



## Clinical trial results:

### An Open-Label, Single Arm Study to Evaluate the Safety and Efficacy of Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir in Treatment-Naïve Adults With Genotype 1b Hepatitis C Virus (HCV) Without Cirrhosis (GARNET)

#### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2015-003370-33   |
| Trial protocol           | DE GB ES IT      |
| Global end of trial date | 01 December 2016 |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 02 December 2017 |
| First version publication date | 02 December 2017 |

#### Trial information

##### Trial identification

|                       |         |
|-----------------------|---------|
| Sponsor protocol code | M15-684 |
|-----------------------|---------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT02582632 |
| 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               | Daniel E. Cohen, MD, AbbVie, 001 847-938-1494, daniel.cohen@abbvie.com                            |
| Scientific contact           | Daniel E. Cohen, MD, AbbVie, 001 847-938-1494, daniel.cohen@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                       | 01 December 2016 |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 01 December 2016 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the efficacy (the percentage of subjects achieving SVR12 [HCV ribonucleic acid {RNA} < lower limit of quantification {LLOQ} 12 weeks following treatment]) of coformulated ombitasvir/paritaprevir/ritonavir and dasabuvir for 8 weeks in treatment-naïve adults with HCV GT1b infection without cirrhosis.

Protection of trial subjects:

Participant and/or legal guardian read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

|                                                           |                  |
|-----------------------------------------------------------|------------------|
| Actual start date of recruitment                          | 24 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 | Canada: 17         |
| Country: Number of subjects enrolled | Australia: 17      |
| Country: Number of subjects enrolled | France: 27         |
| Country: Number of subjects enrolled | Germany: 20        |
| Country: Number of subjects enrolled | United Kingdom: 15 |
| Country: Number of subjects enrolled | Israel: 21         |
| Country: Number of subjects enrolled | Italy: 22          |
| Country: Number of subjects enrolled | Spain: 27          |
| Worldwide total number of subjects   | 166                |
| EEA total number of subjects         | 111                |

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          | 0 |

|                           |     |
|---------------------------|-----|
| months)                   |     |
| Children (2-11 years)     | 0   |
| Adolescents (12-17 years) | 0   |
| Adults (18-64 years)      | 137 |
| From 65 to 84 years       | 29  |
| 85 years and over         | 0   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Eligible subjects had up to 35 days following the Screening Visit to enroll into the study.

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall Study (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Not applicable                 |
| Blinding used                | Not blinded                    |

### Arms

|                  |                                                 |
|------------------|-------------------------------------------------|
| <b>Arm title</b> | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |
|------------------|-------------------------------------------------|

Arm description:

ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) and dasabuvir (250 mg twice daily) administered for 8 weeks

|                                        |                                                                                         |
|----------------------------------------|-----------------------------------------------------------------------------------------|
| Arm type                               | Experimental                                                                            |
| Investigational medicinal product name | Ombitasvir/Paritaprevir/Ritonavir 12.5 mg/75 mg/50 mg Film-Coated Tablets               |
| Investigational medicinal product code |                                                                                         |
| Other name                             | ABT-267/ABT-450/r, ombitasvir also known as ABT-267, paritaprevir also known as ABT-450 |
| Pharmaceutical forms                   | Film-coated tablet                                                                      |
| Routes of administration               | Oral use                                                                                |

Dosage and administration details:

Ombitasvir/paritaprevir/ritonavir will be taken orally as 2 tablets once daily which corresponds to a 25 mg ombitasvir/150 mg paritaprevir/100 mg ritonavir dose once daily.

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Investigational medicinal product name | Dasabuvir 250 mg Film-Coated Tablets |
| Investigational medicinal product code |                                      |
| Other name                             |                                      |
| Pharmaceutical forms                   | Film-coated tablet                   |
| Routes of administration               | Oral use                             |

Dosage and administration details:

Dasabuvir will be taken orally as 1 tablet twice daily, which corresponds to a 250 mg dose twice daily.

|                                       |                                                 |
|---------------------------------------|-------------------------------------------------|
| <b>Number of subjects in period 1</b> | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |
| Started                               | 166                                             |
| Completed                             | 165                                             |
| Not completed                         | 1                                               |
| Not specified                         | 1                                               |



## Baseline characteristics

### Reporting groups

|                       |                                                 |
|-----------------------|-------------------------------------------------|
| Reporting group title | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |
|-----------------------|-------------------------------------------------|

Reporting group description:

ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) and dasabuvir (250 mg twice daily) administered for 8 weeks

| Reporting group values                                                  | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir | Total |  |
|-------------------------------------------------------------------------|-------------------------------------------------|-------|--|
| Number of subjects                                                      | 166                                             | 166   |  |
| Age categorical<br>Units: Subjects                                      |                                                 |       |  |
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 51.3<br>± 13.42                                 | -     |  |
| Gender categorical<br>Units: Subjects                                   |                                                 |       |  |
| Female                                                                  | 94                                              | 94    |  |
| Male                                                                    | 72                                              | 72    |  |

## End points

### End points reporting groups

|                                                                                                                                                                |                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Reporting group title                                                                                                                                          | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |
| Reporting group description:<br>ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) and dasabuvir (250 mg twice daily) administered for 8 weeks |                                                 |

### Primary: Percentage of Subjects Who Achieve Sustained Virologic Response 12 Weeks Post-treatment (SVR12)

|                 |                                                                                                                |
|-----------------|----------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Who Achieve Sustained Virologic Response 12 Weeks Post-treatment (SVR12) <sup>[1]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------|

End point description:

SVR12 is defined as hepatitis C virus (HCV) ribonucleic acid (RNA) < lower limit of quantification (LLOQ) 12 weeks after the last dose of study drugs without any confirmed quantifiable ( $\geq$  LLOQ) post-treatment value before or during that SVR window. Confidence interval calculated using the normal approximation to the binomial distribution.

Intent to Treat population: all enrolled subjects who received at least 1 dose of study drug. Flanking imputation.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

12 weeks after the last actual dose of study drug

Notes:

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

Justification: Descriptive statistics and confidence interval are presented, per protocol.

|                                  |                                                 |  |  |  |
|----------------------------------|-------------------------------------------------|--|--|--|
| <b>End point values</b>          | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |  |  |  |
| Subject group type               | Reporting group                                 |  |  |  |
| Number of subjects analysed      | 166                                             |  |  |  |
| Units: percentage of subjects    |                                                 |  |  |  |
| number (confidence interval 95%) | 97.6 (95.3 to 99.9)                             |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects With On-Treatment Virologic Failure During Treatment Period

|                 |                                                                                    |
|-----------------|------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects With On-Treatment Virologic Failure During Treatment Period |
|-----------------|------------------------------------------------------------------------------------|

End point description:

On-treatment virologic failure is defined as breakthrough (confirmed HCV RNA  $\geq$  LLOQ after HCV RNA < LLOQ during treatment, or confirmed increase from nadir in HCV RNA (two consecutive HCV RNA measurements  $> 1 \log^{10}$  IU/mL above nadir) at any time point during treatment) or failure to suppress during treatment (all on-treatment values of HCV RNA  $\geq$  LLOQ) with at least 6 weeks (defined

as study drug duration  $\geq 36$  days) of treatment. Confidence interval calculated using the normal approximation to the binomial distribution.

Intent to Treat population: all enrolled subjects who received at least 1 dose of study drug.

|                                  |           |
|----------------------------------|-----------|
| End point type                   | Secondary |
| End point timeframe:             |           |
| Up to 8 weeks while on treatment |           |

|                                  |                                                 |  |  |  |
|----------------------------------|-------------------------------------------------|--|--|--|
| <b>End point values</b>          | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |  |  |  |
| Subject group type               | Reporting group                                 |  |  |  |
| Number of subjects analysed      | 166                                             |  |  |  |
| Units: percentage of subjects    |                                                 |  |  |  |
| number (confidence interval 95%) | 0.6 (0.0 to 1.8)                                |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects With Post-Treatment Relapse12

|                 |                                                      |
|-----------------|------------------------------------------------------|
| End point title | Percentage of Subjects With Post-Treatment Relapse12 |
|-----------------|------------------------------------------------------|

End point description:

Relapse12 is defined as confirmed HCV RNA  $\geq$  LLOQ between end of treatment and 12 weeks after last actual dose of active study drug (up to and including the SVR12 window) excluding reinfection among subjects with HCV RNA  $<$  LLOQ at final treatment visit who complete treatment and have post-treatment HCV RNA data. Completion of treatment is defined as a study drug duration  $\geq 51$  days for subjects who receive 8 weeks of treatment. HCV reinfection is defined as confirmed HCV RNA  $\geq$  LLOQ after the end of treatment in a subject who had HCV RNA  $<$  LLOQ at final treatment visit, along with the post treatment detection of a different HCV genotype, subtype, or clade compared with baseline, as determined by phylogenetic analysis of the NS3 or NS5A, and/or NS5B gene sequences. Confidence interval calculated using the normal approximation to the binomial distribution.

Intent to Treat population: all enrolled participants who received at least 1 dose of study drug.

|                                              |           |
|----------------------------------------------|-----------|
| End point type                               | Secondary |
| End point timeframe:                         |           |
| Up to 12 weeks after last dose of study drug |           |

|                                  |                                                 |  |  |  |
|----------------------------------|-------------------------------------------------|--|--|--|
| <b>End point values</b>          | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |  |  |  |
| Subject group type               | Reporting group                                 |  |  |  |
| Number of subjects analysed      | 163                                             |  |  |  |
| Units: percentage of subjects    |                                                 |  |  |  |
| number (confidence interval 95%) | 1.2 (0.0 to 2.9)                                |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Female Subjects Responding With SVR12

|                 |                                                     |
|-----------------|-----------------------------------------------------|
| End point title | Percentage of Female Subjects Responding With SVR12 |
|-----------------|-----------------------------------------------------|

End point description:

SVR12 is defined as HCV RNA < LLOQ 12 weeks after the last dose of study drugs without any confirmed quantifiable ( $\geq$  LLOQ) post-treatment value before or during that SVR window. Confidence interval calculated using the normal approximation to the binomial distribution.

Intent to Treat population: all enrolled female subjects who received at least 1 dose of study drug. Flanking imputation.

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

End point timeframe:

12 weeks after the last actual dose of study drug

|                                  |                                                 |  |  |  |
|----------------------------------|-------------------------------------------------|--|--|--|
| <b>End point values</b>          | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |  |  |  |
| Subject group type               | Reporting group                                 |  |  |  |
| Number of subjects analysed      | 94                                              |  |  |  |
| Units: percentage of subjects    |                                                 |  |  |  |
| number (confidence interval 95%) | 97.9 (95.0 to 100.0)                            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects With Baseline HCV RNA < 6,000,000 IU/mL Responding With SVR12

|                 |                                                                                      |
|-----------------|--------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects With Baseline HCV RNA < 6,000,000 IU/mL Responding With SVR12 |
|-----------------|--------------------------------------------------------------------------------------|

End point description:

SVR12 is defined as HCV RNA < LLOQ 12 weeks after the last dose of study drugs without any confirmed quantifiable ( $\geq$  LLOQ) post-treatment value before or during that SVR window. Confidence interval calculated using the normal approximation to the binomial distribution.

Intent to Treat population: all enrolled subjects who received at least 1 dose of study drug and with baseline HCV RNA < 6,000,000 IU/mL. Flanking imputation.

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

End point timeframe:

Baseline and 12 weeks after the last actual dose of study drug

|                                  |                                                 |  |  |  |
|----------------------------------|-------------------------------------------------|--|--|--|
| <b>End point values</b>          | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |  |  |  |
| Subject group type               | Reporting group                                 |  |  |  |
| Number of subjects analysed      | 154                                             |  |  |  |
| Units: percentage of subjects    |                                                 |  |  |  |
| number (confidence interval 95%) | 98.1 (95.9 to 100.0)                            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Percentage of Subjects Who Achieve SVR12: mITT-GT Population

|                 |                                                              |
|-----------------|--------------------------------------------------------------|
| End point title | Percentage of Subjects Who Achieve SVR12: mITT-GT Population |
|-----------------|--------------------------------------------------------------|

End point description:

SVR12 is defined as HCV RNA < LLOQ 12 weeks after the last dose of study drugs without any confirmed quantifiable ( $\geq$  LLOQ) post-treatment value before or during that SVR window. Confidence interval calculated using the normal approximation to the binomial distribution.

The modified ITT (mITT)-GT population includes subjects who received at least 1 dose of study drug but excludes the subjects who do not have HCV GT1b infection. Flanking imputation.

|                |                     |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

12 weeks after the last actual dose of study drug

|                                  |                                                 |  |  |  |
|----------------------------------|-------------------------------------------------|--|--|--|
| <b>End point values</b>          | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |  |  |  |
| Subject group type               | Reporting group                                 |  |  |  |
| Number of subjects analysed      | 163                                             |  |  |  |
| Units: percentage of subjects    |                                                 |  |  |  |
| number (confidence interval 95%) | 98.2 (96.1 to 100.0)                            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

**Other pre-specified: Percentage of Subjects With On-Treatment Virologic Failure During Treatment Period: mITT-GT Population**

|                 |                                                                                                        |
|-----------------|--------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects With On-Treatment Virologic Failure During Treatment Period: mITT-GT Population |
|-----------------|--------------------------------------------------------------------------------------------------------|

End point description:

On-treatment virologic failure is defined as breakthrough (confirmed HCV RNA  $\geq$  LLOQ after HCV RNA  $<$  LLOQ during treatment, or confirmed increase from nadir in HCV RNA (two consecutive HCV rna measurements  $> 1 \log^{10}$  IU/mL above nadir) at any time point during treatment) or failure to suppress during treatment (all on-treatment values of HCV RNA  $\geq$  LLOQ) with at least 6 weeks (defined as study drug duration  $\geq 36$  days) of treatment. Confidence interval calculated using the Wilson score method.

The mITT-GT population includes subjects who received at least 1 dose of study drug but excludes the subjects who do not have HCV GT1b infection.

|                |                     |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

Up to 8 weeks while on treatment

|                                  |                                                 |  |  |  |
|----------------------------------|-------------------------------------------------|--|--|--|
| <b>End point values</b>          | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |  |  |  |
| Subject group type               | Reporting group                                 |  |  |  |
| Number of subjects analysed      | 163                                             |  |  |  |
| Units: percentage of subjects    |                                                 |  |  |  |
| number (confidence interval 95%) | 0 (0.0 to 2.3)                                  |  |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Other pre-specified: Percentage of Subjects With Post-Treatment Relapse12: mITT-GT Population**

|                 |                                                                          |
|-----------------|--------------------------------------------------------------------------|
| End point title | Percentage of Subjects With Post-Treatment Relapse12: mITT-GT Population |
|-----------------|--------------------------------------------------------------------------|

End point description:

Relapse12 is defined as confirmed HCV RNA  $\geq$  LLOQ between end of treatment and 12 weeks after last actual dose of active study drug (up to and including the SVR12 window) excluding reinfection among subjects with HCV RNA  $<$  LLOQ at final treatment visit who complete treatment and have post-treatment HCV RNA data. Completion of treatment is defined as a study drug duration  $\geq 51$  days for subjects who receive 8 weeks of treatment. HCV reinfection is defined as confirmed HCV RNA  $\geq$  LLOQ after the end of treatment in a subject who had HCV RNA  $<$  LLOQ at final treatment visit, along with the post treatment detection of a different HCV genotype, subtype, or clade compared with baseline, as determined by phylogenetic analysis of the NS3 or NS5A, and/or NS5B gene sequences. Confidence interval calculated using the normal approximation to the binomial distribution. Subjects who did not complete treatment, had no post treatment data, or had HCV RNA  $\geq$  LLOQ at Final Treatment Visit were not included.

|                |                     |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

Up to 12 weeks after last dose of study drug

|                                  |                                                 |  |  |  |
|----------------------------------|-------------------------------------------------|--|--|--|
| <b>End point values</b>          | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |  |  |  |
| Subject group type               | Reporting group                                 |  |  |  |
| Number of subjects analysed      | 161 <sup>[2]</sup>                              |  |  |  |
| Units: percentage of subjects    |                                                 |  |  |  |
| number (confidence interval 95%) | 1.2 (0.0 to 3.0)                                |  |  |  |

Notes:

[2] - mITT population

### Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Percentage of Female Subjects Responding With SVR12: mITT-GT Population

|                 |                                                                         |
|-----------------|-------------------------------------------------------------------------|
| End point title | Percentage of Female Subjects Responding With SVR12: mITT-GT Population |
|-----------------|-------------------------------------------------------------------------|

End point description:

SVR12 is defined as HCV RNA < LLOQ 12 weeks after the last dose of study drugs without any confirmed quantifiable ( $\geq$  LLOQ) post-treatment value before or during that SVR window. Confidence interval calculated using the normal approximation to the binomial distribution.

The mITT-GT population includes subjects who received at least 1 dose of study drug but excludes the subjects who do not have HCV GT1b infection; female subjects. Flanking imputation.

|                |                     |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

12 weeks after the last actual dose of study drug

|                                  |                                                 |  |  |  |
|----------------------------------|-------------------------------------------------|--|--|--|
| <b>End point values</b>          | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |  |  |  |
| Subject group type               | Reporting group                                 |  |  |  |
| Number of subjects analysed      | 93                                              |  |  |  |
| Units: percentage of subjects    |                                                 |  |  |  |
| number (confidence interval 95%) | 97.8 (94.9 to 100.0)                            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Percentage of Subjects With Baseline HCV RNA < 6,000,000 IU/mL Responding With SVR12: mITT-GT Population

|                                                                                                                                                                                                                                                                                     |                                                                                                          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                     | Percentage of Subjects With Baseline HCV RNA < 6,000,000 IU/mL Responding With SVR12: mITT-GT Population |
| End point description:                                                                                                                                                                                                                                                              |                                                                                                          |
| SVR12 is defined as HCV RNA < LLOQ 12 weeks after the last dose of study drugs without any confirmed quantifiable ( $\geq$ LLOQ) post-treatment value before or during that SVR window. Confidence interval calculated using the normal approximation to the binomial distribution. |                                                                                                          |
| The mITT-GT population includes subjects who received at least 1 dose of study drug but excludes the subjects who do not have HCV GT1b infection; subjects with baseline HCV RNA < 6,000,000 IU/mL. Flanking imputation.                                                            |                                                                                                          |
| End point type                                                                                                                                                                                                                                                                      | Other pre-specified                                                                                      |
| End point timeframe:                                                                                                                                                                                                                                                                |                                                                                                          |
| Baseline and 12 weeks after the last actual dose of study drug                                                                                                                                                                                                                      |                                                                                                          |

|                                  |                                                 |  |  |  |
|----------------------------------|-------------------------------------------------|--|--|--|
| <b>End point values</b>          | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |  |  |  |
| Subject group type               | Reporting group                                 |  |  |  |
| Number of subjects analysed      | 151                                             |  |  |  |
| Units: percentage of subjects    |                                                 |  |  |  |
| number (confidence interval 95%) | 98.7 (96.9 to 100.0)                            |  |  |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent AEs (TEAEs) were collected from first dose of study drug until 30 days after the last dose of study drug (up to 12 weeks); SAEs were collected from the time informed consent was obtained (up to 35 days prior to first dose of study drug)

Adverse event reporting additional description:

A TEAE is defined as any AE from the first dose of study drug to 30 days after the last dose.

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

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 19.0 |
|--------------------|------|

### Reporting groups

|                       |                                                 |
|-----------------------|-------------------------------------------------|
| Reporting group title | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |
|-----------------------|-------------------------------------------------|

Reporting group description:

ombitasvir/paritaprevir/ritonavir (25 mg/150 mg/100 mg once daily) and dasabuvir (250 mg twice daily) administered for 8 weeks

| Serious adverse events                            | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir |  |  |
|---------------------------------------------------|-------------------------------------------------|--|--|
| Total subjects affected by serious adverse events |                                                 |  |  |
| subjects affected / exposed                       | 2 / 166 (1.20%)                                 |  |  |
| number of deaths (all causes)                     | 0                                               |  |  |
| number of deaths resulting from adverse events    |                                                 |  |  |
| Nervous system disorders                          |                                                 |  |  |
| Syncope                                           |                                                 |  |  |
| subjects affected / exposed                       | 1 / 166 (0.60%)                                 |  |  |
| occurrences causally related to treatment / all   | 0 / 1                                           |  |  |
| deaths causally related to treatment / all        | 0 / 0                                           |  |  |
| Infections and infestations                       |                                                 |  |  |
| Gastroenteritis                                   |                                                 |  |  |
| subjects affected / exposed                       | 1 / 166 (0.60%)                                 |  |  |
| occurrences causally related to treatment / all   | 0 / 1                                           |  |  |
| deaths causally related to treatment / all        | 0 / 0                                           |  |  |

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

|                                                                                                                                                                                         |                                                      |  |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--|--|
| <b>Non-serious adverse events</b>                                                                                                                                                       | Ombitasvir/Paritaprevir/Ritonavir and Dasabuvir      |  |  |
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed                                                                                                    | 70 / 166 (42.17%)                                    |  |  |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)                                                                                                | 35 / 166 (21.08%)<br>36                              |  |  |
| General disorders and administration site conditions<br>Asthenia<br>subjects affected / exposed<br>occurrences (all)<br><br>Fatigue<br>subjects affected / exposed<br>occurrences (all) | 9 / 166 (5.42%)<br>11<br><br>28 / 166 (16.87%)<br>30 |  |  |
| Gastrointestinal disorders<br>Nausea<br>subjects affected / exposed<br>occurrences (all)                                                                                                | 11 / 166 (6.63%)<br>12                               |  |  |
| Skin and subcutaneous tissue disorders<br>Pruritus<br>subjects affected / exposed<br>occurrences (all)                                                                                  | 14 / 166 (8.43%)<br>15                               |  |  |
| Infections and infestations<br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)                                                                                      | 14 / 166 (8.43%)<br>14                               |  |  |

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported