | | |
| Diarrhoea subjects affected / exposed occurrences (all) | 20 / 202 (9.90%) 20 | 3 / 100 (3.00%) 3 | 5 / 100 (5.00%) 5 |
| Nausea subjects affected / exposed occurrences (all) | 15 / 202 (7.43%) 16 | 4 / 100 (4.00%) 4 | 8 / 100 (8.00%) 8 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 4 / 202 (1.98%) 4 | 5 / 100 (5.00%) 6 | 1 / 100 (1.00%) 1 |
| Skin and subcutaneous tissue disorders | | | |
| Pruritus subjects affected / exposed occurrences (all) | 12 / 202 (5.94%) 12 | 6 / 100 (6.00%) 6 | 5 / 100 (5.00%) 6 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|--|
| 20 August 2015 | The purpose of this amendment was to revise the inclusion criteria, to add a list of potential birth control options, and to expand the categories of treatment-experienced subjects allowed (allowed sofosbuvir [SOF] + ribavirin [RBV] ± pegIFN treatment failures in the study). In addition, this amendment specified a reflex assay used for determination of Chronic Hepatitis C Virus (HCV) genotype/subtype and updated the historical control rate of the Sustained Virologic Response 12 Weeks Post-treatment (SVR12) for primary and secondary efficacy endpoints and the determination of sample size to accommodate the expanded study population |
| 14 October 2015 | The purpose of this amendment was to update the inclusion criteria to require only 1 effective method of contraception and added text detailing allowable methods of contraceptives. In addition, this amendment included an update to the definitions of prior treatment experience, removed prior SOF + RBV ± pegIFN failures from the analysis of the primary endpoint and made it a separate secondary endpoint, and allowed an increase of the total sample size for the study to up to 321 subjects, particularly to increase the sample size of subjects who failed a previous SOF-containing regimen. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported