



## Clinical trial results:

### A Phase II Randomized Clinical Trial to Study the Efficacy and Safety of the combination regimen of MK-5172 and MK-8742 ± Ribavirin (RBV) in Subjects with Chronic Hepatitis C Virus Infection

#### Summary

|                          |                   |
|--------------------------|-------------------|
| EudraCT number           | 2012-003354-89    |
| Trial protocol           | DE DK HU ES SE FR |
| Global end of trial date | 06 May 2015       |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 12 May 2016  |
| First version publication date | 12 May 2016  |

#### Trial information

##### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | 5172-035 |
|-----------------------|----------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT01717326 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Merck Sharp & Dohme Corp.  |
| Sponsor organisation address | 2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033                               |
| Public contact               | Clinical Trials Disclosure, Merck Sharp & Dohme Corp.,<br>ClinicalTrialsDisclosure@merck.com |
| Scientific contact           | Clinical Trials Disclosure, Merck Sharp & Dohme Corp.,<br>ClinicalTrialsDisclosure@merck.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:

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**Results analysis stage**

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|  |             |
|--|-------------|
| Analysis stage                                       | Final       |
| Date of interim/final analysis                       | 06 May 2015 |
| Is this the analysis of the primary completion data? | Yes         |
| Primary completion date                              | 06 May 2015 |
| Global end of trial reached?                         | Yes         |
| Global end of trial date                             | 06 May 2015 |
| Was the trial ended prematurely?                     | No          |

Notes:

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**General information about the trial**

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Main objective of the trial:

This is a study of the safety and efficacy of grazoprevir (MK-5172) in combination with elbasvir (MK-8742) ± ribavirin (RBV). The primary efficacy endpoint will be Sustained Virologic Response 12 weeks after the end of all study therapy (SVR12) in each of the treatment arms.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 07 February 2013 |
| Long term follow-up planned                               | Yes              |
| Long term follow-up rationale                             | Efficacy         |
| Long term follow-up duration                              | 3 Years          |
| Independent data monitoring committee (IDMC) involvement? | No               |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |                    |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Australia: 35      |
| Country: Number of subjects enrolled | Canada: 45         |
| Country: Number of subjects enrolled | Denmark: 40        |
| Country: Number of subjects enrolled | France: 117        |
| Country: Number of subjects enrolled | Hungary: 8         |
| Country: Number of subjects enrolled | Israel: 42         |
| Country: Number of subjects enrolled | New Zealand: 17    |
| Country: Number of subjects enrolled | Spain: 16          |
| Country: Number of subjects enrolled | Sweden: 15         |
| Country: Number of subjects enrolled | Turkey: 11         |
| Country: Number of subjects enrolled | United States: 227 |
| Worldwide total number of subjects   | 573                |
| EEA total number of subjects         | 196                |

Notes:

| <b>Subjects enrolled per age group</b>    |     |
|---|-----|
| 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)                      | 509 |
| From 65 to 84 years                       | 64  |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

Male/female participants with Hepatitis C Virus (HCV) genotype 1 (GT1) or GT3 who were either treatment-naïve (TN) or prior null responder (NR), cirrhotic (C) or noncirrhotic (NC), and monoinfected with HCV or coinfecting with HCV and human immunodeficiency virus (HIV) were recruited based on entry requirements for Parts A, B, C, or D.

### Pre-assignment

Screening details:

573 randomized on study: Part A=65 TN NC GT1 participants. Part B= 94 TN NC participants, 123 TN C participants, 130 NR participants (C and NC), and 59 TN HIV coinfecting participants. Part C= 61 TN NC GT1b participants. Part D= 41 TN NC GT3 participants. One participant randomized to A3 arm was treated on A2 arm (n=28 for safety).

### 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          |

Blinding implementation details:

Part A: Double-blindPart B: Open-labelPart C: Open-labelPart D: Open-label

### Arms

|                              |   |
|------------------------------|---|
| Are arms mutually exclusive? | Yes   |
| <b>Arm title</b>             | A1: TN NC Grazoprevir 100 mg + Elbasvir 20 mg + RBV-12 wk |

Arm description:

GT1a and GT1b participants receive Grazoprevir 100 mg tablet orally once daily (QD) for 12 weeks, Elbasvir 20 mg capsule and Placebo capsule orally QD for 12 weeks, RBV capsules orally twice daily (BID) for 24 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|  |              |
|--|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | Grazoprevir  |
| Investigational medicinal product code |              |
| Other name                             | MK-5172      |
| Pharmaceutical forms                   | Tablet       |
| Routes of administration               | Oral use     |

Dosage and administration details:

100 mg tablet orally QD

|  |          |
|--|----------|
| Investigational medicinal product name | Elbasvir |
| Investigational medicinal product code |          |
| Other name                             | MK-8742  |
| Pharmaceutical forms                   | Capsule  |
| Routes of administration               | Oral use |

Dosage and administration details:

Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD

|  |           |
|--|-----------|
| Investigational medicinal product name | Ribavirin |
| Investigational medicinal product code |           |
| Other name                             | Rebetol™  |
| Pharmaceutical forms                   | Capsule   |
| Routes of administration               | Oral use  |

Dosage and administration details:

Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight

|   |   |
|---|---|
| <b>Arm title</b>  | A2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk     |
| Arm description:  |   |
| GT1a and GT1b participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule and Placebo capsule orally QD for 12 weeks, RBV capsules orally BID for 24 weeks at a total daily dose from 800 to 1400 mg based on participant weight. |   |
| Arm type  | Experimental  |
| Investigational medicinal product name  | Grazoprevir   |
| Investigational medicinal product code  |   |
| Other name  | MK-5172   |
| Pharmaceutical forms  | Tablet  |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| 100 mg tablet orally QD   |   |
| Investigational medicinal product name  | Elbasvir  |
| Investigational medicinal product code  |   |
| Other name  | MK-8742   |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD  |   |
| Investigational medicinal product name  | Ribavirin   |
| Investigational medicinal product code  |   |
| Other name  | Rebetol™  |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight   |   |
| <b>Arm title</b>  | A3: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-12 wk      |
| Arm description:  |   |
| GT1b only participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.   |   |
| Arm type  | Experimental  |
| Investigational medicinal product name  | Elbasvir  |
| Investigational medicinal product code  |   |
| Other name  | MK-8742   |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD  |   |
| Investigational medicinal product name  | Grazoprevir   |
| Investigational medicinal product code  |   |
| Other name  | MK-5172   |
| Pharmaceutical forms  | Tablet  |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| 100 mg tablet orally QD   |   |
| <b>Arm title</b>  | B1: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
| Arm description:  |   |
| GT1a only participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight.                            |   |
| Arm type  | Experimental  |

|  |             |
|--|-------------|
| Investigational medicinal product name | Grazoprevir |
| Investigational medicinal product code |             |
| Other name                             | MK-5172     |
| Pharmaceutical forms                   | Tablet      |
| Routes of administration               | Oral use    |

Dosage and administration details:

100 mg tablet orally QD

|  |           |
|--|-----------|
| Investigational medicinal product name | Ribavirin |
| Investigational medicinal product code |           |
| Other name                             | Rebetol™  |
| Pharmaceutical forms                   | Capsule   |
| Routes of administration               | Oral use  |

Dosage and administration details:

Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight

|  |          |
|--|----------|
| Investigational medicinal product name | Elbasvir |
| Investigational medicinal product code |          |
| Other name                             | MK-8742  |
| Pharmaceutical forms                   | Capsule  |
| Routes of administration               | Oral use |

Dosage and administration details:

Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD

|                  |   |
|------------------|---|
| <b>Arm title</b> | B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|------------------|---|

Arm description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|  |              |
|--|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | Grazoprevir  |
| Investigational medicinal product code |              |
| Other name                             | MK-5172      |
| Pharmaceutical forms                   | Tablet       |
| Routes of administration               | Oral use     |

Dosage and administration details:

100 mg tablet orally QD

|  |           |
|--|-----------|
| Investigational medicinal product name | Ribavirin |
| Investigational medicinal product code |           |
| Other name                             | Rebetol™  |
| Pharmaceutical forms                   | Capsule   |
| Routes of administration               | Oral use  |

Dosage and administration details:

Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight

|  |          |
|--|----------|
| Investigational medicinal product name | Elbasvir |
| Investigational medicinal product code |          |
| Other name                             | MK-8742  |
| Pharmaceutical forms                   | Capsule  |
| Routes of administration               | Oral use |

Dosage and administration details:

Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD

|                  |  |
|------------------|--|
| <b>Arm title</b> | B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk |
|------------------|--|

Arm description:

GT1a only participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.

|  |              |
|--|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | Grazoprevir  |
| Investigational medicinal product code |              |
| Other name                             | MK-5172      |
| Pharmaceutical forms                   | Tablet       |
| Routes of administration               | Oral use     |

Dosage and administration details:

100 mg tablet orally QD

|  |          |
|--|----------|
| Investigational medicinal product name | Elbasvir |
| Investigational medicinal product code |          |
| Other name                             | MK-8742  |
| Pharmaceutical forms                   | Capsule  |
| Routes of administration               | Oral use |

Dosage and administration details:

Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD

|                  |  |
|------------------|--|
| <b>Arm title</b> | B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|------------------|--|

Arm description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|  |              |
|--|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | Grazoprevir  |
| Investigational medicinal product code |              |
| Other name                             | MK-5172      |
| Pharmaceutical forms                   | Tablet       |
| Routes of administration               | Oral use     |

Dosage and administration details:

100 mg tablet orally QD

|  |          |
|--|----------|
| Investigational medicinal product name | Elbasvir |
| Investigational medicinal product code |          |
| Other name                             | MK-8742  |
| Pharmaceutical forms                   | Capsule  |
| Routes of administration               | Oral use |

Dosage and administration details:

Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD

|  |           |
|--|-----------|
| Investigational medicinal product name | Ribavirin |
| Investigational medicinal product code |           |
| Other name                             | Rebetol™  |
| Pharmaceutical forms                   | Capsule   |
| Routes of administration               | Oral use  |

Dosage and administration details:

Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight

|                  |  |
|------------------|--|
| <b>Arm title</b> | B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg for 12 wk |
|------------------|--|

Arm description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.

|  |              |
|--|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | Elbasvir     |
| Investigational medicinal product code |              |
| Other name                             | MK-8742      |
| Pharmaceutical forms                   | Capsule      |
| Routes of administration               | Oral use     |

|  |  |
|--|--|
| Dosage and administration details:   |  |
| Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD   |  |
| Investigational medicinal product name   | Grazoprevir  |
| Investigational medicinal product code   |  |
| Other name   | MK-5172  |
| Pharmaceutical forms   | Tablet   |
| Routes of administration   | Oral use   |
| Dosage and administration details:   |  |
| 100 mg tablet orally QD  |  |
| <b>Arm title</b>   | B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk |
| Arm description:   |  |
| GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks, RBV capsules orally BID for 18 weeks at a total daily dose from 800 to 1400 mg based on participant weight. |  |
| Arm type   | Experimental   |
| Investigational medicinal product name   | Grazoprevir  |
| Investigational medicinal product code   |  |
| Other name   | MK-5172  |
| Pharmaceutical forms   | Tablet   |
| Routes of administration   | Oral use   |
| Dosage and administration details:   |  |
| 100 mg tablet orally QD  |  |
| Investigational medicinal product name   | Elbasvir   |
| Investigational medicinal product code   |  |
| Other name   | MK-8742  |
| Pharmaceutical forms   | Capsule  |
| Routes of administration   | Oral use   |
| Dosage and administration details:   |  |
| Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD   |  |
| Investigational medicinal product name   | Ribavirin  |
| Investigational medicinal product code   |  |
| Other name   | Rebetol™   |
| Pharmaceutical forms   | Capsule  |
| Routes of administration   | Oral use   |
| Dosage and administration details:   |  |
| Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight  |  |
| <b>Arm title</b>   | B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk       |
| Arm description:   |  |
| GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks.   |  |
| Arm type   | Experimental   |
| Investigational medicinal product name   | Elbasvir   |
| Investigational medicinal product code   |  |
| Other name   | MK-8742  |
| Pharmaceutical forms   | Capsule  |
| Routes of administration   | Oral use   |
| Dosage and administration details:   |  |
| Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD   |  |
| Investigational medicinal product name   | Grazoprevir  |
| Investigational medicinal product code   |  |
| Other name   | MK-5172  |
| Pharmaceutical forms   | Tablet   |



|                                    |          |
|------------------------------------|----------|
| Routes of administration           | Oral use |
| Dosage and administration details: |          |
| 100 mg tablet orally QD            |          |

|                  |   |
|------------------|---|
| <b>Arm title</b> | B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk |
|------------------|---|

Arm description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|  |              |
|--|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | Grazoprevir  |
| Investigational medicinal product code |              |
| Other name                             | MK-5172      |
| Pharmaceutical forms                   | Tablet       |
| Routes of administration               | Oral use     |

Dosage and administration details:

100 mg tablet orally QD

|  |          |
|--|----------|
| Investigational medicinal product name | Elbasvir |
| Investigational medicinal product code |          |
| Other name                             | MK-8742  |
| Pharmaceutical forms                   | Capsule  |
| Routes of administration               | Oral use |

Dosage and administration details:

Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD

|  |           |
|--|-----------|
| Investigational medicinal product name | Ribavirin |
| Investigational medicinal product code |           |
| Other name                             | Rebetol™  |
| Pharmaceutical forms                   | Capsule   |
| Routes of administration               | Oral use  |

Dosage and administration details:

Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight

|                  |  |
|------------------|--|
| <b>Arm title</b> | B9: NR Grazoprevir 100 mg + Elbasvir 50 mg-12 wk |
|------------------|--|

Arm description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.

|  |              |
|--|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | Elbasvir     |
| Investigational medicinal product code |              |
| Other name                             | MK-8742      |
| Pharmaceutical forms                   | Capsule      |
| Routes of administration               | Oral use     |

Dosage and administration details:

Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD

|  |             |
|--|-------------|
| Investigational medicinal product name | Grazoprevir |
| Investigational medicinal product code |             |
| Other name                             | MK-5172     |
| Pharmaceutical forms                   | Tablet      |
| Routes of administration               | Oral use    |

Dosage and administration details:

100 mg tablet orally QD

|  |  |
|--|--|
| <b>Arm title</b>   | B10: NR Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk         |
| Arm description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight.    |  |
| Arm type   | Experimental   |
| Investigational medicinal product name   | Grazoprevir  |
| Investigational medicinal product code   |  |
| Other name   | MK-5172  |
| Pharmaceutical forms   | Tablet   |
| Routes of administration   | Oral use   |
| Dosage and administration details:<br>100 mg tablet orally QD  |  |
| Investigational medicinal product name   | Ribavirin  |
| Investigational medicinal product code   |  |
| Other name   | Rebetol™   |
| Pharmaceutical forms   | Capsule  |
| Routes of administration   | Oral use   |
| Dosage and administration details:<br>Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight  |  |
| Investigational medicinal product name   | Elbasvir   |
| Investigational medicinal product code   |  |
| Other name   | MK-8742  |
| Pharmaceutical forms   | Capsule  |
| Routes of administration   | Oral use   |
| Dosage and administration details:<br>Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD   |  |
| <b>Arm title</b>   | B11: NR Grazoprevir 100 mg + Elbasvir 50 mg-18 wk              |
| Arm description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks.   |  |
| Arm type   | Experimental   |
| Investigational medicinal product name   | Elbasvir   |
| Investigational medicinal product code   |  |
| Other name   | MK-8742  |
| Pharmaceutical forms   | Capsule  |
| Routes of administration   | Oral use   |
| Dosage and administration details:<br>Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD   |  |
| Investigational medicinal product name   | Grazoprevir  |
| Investigational medicinal product code   |  |
| Other name   | MK-5172  |
| Pharmaceutical forms   | Tablet   |
| Routes of administration   | Oral use   |
| Dosage and administration details:<br>100 mg tablet orally QD  |  |
| <b>Arm title</b>   | B12: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
| Arm description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight. |  |
| Arm type   | Experimental   |

|   |   |
|---|---|
| Investigational medicinal product name  | Grazoprevir   |
| Investigational medicinal product code  |   |
| Other name  | MK-5172   |
| Pharmaceutical forms  | Tablet  |
| Routes of administration  | Oral use  |
| Dosage and administration details:<br>100 mg tablet orally QD   |   |
| Investigational medicinal product name  | Ribavirin   |
| Investigational medicinal product code  |   |
| Other name  | Rebetol™  |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:<br>Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight   |   |
| Investigational medicinal product name  | Elbasvir  |
| Investigational medicinal product code  |   |
| Other name  | MK-8742   |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:<br>Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD  |   |
| <b>Arm title</b>  | B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg-12 wk      |
| Arm description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks   |   |
| Arm type  | Experimental  |
| Investigational medicinal product name  | Grazoprevir   |
| Investigational medicinal product code  |   |
| Other name  | MK-5172   |
| Pharmaceutical forms  | Tablet  |
| Routes of administration  | Oral use  |
| Dosage and administration details:<br>100 mg tablet orally QD   |   |
| Investigational medicinal product name  | Elbasvir  |
| Investigational medicinal product code  |   |
| Other name  | MK-8742   |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:<br>Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD  |   |
| <b>Arm title</b>  | C1: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
| Arm description:<br>GT1b participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, and RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight. |   |
| Arm type  | Experimental  |
| Investigational medicinal product name  | Grazoprevir   |
| Investigational medicinal product code  |   |
| Other name  | MK-5172   |
| Pharmaceutical forms  | Tablet  |
| Routes of administration  | Oral use  |

|   |   |
|---|---|
| Dosage and administration details:  |   |
| 100 mg tablet orally QD   |   |
| Investigational medicinal product name  | Elbasvir  |
| Investigational medicinal product code  |   |
| Other name  | MK-8742   |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD  |   |
| Investigational medicinal product name  | Ribavirin   |
| Investigational medicinal product code  |   |
| Other name  | Rebetol™  |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight   |   |
| <b>Arm title</b>  | C2: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-8 wk       |
| Arm description:  |   |
| GT1b participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks and Elbasvir 50 mg capsule orally QD for 8 weeks.   |   |
| Arm type  | Experimental  |
| Investigational medicinal product name  | Elbasvir  |
| Investigational medicinal product code  |   |
| Other name  | MK-8742   |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD  |   |
| Investigational medicinal product name  | Grazoprevir   |
| Investigational medicinal product code  |   |
| Other name  | MK-5172   |
| Pharmaceutical forms  | Tablet  |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| 100 mg tablet orally QD   |   |
| <b>Arm title</b>  | D1: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
| Arm description:  |   |
| GT3 participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, and RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight. |   |
| Arm type  | Experimental  |
| Investigational medicinal product name  | Grazoprevir   |
| Investigational medicinal product code  |   |
| Other name  | MK-5172   |
| Pharmaceutical forms  | Tablet  |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| 100 mg tablet orally QD   |   |
| Investigational medicinal product name  | Ribavirin   |
| Investigational medicinal product code  |   |
| Other name  | Rebetol™  |
| Pharmaceutical forms  | Capsule   |

|   |   |
|---|---|
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight   |   |
| Investigational medicinal product name  | Elbasvir  |
| Investigational medicinal product code  |   |
| Other name  | MK-8742   |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD  |   |
| <b>Arm title</b>  | D2: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk |
| Arm description:  |   |
| GT3 participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks, and RBV capsules orally BID for 18 weeks at a total daily dose from 800 to 1400 mg based on participant weight. |   |
| Arm type  | Experimental  |
| Investigational medicinal product name  | Grazoprevir   |
| Investigational medicinal product code  |   |
| Other name  | MK-5172   |
| Pharmaceutical forms  | Tablet  |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| 100 mg tablet orally QD   |   |
| Investigational medicinal product name  | Elbasvir  |
| Investigational medicinal product code  |   |
| Other name  | MK-8742   |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| Part A: 20 or 50 mg capsule orally QD Parts B, C, and D: 50 mg capsule orally QD  |   |
| Investigational medicinal product name  | Ribavirin   |
| Investigational medicinal product code  |   |
| Other name  | Rebetol™  |
| Pharmaceutical forms  | Capsule   |
| Routes of administration  | Oral use  |
| Dosage and administration details:  |   |
| Oral capsules BID at a total daily dose from 800 to 1400 mg based on participant weight   |   |

| <b>Number of subjects in period 1</b> | <b>A1: TN NC<br/>Grazoprevir 100 mg<br/>+ Elbasvir 20 mg +<br/>RBV-12 wk</b> | <b>A2: TN NC<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg +<br/>RBV-12 wk</b> | <b>A3: TN NC/GT1b<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg-12<br/>wk</b> |
|---------------------------------------|--|--|---|
| Started                               | 25   | 27   | 13  |
| Completed                             | 22   | 26   | 13  |
| Not completed                         | 3  | 1  | 0   |
| Adverse event, serious fatal          | -  | -  | -   |
| Consent withdrawn by subject          | -  | 1  | -   |
| Physician decision                    | -  | -  | -   |

|                    |   |   |   |
|--------------------|---|---|---|
| Lost to follow-up  | 3 | - | - |
| Protocol deviation | - | - | - |

| <b>Number of subjects in period 1</b> | B1: TN NC/GT1a<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-8 wk | B2: TN NC<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-12 wk | B3: TN NC/GT1a<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg-12<br>wk |
|---------------------------------------|--|--|---|
| Started                               | 30   | 33   | 31  |
| Completed                             | 28   | 31   | 31  |
| Not completed                         | 2  | 2  | 0   |
| Adverse event, serious fatal          | -  | -  | -   |
| Consent withdrawn by subject          | -  | -  | -   |
| Physician decision                    | -  | -  | -   |
| Lost to follow-up                     | 2  | 1  | -   |
| Protocol deviation                    | -  | 1  | -   |

| <b>Number of subjects in period 1</b> | B4: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-12 wk | B5: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg for<br>12 wk | B6: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-18 wk |
|---------------------------------------|---|---|---|
| Started                               | 31  | 29  | 32  |
| Completed                             | 30  | 29  | 32  |
| Not completed                         | 1   | 0   | 0   |
| Adverse event, serious fatal          | -   | -   | -   |
| Consent withdrawn by subject          | -   | -   | -   |
| Physician decision                    | -   | -   | -   |
| Lost to follow-up                     | 1   | -   | -   |
| Protocol deviation                    | -   | -   | -   |

| <b>Number of subjects in period 1</b> | B7: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg-18<br>wk | B8: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg +RBV-12 wk | B9: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg-12 wk |
|---------------------------------------|---|---|--|
| Started                               | 31  | 32  | 33   |
| Completed                             | 29  | 30  | 33   |
| Not completed                         | 2   | 2   | 0  |
| Adverse event, serious fatal          | -   | 1   | -  |
| Consent withdrawn by subject          | 1   | -   | -  |
| Physician decision                    | 1   | -   | -  |
| Lost to follow-up                     | -   | 1   | -  |
| Protocol deviation                    | -   | -   | -  |

| <b>Number of subjects in period 1</b> | B10: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg + RBV-8 wk | B11: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg-18 wk | B12: TN HIV NC<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-12 wk |
|---------------------------------------|--|---|---|
| Started                               | 33   | 32  | 29  |
| Completed                             | 32   | 32  | 29  |
| Not completed                         | 1  | 0   | 0   |
| Adverse event, serious fatal          | -  | -   | -   |

|                              |   |   |   |
|------------------------------|---|---|---|
| Consent withdrawn by subject | 1 | - | - |
| Physician decision           | - | - | - |
| Lost to follow-up            | - | - | - |
| Protocol deviation           | - | - | - |

| <b>Number of subjects in period 1</b> | <b>B13: TN HIV NC<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg-12<br/>wk</b> | <b>C1: TN NC/GT1b<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg +<br/>RBV-8 wk</b> | <b>C2: TN NC/GT1b<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg-8<br/>wk</b> |
|---------------------------------------|---|--|--|
| Started                               | 30  | 30   | 31   |
| Completed                             | 27  | 29   | 31   |
| Not completed                         | 3   | 1  | 0  |
| Adverse event, serious fatal          | -   | -  | -  |
| Consent withdrawn by subject          | 1   | -  | -  |
| Physician decision                    | -   | -  | -  |
| Lost to follow-up                     | 2   | 1  | -  |
| Protocol deviation                    | -   | -  | -  |

| <b>Number of subjects in period 1</b> | <b>D1: TN NC/GT3<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg +<br/>RBV-12 wk</b> | <b>D2: TN NC/GT3<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg +<br/>RBV-18 wk</b> |
|---------------------------------------|--|--|
| Started                               | 20   | 21   |
| Completed                             | 16   | 15   |
| Not completed                         | 4  | 6  |
| Adverse event, serious fatal          | -  | -  |
| Consent withdrawn by subject          | 2  | 3  |
| Physician decision                    | -  | -  |
| Lost to follow-up                     | 2  | 3  |
| Protocol deviation                    | -  | -  |

## Baseline characteristics

### Reporting groups

|  |   |
|--|---|
| Reporting group title  | A1: TN NC Grazoprevir 100 mg + Elbasvir 20 mg + RBV-12 wk     |
| Reporting group description:<br>GT1a and GT1b participants receive Grazoprevir 100 mg tablet orally once daily (QD) for 12 weeks, Elbasvir 20 mg capsule and Placebo capsule orally QD for 12 weeks, RBV capsules orally twice daily (BID) for 24 weeks at a total daily dose from 800 to 1400 mg based on participant weight. |   |
| Reporting group title  | A2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk     |
| Reporting group description:<br>GT1a and GT1b participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule and Placebo capsule orally QD for 12 weeks, RBV capsules orally BID for 24 weeks at a total daily dose from 800 to 1400 mg based on participant weight.                            |   |
| Reporting group title  | A3: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-12 wk      |
| Reporting group description:<br>GT1b only participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.  |   |
| Reporting group title  | B1: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
| Reporting group description:<br>GT1a only participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight.   |   |
| Reporting group title  | B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk     |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.   |   |
| Reporting group title  | B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk      |
| Reporting group description:<br>GT1a only participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.  |   |
| Reporting group title  | B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk      |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.   |   |
| Reporting group title  | B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg for 12 wk        |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.   |   |
| Reporting group title  | B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk      |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks, RBV capsules orally BID for 18 weeks at a total daily dose from 800 to 1400 mg based on participant weight.   |   |
| Reporting group title  | B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk            |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks.   |   |
| Reporting group title  | B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk         |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.   |   |
| Reporting group title  | B9: NR Grazoprevir 100 mg + Elbasvir 50 mg-12 wk              |



Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.

|                       |  |
|-----------------------|--|
| Reporting group title | B10: NR Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|                       |   |
|-----------------------|---|
| Reporting group title | B11: NR Grazoprevir 100 mg + Elbasvir 50 mg-18 wk |
|-----------------------|---|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks.

|                       |  |
|-----------------------|--|
| Reporting group title | B12: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|                       |  |
|-----------------------|--|
| Reporting group title | B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg-12 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks

|                       |   |
|-----------------------|---|
| Reporting group title | C1: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
|-----------------------|---|

Reporting group description:

GT1b participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, and RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|                       |   |
|-----------------------|---|
| Reporting group title | C2: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-8 wk |
|-----------------------|---|

Reporting group description:

GT1b participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks and Elbasvir 50 mg capsule orally QD for 8 weeks.

|                       |   |
|-----------------------|---|
| Reporting group title | D1: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|-----------------------|---|

Reporting group description:

GT3 participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, and RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|                       |   |
|-----------------------|---|
| Reporting group title | D2: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk |
|-----------------------|---|

Reporting group description:

GT3 participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks, and RBV capsules orally BID for 18 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

| Reporting group values             | A1: TN NC<br>Grazoprevir 100 mg<br>+ Elbasvir 20 mg +<br>RBV-12 wk | A2: TN NC<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-12 wk | A3: TN NC/GT1b<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg-12<br>wk |
|------------------------------------|--|--|---|
| Number of subjects                 | 25   | 27   | 13  |
| Age categorical<br>Units: Subjects |  |  |   |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Age Continuous  <br>Units: years<br>arithmetic mean<br>standard deviation | 48.7<br>± 12.5 | 43.9<br>± 12.6 | 43.3<br>± 13.5 |
|---|----------------|----------------|----------------|

|  |    |    |   |
|--|----|----|---|
| Gender, Male/Female<br>Units: participants |    |    |   |
| Female                                     | 13 | 17 | 6 |
| Male                                       | 12 | 10 | 7 |

|                                    |  |  |   |
|------------------------------------|--|--|---|
| <b>Reporting group values</b>      | B1: TN NC/GT1a<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-8 wk | B2: TN NC<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-12 wk | B3: TN NC/GT1a<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg-12<br>wk |
| Number of subjects                 | 30   | 33   | 31  |
| Age categorical<br>Units: Subjects |  |  |   |

|   |                |                |               |
|---|----------------|----------------|---------------|
| Age Continuous  <br>Units: years<br>arithmetic mean<br>standard deviation | 48.4<br>± 11.9 | 49.7<br>± 11.5 | 53.6<br>± 8.4 |
| Gender, Male/Female<br>Units: participants                                |                |                |               |
| Female  | 12             | 15             | 15            |
| Male  | 18             | 18             | 16            |

|                                    |   |   |   |
|------------------------------------|---|---|---|
| <b>Reporting group values</b>      | B4: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-12 wk | B5: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg for<br>12 wk | B6: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-18 wk |
| Number of subjects                 | 31  | 29  | 32  |
| Age categorical<br>Units: Subjects |   |   |   |

|   |           |             |               |
|---|-----------|-------------|---------------|
| Age Continuous  <br>Units: years<br>arithmetic mean<br>standard deviation | 57<br>± 7 | 59<br>± 7.8 | 58.8<br>± 8.2 |
| Gender, Male/Female<br>Units: participants                                |           |             |               |
| Female  | 12        | 10          | 17            |
| Male  | 19        | 19          | 15            |

|                                    |   |   |  |
|------------------------------------|---|---|--|
| <b>Reporting group values</b>      | B7: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg-18<br>wk | B8: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg +RBV-12 wk | B9: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg-12 wk |
| Number of subjects                 | 31  | 32  | 33   |
| Age categorical<br>Units: Subjects |   |   |  |

|   |             |               |               |
|---|-------------|---------------|---------------|
| Age Continuous  <br>Units: years<br>arithmetic mean<br>standard deviation | 58.9<br>± 8 | 52.2<br>± 8.8 | 54.4<br>± 9.1 |
| Gender, Male/Female<br>Units: participants                                |             |               |               |
| Female  | 10          | 12            | 13            |

|      |    |    |    |
|------|----|----|----|
| Male | 21 | 20 | 20 |
|------|----|----|----|

| Reporting group values             | B10: NR Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk | B11: NR Grazoprevir 100 mg + Elbasvir 50 mg-18 wk | B12: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|------------------------------------|--|---|--|
| Number of subjects                 | 33   | 32  | 29   |
| Age categorical<br>Units: Subjects |  |   |  |

|   |                |                |               |
|---|----------------|----------------|---------------|
| Age Continuous  <br>Units: years<br>arithmetic mean<br>standard deviation | 56.2<br>± 10.9 | 54.3<br>± 12.3 | 46.2<br>± 8.4 |
| Gender, Male/Female<br>Units: participants                                |                |                |               |
| Female  | 17             | 14             | 6             |
| Male  | 16             | 18             | 23            |

| Reporting group values             | B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg-12 wk | C1: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk | C2: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-8 wk |
|------------------------------------|--|---|---|
| Number of subjects                 | 30   | 30  | 31  |
| Age categorical<br>Units: Subjects |  |   |   |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Age Continuous  <br>Units: years<br>arithmetic mean<br>standard deviation | 43.5<br>± 10.4 | 50.6<br>± 10.9 | 55.3<br>± 10.3 |
| Gender, Male/Female<br>Units: participants                                |                |                |                |
| Female  | 6              | 14             | 18             |
| Male  | 24             | 16             | 13             |

| Reporting group values             | D1: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk | D2: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk | Total |
|------------------------------------|---|---|-------|
| Number of subjects                 | 20  | 21  | 573   |
| Age categorical<br>Units: Subjects |   |   |       |

|   |              |                |     |
|---|--------------|----------------|-----|
| Age Continuous  <br>Units: years<br>arithmetic mean<br>standard deviation | 49<br>± 11.5 | 42.4<br>± 10.8 | -   |
| Gender, Male/Female<br>Units: participants                                |              |                |     |
| Female  | 12           | 13             | 252 |
| Male  | 8            | 8              | 321 |



## End points

### End points reporting groups

|  |   |
|--|---|
| Reporting group title  | A1: TN NC Grazoprevir 100 mg + Elbasvir 20 mg + RBV-12 wk     |
| Reporting group description:<br>GT1a and GT1b participants receive Grazoprevir 100 mg tablet orally once daily (QD) for 12 weeks, Elbasvir 20 mg capsule and Placebo capsule orally QD for 12 weeks, RBV capsules orally twice daily (BID) for 24 weeks at a total daily dose from 800 to 1400 mg based on participant weight. |   |
| Reporting group title  | A2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk     |
| Reporting group description:<br>GT1a and GT1b participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule and Placebo capsule orally QD for 12 weeks, RBV capsules orally BID for 24 weeks at a total daily dose from 800 to 1400 mg based on participant weight.                            |   |
| Reporting group title  | A3: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-12 wk      |
| Reporting group description:<br>GT1b only participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.  |   |
| Reporting group title  | B1: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
| Reporting group description:<br>GT1a only participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight.   |   |
| Reporting group title  | B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk     |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.   |   |
| Reporting group title  | B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk      |
| Reporting group description:<br>GT1a only participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.  |   |
| Reporting group title  | B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk      |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.   |   |
| Reporting group title  | B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg for 12 wk        |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.   |   |
| Reporting group title  | B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk      |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks, RBV capsules orally BID for 18 weeks at a total daily dose from 800 to 1400 mg based on participant weight.   |   |
| Reporting group title  | B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk            |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks.   |   |
| Reporting group title  | B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk         |
| Reporting group description:<br>GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.   |   |
| Reporting group title  | B9: NR Grazoprevir 100 mg + Elbasvir 50 mg-12 wk              |

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks.

|                       |  |
|-----------------------|--|
| Reporting group title | B10: NR Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|                       |   |
|-----------------------|---|
| Reporting group title | B11: NR Grazoprevir 100 mg + Elbasvir 50 mg-18 wk |
|-----------------------|---|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks.

|                       |  |
|-----------------------|--|
| Reporting group title | B12: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|                       |  |
|-----------------------|--|
| Reporting group title | B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg-12 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks

|                       |   |
|-----------------------|---|
| Reporting group title | C1: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
|-----------------------|---|

Reporting group description:

GT1b participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, and RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|                       |   |
|-----------------------|---|
| Reporting group title | C2: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-8 wk |
|-----------------------|---|

Reporting group description:

GT1b participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks and Elbasvir 50 mg capsule orally QD for 8 weeks.

|                       |   |
|-----------------------|---|
| Reporting group title | D1: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|-----------------------|---|

Reporting group description:

GT3 participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, and RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

|                       |   |
|-----------------------|---|
| Reporting group title | D2: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk |
|-----------------------|---|

Reporting group description:

GT3 participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks, and RBV capsules orally BID for 18 weeks at a total daily dose from 800 to 1400 mg based on participant weight.

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## **Primary: Percentage of participants achieving Sustained Virologic Response 12 weeks after the end of all study therapy (SVR12)**

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|                 |  |
|-----------------|--|
| End point title | Percentage of participants achieving Sustained Virologic Response 12 weeks after the end of all study therapy (SVR12) <sup>[1]</sup> |
|-----------------|--|

End point description:

Blood was drawn from each participant to assess Hepatitis C Virus ribonucleic acid (HCV RNA) plasma levels using the Roche COBAS™ Taqman™ HCV Test, v2.0 at various time points prior to, during, and after dosing. The Roche COBAS Taqman HCV Test, v2.0 assay (High Pure System) had a lower limit of quantification (LLoQ) of 25 IU/mL and a limit of detection of 15.1 IU/mL (in plasma). SVR12 was defined as HCV RNA <25 IU/ml at 12 weeks after the end of all study therapy. 95% confidence intervals provided based on the Clopper-Pearson method. The Per-Protocol (PP) population was analyzed: all randomized participants who

received  $\geq 1$  dose of study treatment and without important protocol deviations who had data available at the respective time point.

|  |         |
|--|---------|
| End point type                                 | Primary |
| End point timeframe:                           |         |
| 12 weeks after end of therapy (up to 30 weeks) |         |

Notes:

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

Justification: There was no formal efficacy hypothesis testing planned for this endpoint, and there were no between-group statistical comparisons performed.

|                                   |   |   |   |  |
|-----------------------------------|---|---|---|--|
| <b>End point values</b>           | A1: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 20 mg<br>+ RBV-12 wk | A2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | A3: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B1: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk |
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed       | 22  | 24  | 12  | 29   |
| Units: percentage of participants |   |   |   |  |
| number (confidence interval 95%)  | 100 (84.6 to<br>100)  | 95.8 (78.9 to<br>99.9)  | 100 (73.5 to<br>100)  | 82.8 (64.2 to<br>94.2)   |

|                                   |   |   |  |  |
|-----------------------------------|---|---|--|--|
| <b>End point values</b>           | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
| Subject group type                | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 29  | 31  | 30   | 29   |
| Units: percentage of participants |   |   |  |  |
| number (confidence interval 95%)  | 100 (88.1 to<br>100)  | 96.8 (83.3 to<br>99.9)  | 90 (73.5 to<br>97.9)   | 96.6 (82.2 to<br>99.9)   |

|                                   |  |  |   |  |
|-----------------------------------|--|--|---|--|
| <b>End point values</b>           | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed       | 31   | 31   | 30  | 33   |
| Units: percentage of participants |  |  |   |  |
| number (confidence interval 95%)  | 100 (88.8 to<br>100)   | 93.5 (78.6 to<br>99.2)   | 100 (88.4 to<br>100)  | 90.9 (75.7 to<br>98.1)                                       |

|                         |  |   |   |  |
|-------------------------|--|---|---|--|
| <b>End point values</b> | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 |
|-------------------------|--|---|---|--|

|                                   | + RBV-8 wk        | mg-18 wk            | + RBV-12 wk         | mg-12 wk            |
|-----------------------------------|-------------------|---------------------|---------------------|---------------------|
| Subject group type                | Reporting group   | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed       | 33                | 32                  | 29                  | 28                  |
| Units: percentage of participants |                   |                     |                     |                     |
| number (confidence interval 95%)  | 100 (89.4 to 100) | 96.9 (83.8 to 99.9) | 96.6 (82.2 to 99.9) | 92.9 (76.5 to 99.1) |

| End point values                  | C1: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | C2: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>mg-8 wk | D1: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | D2: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk |
|-----------------------------------|--|---|---|---|
| Subject group type                | Reporting group  | Reporting group   | Reporting group   | Reporting group   |
| Number of subjects analysed       | 29   | 31  | 19  | 18  |
| Units: percentage of participants |  |   |   |   |
| number (confidence interval 95%)  | 93.1 (77.2 to 99.2)  | 93.5 (78.6 to 99.2)   | 47.4 (24.4 to 71.1)   | 61.1 (35.7 to 82.7)   |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of participants experiencing at least one Adverse Event (AE) during the treatment period and first 14 follow-up days

|                 |  |
|-----------------|--|
| End point title | Percentage of participants experiencing at least one Adverse Event (AE) during the treatment period and first 14 follow-up days <sup>[2]</sup> |
|-----------------|--|

End point description:

An AE was defined as any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product or protocol-specified procedure, whether or not considered related to the medicinal product or protocol-specified procedure. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition which is temporally associated with the use of the SPONSOR's product, was also an AE. All Participants as Treated (APaT) population was analyzed: all randomized who received  $\geq 1$  dose of study treatment according to treatment actually received. One participant randomized to A3 arm was treated on A2 arm and thus was counted under the A2 arm (n=28).

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

End point timeframe:

From Day 1 [post-dose] through 14 days following last dose of study drug (up to 20 weeks)

Notes:

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

Justification: There was no formal safety hypothesis testing planned for this endpoint, and there were no between-group statistical comparisons performed.



|                                   |   |   |   |  |
|-----------------------------------|---|---|---|--|
| <b>End point values</b>           | A1: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 20 mg<br>+ RBV-12 wk | A2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | A3: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B1: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk |
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed       | 25  | 27 <sup>[3]</sup>   | 12  | 30   |
| Units: percentage of participants |   |   |   |  |
| number (confidence interval 95%)  | 88 (68.8 to<br>97.5)  | 85.7 (67.3 to<br>96)  | 91.7 (61.5 to<br>99.8)  | 90 (73.5 to<br>97.9)   |

Notes:

[3] - Excludes 1 A3 participant treated on A2, Total n=28

|                                   |   |   |  |  |
|-----------------------------------|---|---|--|--|
| <b>End point values</b>           | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
| Subject group type                | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 33  | 31  | 31   | 29   |
| Units: percentage of participants |   |   |  |  |
| number (confidence interval 95%)  | 72.7 (54.5 to<br>86.7)  | 87.1 (70.2 to<br>96.4)  | 77.4 (58.9 to<br>90.4)   | 65.5 (45.7 to<br>82.1)   |

|                                   |  |  |   |  |
|-----------------------------------|--|--|---|--|
| <b>End point values</b>           | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed       | 32   | 31   | 32  | 33   |
| Units: percentage of participants |  |  |   |  |
| number (confidence interval 95%)  | 87.5 (71 to<br>96.5)   | 83.9 (66.3 to<br>94.5)   | 81.3 (63.6 to<br>92.8)  | 78.8 (61.1 to<br>91)   |

|                                   |  |   |  |  |
|-----------------------------------|--|---|--|--|
| <b>End point values</b>           | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
| Subject group type                | Reporting group  | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 33   | 32  | 29   | 30   |
| Units: percentage of participants |  |   |  |  |
| number (confidence interval 95%)  | 97 (84.2 to<br>99.9)   | 81.3 (63.6 to<br>92.8)  | 65.5 (45.7 to<br>82.1)   | 53.3 (34.3 to<br>71.7)   |

|                         |                   |                   |                              |                              |
|-------------------------|-------------------|-------------------|------------------------------|------------------------------|
| <b>End point values</b> | C1: TN<br>NC/GT1b | C2: TN<br>NC/GT1b | D1: TN NC/GT3<br>Grazoprevir | D2: TN NC/GT3<br>Grazoprevir |
|-------------------------|-------------------|-------------------|------------------------------|------------------------------|

|                                   | Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-8 wk | 100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | 100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk |
|-----------------------------------|---|---|---|---|
| Subject group type                | Reporting group   | Reporting group                                   | Reporting group                           | Reporting group                           |
| Number of subjects analysed       | 30  | 31  | 20  | 21  |
| Units: percentage of participants |   |   |   |   |
| number (confidence interval 95%)  | 73.3 (54.1 to<br>87.7)                                  | 54.8 (36 to<br>72.7)                              | 85 (62.1 to<br>96.8)                      | 90.5 (69.6 to<br>98.8)                    |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of participants discontinuing study therapy due to an AE during the treatment period and first 14 follow-up days

|                 |  |
|-----------------|--|
| End point title | Percentage of participants discontinuing study therapy due to an AE during the treatment period and first 14 follow-up days <sup>[4]</sup> |
|-----------------|--|

End point description:

An AE was defined as any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product or protocol-specified procedure, whether or not considered related to the medicinal product or protocol-specified procedure. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition which is temporally associated with the use of the SPONSOR's product, was also an AE. APaT population was analyzed: all randomized who received ≥1 dose of study treatment according to treatment actually received. One participant randomized to A3 arm was treated on A2 arm and thus was counted under the A2 arm (n=28).

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

End point timeframe:

From Day 1 [post-dose] through 14 days following last dose of study drug (up to 20 weeks)

Notes:

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

Justification: There was no formal safety hypothesis testing planned for this endpoint, and there were no between-group statistical comparisons performed.

| End point values                  | A1: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 20 mg<br>+ RBV-12 wk | A2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | A3: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B1: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk |
|-----------------------------------|---|---|---|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed       | 25  | 27 <sup>[5]</sup>   | 12  | 30   |
| Units: percentage of participants |   |   |   |  |
| number (confidence interval 95%)  | 0 (0 to 13.7)   | 0 (0 to 12.3)   | 0 (0 to 26.5)   | 0 (0 to 11.6)  |

Notes:

[5] - Excludes 1 A3 participant treated on A2, Total n=28

| End point values | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
|------------------|---|---|--|--|
|------------------|---|---|--|--|

|                                   |                 |                 |                 |                 |
|-----------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type                | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed       | 33              | 31              | 31              | 29              |
| Units: percentage of participants |                 |                 |                 |                 |
| number (confidence interval 95%)  | 0 (0 to 10.6)   | 0 (0 to 11.2)   | 0 (0 to 11.2)   | 0 (0 to 11.9)   |

|                                   |  |  |   |  |
|-----------------------------------|--|--|---|--|
| <b>End point values</b>           | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed       | 32   | 31   | 32  | 33   |
| Units: percentage of participants |  |  |   |  |
| number (confidence interval 95%)  | 6.3 (0.8 to<br>20.8)   | 0 (0 to 11.2)  | 3.1 (0.1 to<br>16.2)  | 0 (0 to 10.6)  |

|                                   |  |   |  |  |
|-----------------------------------|--|---|--|--|
| <b>End point values</b>           | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
| Subject group type                | Reporting group  | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 33   | 32  | 29   | 30   |
| Units: percentage of participants |  |   |  |  |
| number (confidence interval 95%)  | 0 (0 to 10.6)  | 0 (0 to 10.9)   | 0 (0 to 11.9)  | 0 (0 to 11.6)  |

|                                   |  |  |   |   |
|-----------------------------------|--|--|---|---|
| <b>End point values</b>           | C1: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | C2: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-8 wk | D1: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | D2: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk |
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group   |
| Number of subjects analysed       | 30   | 31   | 20  | 21  |
| Units: percentage of participants |  |  |   |   |
| number (confidence interval 95%)  | 0 (0 to 11.6)  | 0 (0 to 11.2)  | 0 (0 to 16.8)   | 4.8 (0.1 to<br>23.8)  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean time to first achievement of undetectable hepatitis C virus ribonucleic acid (HCV RNA)

|                 |   |
|-----------------|---|
| End point title | Mean time to first achievement of undetectable hepatitis C virus ribonucleic acid (HCV RNA) |
|-----------------|---|

End point description:

Blood was drawn from each participant to assess HCV RNA plasma levels using the Roche COBAS™ Taqman™ HCV Test, v2.0 at various time points prior to, during, and after dosing. Kaplan Meier summary statistics were used to characterize the time to first achievement of undetectable HCV RNA. The Full Analysis Set (FAS) was analyzed: all randomized participants who received ≥1 dose of study treatment.

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

End point timeframe:

From first dose of study medication until first achievement of undetectable HCV RNA (up to 18 weeks of treatment)

| End point values                 | A1: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 20 mg<br>+ RBV-12 wk | A2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | A3: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B1: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk |
|----------------------------------|---|---|---|--|
| Subject group type               | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed      | 25  | 27  | 13  | 30   |
| Units: days                      |   |   |   |  |
| arithmetic mean (standard error) | 21.7 (± 2.2)  | 19.2 (± 1.8)  | 23.4 (± 2.9)  | 27.9 (± 3)   |

| End point values                 | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
|----------------------------------|---|---|--|--|
| Subject group type               | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed      | 33  | 31  | 31   | 29   |
| Units: days                      |   |   |  |  |
| arithmetic mean (standard error) | 30.7 (± 2.3)  | 32 (± 3)  | 37 (± 2.8)   | 33.2 (± 2.4)   |

| End point values                 | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
|----------------------------------|--|--|---|--|
| Subject group type               | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed      | 32   | 31   | 32  | 33   |
| Units: days                      |  |  |   |  |
| arithmetic mean (standard error) | 33.1 (± 2.8)   | 33.7 (± 2.6)   | 31.9 (± 2.2)  | 37.4 (± 2.5)   |

| End point values | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 |
|------------------|--|---|---|--|
|------------------|--|---|---|--|

|                                  | + RBV-8 wk      | mg-18 wk        | + RBV-12 wk     | mg-12 wk        |
|----------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type               | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed      | 33              | 32              | 29              | 30              |
| Units: days                      |                 |                 |                 |                 |
| arithmetic mean (standard error) | 37.4 (± 2.7)    | 42.7 (± 3.3)    | 27.6 (± 3)      | 29 (± 2.9)      |

| End point values                 | C1: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | C2: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>mg-8 wk | D1: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | D2: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk |
|----------------------------------|--|---|---|---|
| Subject group type               | Reporting group  | Reporting group   | Reporting group   | Reporting group   |
| Number of subjects analysed      | 30   | 31  | 20  | 21  |
| Units: days                      |  |   |   |   |
| arithmetic mean (standard error) | 23.7 (± 2.1)   | 34.5 (± 2.6)  | 30.1 (± 3.7)  | 19.8 (± 2.3)  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of participants achieving undetectable HCV RNA at Week 2

|                 |   |
|-----------------|---|
| End point title | Percentage of participants achieving undetectable HCV RNA at Week 2 |
|-----------------|---|

End point description:

HCV-RNA levels in plasma were measured using the Roche COBAS™ Taqman™ HCV Test (v.2.0) on blood samples drawn from each participant during treatment at various time points prior to, during, and after dosing. Undetectable HCV RNA was defined as below the 15.1 IU/ml limit of detection. The percentage of participants achieving undetectable HCV RNA and accompanying 95% CIs were reported at TW2 for each treatment arm of the PP Population (all randomized participants who received ≥1 dose of study treatment and without important protocol deviations who had data available at the respective time point). 95% confidence intervals provided based on the Clopper-Pearson method.

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

End point timeframe:

Week 2

| End point values                  | A1: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 20 mg<br>+ RBV-12 wk | A2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | A3: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg-12 wk | B1: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk |
|-----------------------------------|---|---|--|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 23  | 25  | 12   | 29   |
| Units: percentage of participants |   |   |  |  |
| number (confidence interval 95%)  | 52.2 (30.6 to 73.2)   | 44 (24.4 to 65.1)   | 41.7 (15.2 to 72.3)  | 44.8 (26.4 to 64.3)  |

|                                   |   |   |  |  |
|-----------------------------------|---|---|--|--|
| <b>End point values</b>           | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
| Subject group type                | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 30  | 31  | 30   | 29   |
| Units: percentage of participants |   |   |  |  |
| number (confidence interval 95%)  | 20 (7.7 to<br>38.6)   | 16.1 (5.5 to<br>33.7)   | 6.7 (0.8 to<br>22.1)   | 10.3 (2.2 to<br>27.4)  |

|                                   |  |  |   |  |
|-----------------------------------|--|--|---|--|
| <b>End point values</b>           | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed       | 32   | 31   | 31  | 33   |
| Units: percentage of participants |  |  |   |  |
| number (confidence interval 95%)  | 25 (11.5 to<br>43.4)   | 16.1 (5.5 to<br>33.7)  | 12.9 (3.6 to<br>29.8)   | 6.1 (0.7 to<br>20.2)   |

|                                   |  |   |  |  |
|-----------------------------------|--|---|--|--|
| <b>End point values</b>           | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
| Subject group type                | Reporting group  | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 33   | 32  | 29   | 30   |
| Units: percentage of participants |  |   |  |  |
| number (confidence interval 95%)  | 6.1 (0.7 to<br>20.2)   | 6.3 (0.8 to<br>20.8)  | 37.9 (20.7 to<br>57.7)   | 40 (22.7 to<br>59.4)   |

|                                   |  |  |   |   |
|-----------------------------------|--|--|---|---|
| <b>End point values</b>           | C1: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | C2: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-8 wk | D1: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | D2: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk |
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group   |
| Number of subjects analysed       | 30   | 31   | 20  | 20  |
| Units: percentage of participants |  |  |   |   |
| number (confidence interval 95%)  | 46.7 (28.3 to<br>65.7)   | 12.9 (3.6 to<br>29.8)  | 40 (19.1 to<br>63.9)  | 70 (45.7 to<br>88.1)  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of participants achieving undetectable HCV RNA at Week 4

|                 |   |
|-----------------|---|
| End point title | Percentage of participants achieving undetectable HCV RNA at Week 4 |
|-----------------|---|

End point description:

HCV-RNA levels in plasma were measured using the Roche COBAS™ Taqman™ HCV Test (v.2.0) on blood samples drawn from each participant during treatment at various time points prior to, during, and after dosing. Undetectable HCV RNA was defined as below the 15.1 IU/ml limit of detection. The percentage of participants achieving undetectable HCV RNA and accompanying 95% CIs were reported at TW4 for each treatment arm of the PP Population (all randomized participants who received ≥1 dose of study treatment and without important protocol deviations who had data available at the respective time point). 95% confidence intervals provided based on the Clopper-Pearson method.

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

End point timeframe:

Week 4

| End point values                  | A1: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 20 mg<br>+ RBV-12 wk | A2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | A3: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B1: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk |
|-----------------------------------|---|---|---|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed       | 23  | 24  | 12  | 30   |
| Units: percentage of participants |   |   |   |  |
| number (confidence interval 95%)  | 73.9 (51.6 to 89.8)   | 91.7 (73 to 99)   | 75 (42.8 to 94.5)   | 73.3 (54.1 to 87.7)  |

| End point values                  | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
|-----------------------------------|---|---|--|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 30  | 31  | 30   | 29   |
| Units: percentage of participants |   |   |  |  |
| number (confidence interval 95%)  | 83.3 (65.3 to 94.4)   | 77.4 (58.9 to 90.4)   | 60 (40.6 to 77.3)  | 79.3 (60.3 to 92)  |

| <b>End point values</b>           | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
|-----------------------------------|--|--|---|--|
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed       | 32   | 31   | 30  | 32   |
| Units: percentage of participants |  |  |   |  |
| number (confidence interval 95%)  | 71.9 (53.3 to<br>86.3)   | 71 (52 to 85.8)  | 83.3 (65.3 to<br>94.4)  | 68.8 (50 to<br>83.9)   |

| <b>End point values</b>           | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
|-----------------------------------|--|---|--|--|
| Subject group type                | Reporting group  | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 33   | 32  | 29   | 28   |
| Units: percentage of participants |  |   |  |  |
| number (confidence interval 95%)  | 69.7 (51.3 to<br>84.4)   | 53.1 (34.7 to<br>70.9)  | 75.9 (56.5 to<br>89.7)   | 78.6 (59 to<br>91.7)   |

| <b>End point values</b>           | C1: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | C2: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-8 wk | D1: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | D2: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk |
|-----------------------------------|--|--|---|---|
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group   |
| Number of subjects analysed       | 30   | 31   | 20  | 18  |
| Units: percentage of participants |  |  |   |   |
| number (confidence interval 95%)  | 86.7 (69.3 to<br>96.2)   | 74.2 (55.4 to<br>88.1)   | 50 (27.2 to<br>72.8)  | 77.8 (52.4 to<br>93.6)  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of participants achieving undetectable HCV RNA at Week 12

|                 |  |
|-----------------|--|
| End point title | Percentage of participants achieving undetectable HCV RNA at Week 12 |
|-----------------|--|

End point description:

HCV-RNA levels in plasma were measured using the Roche COBAS™ Taqman™ HCV Test (v.2.0) on blood samples drawn from each participant during treatment at various time points prior to, during, and after dosing. Undetectable HCV RNA was defined as below the 15.1 IU/ml limit of detection. The percentage of participants achieving undetectable HCV RNA and accompanying 95% CIs were reported



at TW12 for each treatment arm of the PP Population (all randomized participants who received  $\geq 1$  dose of study treatment and without important protocol deviations who had data available at the respective time point) as applicable. The B1, C1, and C2 arms only received 8 weeks of treatment and were thus excluded from this analysis. 95% confidence intervals provided based on the Clopper-Pearson method.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 12              |           |

| End point values                  | A1: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 20 mg<br>+ RBV-12 wk | A2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | A3: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B1: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk |
|-----------------------------------|---|---|---|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed       | 22  | 24  | 12  | 0 <sup>[6]</sup>   |
| Units: percentage of participants |   |   |   |  |
| number (confidence interval 95%)  | 100 (84.6 to<br>100)  | 100 (85.8 to<br>100)  | 100 (73.5 to<br>100)  | ( to )   |

Notes:

[6] - Participants only received 8 weeks of treatment and were therefore not analyzed at Week 12.

| End point values                  | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
|-----------------------------------|---|---|--|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 29  | 31  | 30   | 29   |
| Units: percentage of participants |   |   |  |  |
| number (confidence interval 95%)  | 100 (88.1 to<br>100)  | 100 (88.8 to<br>100)  | 93.3 (77.9 to<br>99.2)   | 96.6 (82.2 to<br>99.9)   |

| End point values                  | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
|-----------------------------------|--|--|---|--|
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed       | 31   | 31   | 30  | 32   |
| Units: percentage of participants |  |  |   |  |
| number (confidence interval 95%)  | 100 (88.8 to<br>100)   | 100 (88.8 to<br>100)   | 100 (88.4 to<br>100)  | 93.8 (79.2 to<br>99.2)                                       |

| End point values | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
|------------------|--|---|--|--|
|------------------|--|---|--|--|

| Subject group type                | Reporting group   | Reporting group     | Reporting group     | Reporting group     |
|-----------------------------------|-------------------|---------------------|---------------------|---------------------|
| Number of subjects analysed       | 33                | 32                  | 29                  | 28                  |
| Units: percentage of participants |                   |                     |                     |                     |
| number (confidence interval 95%)  | 100 (89.4 to 100) | 96.9 (83.8 to 99.9) | 93.1 (77.2 to 99.2) | 92.9 (76.5 to 99.1) |

| End point values                  | C1: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk | C2: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-8 wk | D1: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk | D2: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk |
|-----------------------------------|---|---|---|---|
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Reporting group   |
| Number of subjects analysed       | 0 <sup>[7]</sup>  | 0 <sup>[8]</sup>  | 19  | 20  |
| Units: percentage of participants |   |   |   |   |
| number (confidence interval 95%)  | ( to )  | ( to )  | 47.7 (24.4 to 71.1)   | 65 (40.8 to 84.6)   |

Notes:

[7] - Participants only received 8 weeks of treatment and were therefore not analyzed at Week 12.

[8] - Participants only received 8 weeks of treatment and were therefore not analyzed at Week 12.

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of participants achieving HCV RNA <25 IU/mL at Week 2

|                 |  |
|-----------------|--|
| End point title | Percentage of participants achieving HCV RNA <25 IU/mL at Week 2 |
|-----------------|--|

End point description:

HCV-RNA levels in plasma were measured using the Roche COBAS™ Taqman™ HCV Test (v.2.0) on blood samples drawn from each participant during treatment at various time points prior to, during, and after dosing. The Roche COBAS Taqman HCV Test, v2.0 assay (High Pure System) had a LLoQ of 25 IU/mL and a limit of detection of 15.1 IU/mL (in plasma). The percentage of participants achieving HCV RNA levels <25 IU/ml and accompanying 95% CIs were reported at TW2 for each treatment arm of the PP Population (all randomized participants who received ≥1 dose of study treatment and without important protocol deviations who had data available at the respective time point). 95% confidence intervals provided based on the Clopper-Pearson method.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 2               |           |

| End point values                  | A1: TN NC Grazoprevir 100 mg + Elbasvir 20 mg + RBV-12 wk | A2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk | A3: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-12 wk | B1: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
|-----------------------------------|---|---|--|---|
| Subject group type                | Reporting group   | Reporting group   | Reporting group  | Reporting group   |
| Number of subjects analysed       | 23  | 25  | 12   | 29  |
| Units: percentage of participants |   |   |  |   |
| number (confidence interval 95%)  | 91.3 (72 to 98.9)   | 92 (74 to 99)   | 91.7 (61.5 to 99.8)                                      | 86.2 (68.3 to 96.1)   |

| <b>End point values</b>           | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
|-----------------------------------|---|---|--|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 30  | 31  | 30   | 29   |
| Units: percentage of participants |   |   |  |  |
| number (confidence interval 95%)  | 73.3 (54.1 to<br>87.7)  | 77.4 (58.9 to<br>90.4)  | 60 (40.6 to<br>77.3)   | 79.3 (60.3 to<br>92)   |

| <b>End point values</b>           | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
|-----------------------------------|--|--|---|--|
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed       | 32   | 31   | 31  | 33   |
| Units: percentage of participants |  |  |   |  |
| number (confidence interval 95%)  | 78.1 (60 to<br>90.7)   | 67.7 (48.6 to<br>83.3)   | 77.4 (58.9 to<br>90.4)  | 66.7 (48.2 to<br>82)   |

| <b>End point values</b>           | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
|-----------------------------------|--|---|--|--|
| Subject group type                | Reporting group  | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 33   | 32  | 29   | 30   |
| Units: percentage of participants |  |   |  |  |
| number (confidence interval 95%)  | 57.6 (39.2 to<br>74.5)   | 62.5 (43.7 to<br>78.9)  | 89.7 (72.6 to<br>97.8)   | 76.7 (57.7 to<br>90.1)   |

| <b>End point values</b>           | C1: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | C2: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-8 wk | D1: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | D2: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk |
|-----------------------------------|--|--|---|---|
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group   |
| Number of subjects analysed       | 30   | 31   | 20  | 20  |
| Units: percentage of participants |  |  |   |   |
| number (confidence interval 95%)  | 76.7 (57.7 to<br>90.1)   | 61.3 (42.2 to<br>78.2)   | 70 (45.7 to<br>88.1)  | 85 (62.1 to<br>96.8)  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of participants achieving HCV RNA <25 IU/mL at Week 4

|                 |  |
|-----------------|--|
| End point title | Percentage of participants achieving HCV RNA <25 IU/mL at Week 4 |
|-----------------|--|

End point description:

HCV-RNA levels in plasma were measured using the Roche COBAS™ Taqman™ HCV Test (v.2.0) on blood samples drawn from each participant during treatment at various time points prior to, during, and after dosing. The Roche COBAS Taqman HCV Test, v2.0 assay (High Pure System) had a LLoQ of 25 IU/mL and a limit of detection of 15.1 IU/mL (in plasma). The percentage of participants achieving HCV RNA levels <25 IU/ml and accompanying 95% CIs were reported at TW4 for each treatment arm of the PP Population (all randomized participants who received ≥1 dose of study treatment and without important protocol deviations who had data available at the respective time point). 95% confidence intervals provided based on the Clopper-Pearson method.

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

End point timeframe:

Week 4

| End point values                  | A1: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 20 mg<br>+ RBV-12 wk | A2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | A3: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B1: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk |
|-----------------------------------|---|---|---|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed       | 23  | 24  | 12  | 30   |
| Units: percentage of participants |   |   |   |  |
| number (confidence interval 95%)  | 100 (85.2 to<br>100)  | 100 (85.8 to<br>100)  | 100 (73.5 to<br>100)  | 100 (88.4 to<br>100)   |

| End point values                  | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
|-----------------------------------|---|---|--|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 30  | 31  | 30   | 29   |
| Units: percentage of participants |   |   |  |  |
| number (confidence interval 95%)  | 100 (88.4 to<br>100)  | 100 (88.8 to<br>100)  | 90 (73.5 to<br>97.9)   | 100 (88.1 to<br>100)   |

| <b>End point values</b>           | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
|-----------------------------------|--|--|---|--|
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed       | 32   | 31   | 30  | 32   |
| Units: percentage of participants |  |  |   |  |
| number (confidence interval 95%)  | 100 (89.1 to<br>100)   | 90.3 (74.2 to<br>98)   | 100 (88.4 to<br>100)  | 96.9 (83.8 to<br>99.9)                                       |

| <b>End point values</b>           | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
|-----------------------------------|--|---|--|--|
| Subject group type                | Reporting group  | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 33   | 32  | 29   | 28   |
| Units: percentage of participants |  |   |  |  |
| number (confidence interval 95%)  | 97 (84.2 to<br>99.9)   | 93.8 (79.2 to<br>99.2)  | 100 (88.1 to<br>100)   | 100 (87.7 to<br>100)   |

| <b>End point values</b>           | C1: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | C2: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-8 wk | D1: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | D2: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk |
|-----------------------------------|--|--|---|---|
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group   |
| Number of subjects analysed       | 30   | 31   | 20  | 18  |
| Units: percentage of participants |  |  |   |   |
| number (confidence interval 95%)  | 100 (88.4 to<br>100)   | 96.8 (83.3 to<br>99.9)   | 65 (40.8 to<br>84.6)  | 83.3 (58.6 to<br>96.4)  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of participants achieving HCV RNA <25 IU/mL at Week 12

|                 |   |
|-----------------|---|
| End point title | Percentage of participants achieving HCV RNA <25 IU/mL at Week 12 |
|-----------------|---|

End point description:

HCV-RNA levels in plasma were measured using the Roche COBAS™ Taqman™ HCV Test (v.2.0) on blood samples drawn from each participant during treatment at various time points prior to, during, and after dosing. The Roche COBAS Taqman HCV Test, v2.0 assay (High Pure System) had a LLoQ of 25 IU/mL and a limit of detection of 15.1 IU/mL (in plasma). The percentage of participants achieving HCV

RNA levels <25 IU/ml and accompanying 95% CIs were reported at TW12 for each treatment arm of the PP Population (all randomized participants who received ≥1 dose of study treatment and without important protocol deviations who had data available at the respective time point) as applicable. The B1, C1, and C2 arms only received 8 weeks of treatment and were thus excluded from this analysis. 95% confidence intervals provided based on the Clopper-Pearson method.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Week 12              |           |

| End point values                  | A1: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 20 mg<br>+ RBV-12 wk | A2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | A3: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B1: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk |
|-----------------------------------|---|---|---|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed       | 22  | 24  | 12  | 0 <sup>[9]</sup>   |
| Units: percentage of participants |   |   |   |  |
| number (confidence interval 95%)  | 100 (84.6 to<br>100)  | 100 (85.8 to<br>100)  | 100 (73.5 to<br>100)  | ( to )   |

Notes:

[9] - Participants only received 8 weeks of treatment and were therefore not analyzed at Week 12.

| End point values                  | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
|-----------------------------------|---|---|--|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 29  | 31  | 30   | 29   |
| Units: percentage of participants |   |   |  |  |
| number (confidence interval 95%)  | 100 (88.1 to<br>100)  | 100 (88.8 to<br>100)  | 93.3 (77.9 to<br>99.2)   | 100 (88.1 to<br>100)   |

| End point values                  | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
|-----------------------------------|--|--|---|--|
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed       | 31   | 31   | 30  | 32   |
| Units: percentage of participants |  |  |   |  |
| number (confidence interval 95%)  | 100 (88.8 to<br>100)   | 100 (88.8 to<br>100)   | 100 (88.4 to<br>100)  | 100 (89.1 to<br>100)   |

| End point values | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 |
|------------------|--|---|---|--|
|------------------|--|---|---|--|

|                                   | + RBV-8 wk        | mg-18 wk            | + RBV-12 wk       | mg-12 wk            |
|-----------------------------------|-------------------|---------------------|-------------------|---------------------|
| Subject group type                | Reporting group   | Reporting group     | Reporting group   | Reporting group     |
| Number of subjects analysed       | 33                | 32                  | 29                | 28                  |
| Units: percentage of participants |                   |                     |                   |                     |
| number (confidence interval 95%)  | 100 (89.4 to 100) | 96.9 (83.8 to 99.9) | 100 (88.1 to 100) | 92.9 (76.5 to 99.1) |

| End point values                  | C1: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | C2: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>mg-8 wk | D1: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | D2: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk |
|-----------------------------------|--|---|---|---|
| Subject group type                | Reporting group  | Reporting group   | Reporting group   | Reporting group   |
| Number of subjects analysed       | 0 <sup>[10]</sup>  | 0 <sup>[11]</sup>   | 19  | 20  |
| Units: percentage of participants |  |   |   |   |
| number (confidence interval 95%)  | ( to )   | ( to )  | 47.4 (24.4 to 71.1)   | 75 (50.9 to 91.3)   |

Notes:

[10] - Participants only received 8 weeks of treatment and were therefore not analyzed at Week 12.

[11] - Participants only received 8 weeks of treatment and were therefore not analyzed at Week 12.

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of participants achieving Sustained Virologic Response 4 weeks after the end of all therapy (SVR4)

|                 |   |
|-----------------|---|
| End point title | Percentage of participants achieving Sustained Virologic Response 4 weeks after the end of all therapy (SVR4) |
|-----------------|---|

End point description:

Blood was drawn from each participant to assess Hepatitis C Virus ribonucleic acid (HCV RNA) plasma levels using the Roche COBAS™ Taqman™ HCV Test, v2.0 at various time points prior to, during, and after dosing. The Roche COBAS Taqman HCV Test, v2.0 assay (High Pure System) had a LLoQ of 25 IU/mL and a limit of detection of 15.1 IU/mL (in plasma). SVR4 was defined as HCV RNA <25 IU/ml at 4 weeks after the end of all study therapy. The percentage of participants achieving SVR4 and accompanying 95% CIs were reported at Follow-up Week (FW) 4 for each treatment arm of the PP Population (all randomized participants who received ≥1 dose of study treatment and without important protocol deviations who had data available at the respective time point).

95% confidence intervals provided based on the Clopper-Pearson method.

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

End point timeframe:

4 weeks after end of therapy (up to 22 weeks)

|                                   |   |   |   |  |
|-----------------------------------|---|---|---|--|
| <b>End point values</b>           | A1: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 20 mg<br>+ RBV-12 wk | A2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | A3: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B1: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk |
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed       | 22  | 24  | 12  | 30   |
| Units: percentage of participants |   |   |   |  |
| number (confidence interval 95%)  | 100 (84.6 to<br>100)  | 95.8 (78.9 to<br>99.9)  | 100 (73.5 to<br>100)  | 93.3 (77.9 to<br>99.2)   |

|                                   |   |   |  |  |
|-----------------------------------|---|---|--|--|
| <b>End point values</b>           | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
| Subject group type                | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 29  | 31  | 30   | 29   |
| Units: percentage of participants |   |   |  |  |
| number (confidence interval 95%)  | 100 (88.1 to<br>100)  | 96.8 (83.3 to<br>99.9)  | 96.7 (82.8 to<br>99.9)   | 96.6 (82.2 to<br>99.9)   |

|                                   |  |  |   |  |
|-----------------------------------|--|--|---|--|
| <b>End point values</b>           | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed       | 31   | 31   | 30  | 33   |
| Units: percentage of participants |  |  |   |  |
| number (confidence interval 95%)  | 100 (88.8 to<br>100)   | 96.8 (83.3 to<br>99.9)   | 100 (88.4 to<br>100)  | 93.9 (79.8 to<br>99.3)                                       |

|                                   |  |   |  |  |
|-----------------------------------|--|---|--|--|
| <b>End point values</b>           | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
| Subject group type                | Reporting group  | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 33   | 32  | 29   | 29   |
| Units: percentage of participants |  |   |  |  |
| number (confidence interval 95%)  | 100 (89.4 to<br>100)   | 96.9 (83.8 to<br>99.9)  | 96.6 (82.2 to<br>99.9)   | 93.1 (77.2 to<br>99.2)   |

|                         |                   |                   |                              |                              |
|-------------------------|-------------------|-------------------|------------------------------|------------------------------|
| <b>End point values</b> | C1: TN<br>NC/GT1b | C2: TN<br>NC/GT1b | D1: TN NC/GT3<br>Grazoprevir | D2: TN NC/GT3<br>Grazoprevir |
|-------------------------|-------------------|-------------------|------------------------------|------------------------------|



|                                   | Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-8 wk | 100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | 100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk |
|-----------------------------------|---|---|---|---|
| Subject group type                | Reporting group   | Reporting group                                   | Reporting group                           | Reporting group                           |
| Number of subjects analysed       | 29  | 31  | 20  | 18  |
| Units: percentage of participants |   |   |   |   |
| number (confidence interval 95%)  | 93.1 (77.2 to<br>99.2)                                  | 96.8 (83.3 to<br>99.9)                            | 50 (27.2 to<br>72.8)                      | 61.1 (35.7 to<br>82.7)                    |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of participants achieving Sustained Virologic Response 24 weeks after the end of all study therapy (SVR24)

|  |   |
|--|---|
| End point title  | Percentage of participants achieving Sustained Virologic Response 24 weeks after the end of all study therapy (SVR24) |
| End point description:   |   |
| Blood was drawn from each participant to assess Hepatitis C Virus ribonucleic acid (HCV RNA) plasma levels using the Roche COBAS™ Taqman™ HCV Test, v2.0 at various time points prior to, during, and after dosing. The Roche COBAS Taqman HCV Test, v2.0 assay (High Pure System) had a LLoQ of 25 IU/mL and a limit of detection of 15.1 IU/mL (in plasma). SVR24 was defined as HCV RNA <25 IU/ml at 24 weeks after the end of all study therapy. The percentage of participants achieving SVR24 and accompanying 95% CIs were reported at FW24 for each treatment arm of the PP Population (all randomized participants who received ≥1 dose of study treatment and without important protocol deviations who had data available at the respective time point). 95% confidence intervals provided based on the Clopper-Pearson method. |   |
| End point type   | Secondary   |
| End point timeframe:   |   |
| 24 weeks after end of therapy (up to 42 weeks)   |   |

| End point values                  | A1: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 20 mg<br>+ RBV-12 wk | A2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | A3: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B1: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk |
|-----------------------------------|---|---|---|--|
| Subject group type                | Reporting group   | Reporting group   | Reporting group   | Reporting group  |
| Number of subjects analysed       | 20  | 24  | 12  | 28   |
| Units: percentage of participants |   |   |   |  |
| number (confidence interval 95%)  | 100 (83.2 to<br>100)  | 95.8 (78.9 to<br>99.9)  | 100 (73.5 to<br>100)  | 78.6 (59 to<br>91.7)   |

| End point values | B2: TN NC<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B3: TN<br>NC/GT1a<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk | B4: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B5: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>for 12 wk |
|------------------|---|---|--|--|
|------------------|---|---|--|--|

|                                   |                   |                     |                   |                     |
|-----------------------------------|-------------------|---------------------|-------------------|---------------------|
| Subject group type                | Reporting group   | Reporting group     | Reporting group   | Reporting group     |
| Number of subjects analysed       | 29                | 31                  | 30                | 29                  |
| Units: percentage of participants |                   |                     |                   |                     |
| number (confidence interval 95%)  | 100 (88.1 to 100) | 96.8 (83.3 to 99.9) | 90 (73.5 to 97.9) | 96.6 (82.2 to 99.9) |

|                                   |  |  |   |  |
|-----------------------------------|--|--|---|--|
| <b>End point values</b>           | B6: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk | B7: TN C<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B8: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+RBV-12 wk | B9: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group  |
| Number of subjects analysed       | 31   | 29   | 29  | 33   |
| Units: percentage of participants |  |  |   |  |
| number (confidence interval 95%)  | 100 (88.8 to 100)  | 93.1 (77.2 to 99.2)  | 100 (88.1 to 100)   | 90.9 (75.7 to 98.1)  |

|                                   |  |   |  |  |
|-----------------------------------|--|---|--|--|
| <b>End point values</b>           | B10: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | B11: NR<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-18 wk | B12: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | B13: TN HIV<br>NC Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-12 wk |
| Subject group type                | Reporting group  | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed       | 32   | 32  | 29   | 27   |
| Units: percentage of participants |  |   |  |  |
| number (confidence interval 95%)  | 100 (89.1 to 100)  | 96.9 (83.8 to 99.9)   | 96.6 (82.2 to 99.9)  | 88.9 (70.8 to 97.6)  |

|                                   |  |  |   |   |
|-----------------------------------|--|--|---|---|
| <b>End point values</b>           | C1: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-8 wk | C2: TN<br>NC/GT1b<br>Grazoprevir<br>100 mg +<br>Elbasvir 50<br>mg-8 wk | D1: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-12 wk | D2: TN NC/GT3<br>Grazoprevir<br>100 mg +<br>Elbasvir 50 mg<br>+ RBV-18 wk |
| Subject group type                | Reporting group  | Reporting group  | Reporting group   | Reporting group   |
| Number of subjects analysed       | 29   | 31   | 19  | 17  |
| Units: percentage of participants |  |  |   |   |
| number (confidence interval 95%)  | 93.1 (77.2 to 99.2)  | 93.5 (78.6 to 99.2)  | 47.4 (24.4 to 71.1)   | 58.8 (32.9 to 81.6)   |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Treatment and Follow-up periods (up to 42 weeks)

Adverse event reporting additional description:

All Participants as Treated (APaT) population; all randomized who received  $\geq 1$  dose of study treatment according to treatment actually received. One participant randomized to A3 arm was treated on A2 arm and thus was counted under the A2 arm (n=28).

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 18.0 |
|--------------------|------|

### Reporting groups

|                       |   |
|-----------------------|---|
| Reporting group title | A1: TN NC Grazoprevir 100 mg + Elbasvir 20 mg + RBV-12 wk |
|-----------------------|---|

Reporting group description:

GT1a and GT1b participants receive Grazoprevir 100 mg tablet orally once daily (QD) for 12 weeks, Elbasvir 20 mg capsule and Placebo capsule orally QD for 12 weeks, RBV capsules orally twice daily (BID) for 24 weeks at a total daily dose from 800 to 1400 mg based on participant weight

|                       |   |
|-----------------------|---|
| Reporting group title | A2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|-----------------------|---|

Reporting group description:

GT1a and GT1b participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule and Placebo capsule orally QD for 12 weeks, RBV capsules orally BID for 24 weeks at a total daily dose from 800 to 1400 mg based on participant weight. Includes 1 additional participant that was randomized to A3 Arm but treated on A2 Arm.

|                       |  |
|-----------------------|--|
| Reporting group title | A3: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-12 wk |
|-----------------------|--|

Reporting group description:

GT1b only participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks. Excludes 1 additional participant that was randomized to A3 Arm but treated on A2 Arm.

|                       |   |
|-----------------------|---|
| Reporting group title | B1: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
|-----------------------|---|

Reporting group description:

GT1a only participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight

|                       |   |
|-----------------------|---|
| Reporting group title | B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|-----------------------|---|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight

|                       |  |
|-----------------------|--|
| Reporting group title | B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk |
|-----------------------|--|

Reporting group description:

GT1a only participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks

|                       |  |
|-----------------------|--|
| Reporting group title | B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant

|                       |  |
|-----------------------|--|
| Reporting group title | B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg for 12 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks

|                       |  |
|-----------------------|--|
| Reporting group title | B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks, RBV capsules orally BID for 18 weeks at a total daily dose from 800 to 1400 mg based on participant weight

|                       |  |
|-----------------------|--|
| Reporting group title | B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks

|                       |  |
|-----------------------|--|
| Reporting group title | B9: NR Grazoprevir 100 mg + Elbasvir 50 mg-12 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks

|                       |   |
|-----------------------|---|
| Reporting group title | B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk |
|-----------------------|---|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight

|                       |  |
|-----------------------|--|
| Reporting group title | B10: NR Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight

|                       |   |
|-----------------------|---|
| Reporting group title | B11: NR Grazoprevir 100 mg + Elbasvir 50 mg-18 wk |
|-----------------------|---|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks

|                       |  |
|-----------------------|--|
| Reporting group title | B12: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight

|                       |  |
|-----------------------|--|
| Reporting group title | B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg-12 wk |
|-----------------------|--|

Reporting group description:

GT1a/non-a participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks

|                       |   |
|-----------------------|---|
| Reporting group title | C1: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk |
|-----------------------|---|

Reporting group description:

GT1b participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks, Elbasvir 50 mg capsule orally QD for 8 weeks, and RBV capsules orally BID for 8 weeks at a total daily dose from 800 to 1400 mg based on participant weight

|                       |   |
|-----------------------|---|
| Reporting group title | D1: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|-----------------------|---|

Reporting group description:

GT3 participants receive Grazoprevir 100 mg tablet orally QD for 12 weeks, Elbasvir 50 mg capsule orally QD for 12 weeks, and RBV capsules orally BID for 12 weeks at a total daily dose from 800 to 1400 mg based on participant weight

|                       |   |
|-----------------------|---|
| Reporting group title | C2: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-8 wk |
|-----------------------|---|

Reporting group description:

GT1b participants receive Grazoprevir 100 mg tablet orally QD for 8 weeks and Elbasvir 50 mg capsule orally QD for 8 weeks

|                       |   |
|-----------------------|---|
| Reporting group title | D2: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk |
|-----------------------|---|

Reporting group description:

GT3 participants receive Grazoprevir 100 mg tablet orally QD for 18 weeks, Elbasvir 50 mg capsule orally QD for 18 weeks, and RBV capsules orally BID for 18 weeks at a total daily dose from 800 to 1400 mg based on participant weight

| <b>Serious adverse events</b>                                       | <b>A1: TN NC<br/>Grazoprevir 100 mg<br/>+ Elbasvir 20 mg +<br/>RBV-12 wk</b> | <b>A2: TN NC<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg +<br/>RBV-12 wk</b> | <b>A3: TN NC/GT1b<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg-12<br/>wk</b> |
|---|--|--|---|
| Total subjects affected by serious adverse events                   |  |  |   |
| subjects affected / exposed   | 1 / 25 (4.00%)   | 0 / 28 (0.00%)   | 0 / 12 (0.00%)  |
| number of deaths (all causes)                                       | 0  | 0  | 0   |
| number of deaths resulting from adverse events                      | 0  | 0  | 0   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |  |  |   |
| Hepatic cancer  |  |  |   |
| subjects affected / exposed   | 0 / 25 (0.00%)   | 0 / 28 (0.00%)   | 0 / 12 (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   |
| Transitional cell carcinoma   |  |  |   |
| subjects affected / exposed   | 0 / 25 (0.00%)   | 0 / 28 (0.00%)   | 0 / 12 (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   |
| Injury, poisoning and procedural complications                      |  |  |   |
| Road traffic accident   |  |  |   |
| subjects affected / exposed   | 0 / 25 (0.00%)   | 0 / 28 (0.00%)   | 0 / 12 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0  | 0 / 0  | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0  | 0 / 0  | 0 / 0   |
| Cardiac disorders   |  |  |   |
| Atrial fibrillation   |  |  |   |
| subjects affected / exposed   | 0 / 25 (0.00%)   | 0 / 28 (0.00%)   | 0 / 12 (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   |
| General disorders and administration site conditions                |  |  |   |
| Asthenia  |  |  |   |
| subjects affected / exposed   | 0 / 25 (0.00%)   | 0 / 28 (0.00%)   | 0 / 12 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0  | 0 / 0  | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0  | 0 / 0  | 0 / 0   |
| Chest pain  |  |  |   |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 28 (0.00%) | 0 / 12 (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          |
| <b>Gastrointestinal disorders</b>               |                |                |                |
| Abdominal pain                                  |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 28 (0.00%) | 0 / 12 (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          |
| Gastritis                                       |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 28 (0.00%) | 0 / 12 (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          |
| Nausea  |                |                |                |
| subjects affected / exposed                     | 1 / 25 (4.00%) | 0 / 28 (0.00%) | 0 / 12 (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          |
| <b>Hepatobiliary disorders</b>                  |                |                |                |
| Cholangitis                                     |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 28 (0.00%) | 0 / 12 (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          |
| Cholecystitis acute                             |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 28 (0.00%) | 0 / 12 (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          |
| <b>Psychiatric disorders</b>                    |                |                |                |
| Depression                                      |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 28 (0.00%) | 0 / 12 (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          |
| <b>Renal and urinary disorders</b>              |                |                |                |
| Hydronephrosis                                  |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 28 (0.00%) | 0 / 12 (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          |
| <b>Infections and infestations</b>              |                |                |                |
| Bacteraemia                                     |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 28 (0.00%) | 0 / 12 (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          |
| Scrotal abscess                                 |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 28 (0.00%) | 0 / 12 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Staphylococcal infection                        |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 28 (0.00%) | 0 / 12 (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          |

| <b>Serious adverse events</b>  | B1: TN NC/GT1a<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-8 wk | B2: TN NC<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-12 wk | B3: TN NC/GT1a<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg-12<br>wk |
|--|--|--|---|
| <b>Total subjects affected by serious adverse events</b>                   |  |  |   |
| subjects affected / exposed  | 0 / 30 (0.00%)   | 0 / 33 (0.00%)   | 0 / 31 (0.00%)  |
| number of deaths (all causes)  | 0  | 0  | 0   |
| number of deaths resulting from adverse events                             | 0  | 0  | 0   |
| <b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b> |  |  |   |
| Hepatic cancer   |  |  |   |
| subjects affected / exposed  | 0 / 30 (0.00%)   | 0 / 33 (0.00%)   | 0 / 31 (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   |
| Transitional cell carcinoma  |  |  |   |
| subjects affected / exposed  | 0 / 30 (0.00%)   | 0 / 33 (0.00%)   | 0 / 31 (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   |
| <b>Injury, poisoning and procedural complications</b>                      |  |  |   |
| Road traffic accident  |  |  |   |

|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 30 (0.00%) | 0 / 33 (0.00%) | 0 / 31 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Cardiac disorders                                    |                |                |                |
| Atrial fibrillation                                  |                |                |                |
| subjects affected / exposed                          | 0 / 30 (0.00%) | 0 / 33 (0.00%) | 0 / 31 (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          |
| General disorders and administration site conditions |                |                |                |
| Asthenia   |                |                |                |
| subjects affected / exposed                          | 0 / 30 (0.00%) | 0 / 33 (0.00%) | 0 / 31 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Chest pain   |                |                |                |
| subjects affected / exposed                          | 0 / 30 (0.00%) | 0 / 33 (0.00%) | 0 / 31 (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          |
| Gastrointestinal disorders                           |                |                |                |
| Abdominal pain                                       |                |                |                |
| subjects affected / exposed                          | 0 / 30 (0.00%) | 0 / 33 (0.00%) | 0 / 31 (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          |
| Gastritis  |                |                |                |
| subjects affected / exposed                          | 0 / 30 (0.00%) | 0 / 33 (0.00%) | 0 / 31 (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          |
| Nausea   |                |                |                |
| subjects affected / exposed                          | 0 / 30 (0.00%) | 0 / 33 (0.00%) | 0 / 31 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                              |                |                |                |
| Cholangitis  |                |                |                |



|   |   |   |   |
|---|---|---|---|
| subjects affected / exposed                       | 0 / 30 (0.00%)  | 0 / 33 (0.00%)  | 0 / 31 (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   |
| Cholecystitis acute                               |   |   |   |
| subjects affected / exposed                       | 0 / 30 (0.00%)  | 0 / 33 (0.00%)  | 0 / 31 (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   |
| Psychiatric disorders                             |   |   |   |
| Depression  |   |   |   |
| subjects affected / exposed                       | 0 / 30 (0.00%)  | 0 / 33 (0.00%)  | 0 / 31 (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   |
| Renal and urinary disorders                       |   |   |   |
| Hydronephrosis                                    |   |   |   |
| subjects affected / exposed                       | 0 / 30 (0.00%)  | 0 / 33 (0.00%)  | 0 / 31 (0.00%)  |
| occurrences causally related to treatment / all   | 0 / 0   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all        | 0 / 0   | 0 / 0   | 0 / 0   |
| Infections and infestations                       |   |   |   |
| Bacteraemia                                       |   |   |   |
| subjects affected / exposed                       | 0 / 30 (0.00%)  | 0 / 33 (0.00%)  | 0 / 31 (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   |
| Scrotal abscess                                   |   |   |   |
| subjects affected / exposed                       | 0 / 30 (0.00%)  | 0 / 33 (0.00%)  | 0 / 31 (0.00%)  |
| occurrences causally related to treatment / all   | 0 / 0   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all        | 0 / 0   | 0 / 0   | 0 / 0   |
| Staphylococcal infection                          |   |   |   |
| subjects affected / exposed                       | 0 / 30 (0.00%)  | 0 / 33 (0.00%)  | 0 / 31 (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   |
| <b>Serious adverse events</b>                     | B4: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-12 wk | B5: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg for<br>12 wk | B6: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-18 wk |
| Total subjects affected by serious adverse events |   |   |   |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed   | 1 / 31 (3.23%) | 2 / 29 (6.90%) | 1 / 32 (3.13%) |
| number of deaths (all causes)                                       | 0              | 0              | 0              |
| number of deaths resulting from adverse events                      | 0              | 0              | 0              |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                |                |                |
| Hepatic cancer  |                |                |                |
| subjects affected / exposed   | 1 / 31 (3.23%) | 0 / 29 (0.00%) | 0 / 32 (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          |
| Transitional cell carcinoma   |                |                |                |
| subjects affected / exposed   | 0 / 31 (0.00%) | 1 / 29 (3.45%) | 0 / 32 (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          |
| Injury, poisoning and procedural complications                      |                |                |                |
| Road traffic accident   |                |                |                |
| subjects affected / exposed   | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0          |
| Cardiac disorders   |                |                |                |
| Atrial fibrillation   |                |                |                |
| subjects affected / exposed   | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (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          |
| General disorders and administration site conditions                |                |                |                |
| Asthenia  |                |                |                |
| subjects affected / exposed   | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all                     | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0          | 0 / 0          |
| Chest pain  |                |                |                |
| subjects affected / exposed   | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (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          |
| Gastrointestinal disorders  |                |                |                |
| Abdominal pain  |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 29 (3.45%) | 0 / 32 (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          |
| Gastritis                                       |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Nausea  |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                         |                |                |                |
| Cholangitis                                     |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (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          |
| Cholecystitis acute                             |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (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          |
| Psychiatric disorders                           |                |                |                |
| Depression                                      |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (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          |
| Renal and urinary disorders                     |                |                |                |
| Hydronephrosis                                  |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                |                |                |
| Bacteraemia                                     |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (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          |
| Scrotal abscess                                 |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Staphylococcal infection                        |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (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          |

| <b>Serious adverse events</b>                                       | B7: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg-18<br>wk | B9: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg-12 wk | B8: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg +RBV-12 wk |
|---|---|--|---|
| Total subjects affected by serious adverse events                   |   |  |   |
| subjects affected / exposed   | 1 / 31 (3.23%)  | 1 / 33 (3.03%)   | 2 / 32 (6.25%)  |
| number of deaths (all causes)                                       | 0   | 0  | 1   |
| number of deaths resulting from adverse events                      | 0   | 0  | 0   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |  |   |
| Hepatic cancer  |   |  |   |
| subjects affected / exposed   | 0 / 31 (0.00%)  | 0 / 33 (0.00%)   | 0 / 32 (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   |
| Transitional cell carcinoma   |   |  |   |
| subjects affected / exposed   | 0 / 31 (0.00%)  | 0 / 33 (0.00%)   | 0 / 32 (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   |
| Injury, poisoning and procedural complications                      |   |  |   |
| Road traffic accident   |   |  |   |
| subjects affected / exposed   | 0 / 31 (0.00%)  | 0 / 33 (0.00%)   | 1 / 32 (3.13%)  |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0  | 0 / 1   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0  | 0 / 1   |
| Cardiac disorders   |   |  |   |
| Atrial fibrillation   |   |  |   |

|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                |                |                |
| Asthenia   |                |                |                |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Chest pain   |                |                |                |
| subjects affected / exposed                          | 1 / 31 (3.23%) | 0 / 33 (0.00%) | 0 / 32 (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                           |                |                |                |
| Abdominal pain                                       |                |                |                |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (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          |
| Gastritis  |                |                |                |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (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          |
| Nausea   |                |                |                |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                              |                |                |                |
| Cholangitis  |                |                |                |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (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          |
| Cholecystitis acute                                  |                |                |                |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (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          |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Psychiatric disorders                           |                |                |                |
| Depression                                      |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (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          |
| Renal and urinary disorders                     |                |                |                |
| Hydronephrosis                                  |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                |                |                |
| Bacteraemia                                     |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (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          |
| Scrotal abscess                                 |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 33 (3.03%) | 0 / 32 (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          |
| Staphylococcal infection                        |                |                |                |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (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          |

| <b>Serious adverse events</b>                                       | B10: NR Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk | B11: NR Grazoprevir 100 mg + Elbasvir 50 mg-18 wk | B12: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk |
|---|--|---|--|
| Total subjects affected by serious adverse events                   |  |   |  |
| subjects affected / exposed   | 0 / 33 (0.00%)   | 1 / 32 (3.13%)                                    | 1 / 29 (3.45%)   |
| number of deaths (all causes)                                       | 0  | 0   | 0  |
| number of deaths resulting from adverse events                      | 0  | 0   | 0  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |  |   |  |
| Hepatic cancer  |  |   |  |
| subjects affected / exposed   | 0 / 33 (0.00%)   | 0 / 32 (0.00%)                                    | 0 / 29 (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  |

|  |                |                |                |
|--|----------------|----------------|----------------|
| Transitional cell carcinoma<br>subjects affected / exposed | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences causally related to<br>treatment / all         | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all              | 0 / 0          | 0 / 0          | 0 / 0          |
| Injury, poisoning and procedural<br>complications          |                |                |                |
| Road traffic accident<br>subjects affected / exposed       | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences causally related to<br>treatment / all         | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all              | 0 / 0          | 0 / 0          | 0 / 0          |
| Cardiac disorders  |                |                |                |
| Atrial fibrillation<br>subjects affected / exposed         | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences causally related to<br>treatment / all         | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all              | 0 / 0          | 0 / 0          | 0 / 0          |
| General disorders and administration<br>site conditions    |                |                |                |
| Asthenia<br>subjects affected / exposed                    | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 1 / 29 (3.45%) |
| occurrences causally related to<br>treatment / all         | 0 / 0          | 0 / 0          | 1 / 1          |
| deaths causally related to<br>treatment / all              | 0 / 0          | 0 / 0          | 0 / 0          |
| Chest pain<br>subjects affected / exposed                  | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences causally related to<br>treatment / all         | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all              | 0 / 0          | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                                 |                |                |                |
| Abdominal pain<br>subjects affected / exposed              | 0 / 33 (0.00%) | 1 / 32 (3.13%) | 0 / 29 (0.00%) |
| occurrences causally related to<br>treatment / all         | 0 / 0          | 1 / 1          | 0 / 0          |
| deaths causally related to<br>treatment / all              | 0 / 0          | 0 / 0          | 0 / 0          |
| Gastritis<br>subjects affected / exposed                   | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences causally related to<br>treatment / all         | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all              | 0 / 0          | 0 / 0          | 0 / 0          |
| Nausea   |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                         |                |                |                |
| Cholangitis                                     |                |                |                |
| subjects affected / exposed                     | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (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          |
| Cholecystitis acute                             |                |                |                |
| subjects affected / exposed                     | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (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          |
| Psychiatric disorders                           |                |                |                |
| Depression                                      |                |                |                |
| subjects affected / exposed                     | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (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          |
| Renal and urinary disorders                     |                |                |                |
| Hydronephrosis                                  |                |                |                |
| subjects affected / exposed                     | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                |                |                |
| Bacteraemia                                     |                |                |                |
| subjects affected / exposed                     | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (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          |
| Scrotal abscess                                 |                |                |                |
| subjects affected / exposed                     | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Staphylococcal infection                        |                |                |                |



|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 33 (0.00%) | 0 / 32 (0.00%) | 0 / 29 (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          |

| <b>Serious adverse events</b>                                       | <b>B13: TN HIV NC<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg-12<br/>wk</b> | <b>C1: TN NC/GT1b<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg +<br/>RBV-8 wk</b> | <b>D1: TN NC/GT3<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg +<br/>RBV-12 wk</b> |
|---|---|--|--|
| Total subjects affected by serious adverse events                   |   |  |  |
| subjects affected / exposed   | 2 / 30 (6.67%)  | 1 / 30 (3.33%)   | 0 / 20 (0.00%)   |
| number of deaths (all causes)                                       | 0   | 0  | 0  |
| number of deaths resulting from adverse events                      | 0   | 0  | 0  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |  |  |
| Hepatic cancer  |   |  |  |
| subjects affected / exposed   | 0 / 30 (0.00%)  | 0 / 30 (0.00%)   | 0 / 20 (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  |
| Transitional cell carcinoma   |   |  |  |
| subjects affected / exposed   | 0 / 30 (0.00%)  | 0 / 30 (0.00%)   | 0 / 20 (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  |
| Injury, poisoning and procedural complications                      |   |  |  |
| Road traffic accident   |   |  |  |
| subjects affected / exposed   | 0 / 30 (0.00%)  | 0 / 30 (0.00%)   | 0 / 20 (0.00%)   |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0  | 0 / 0  |
| Cardiac disorders   |   |  |  |
| Atrial fibrillation   |   |  |  |
| subjects affected / exposed   | 0 / 30 (0.00%)  | 0 / 30 (0.00%)   | 0 / 20 (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  |
| General disorders and administration site conditions                |   |  |  |
| Asthenia  |   |  |  |
| subjects affected / exposed   | 0 / 30 (0.00%)  | 0 / 30 (0.00%)   | 0 / 20 (0.00%)   |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0  | 0 / 0  |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Chest pain                                      |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (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          |
| Gastrointestinal disorders                      |                |                |                |
| Abdominal pain                                  |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 1 / 30 (3.33%) | 0 / 20 (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          |
| Gastritis                                       |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (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          |
| Nausea  |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                         |                |                |                |
| Cholangitis                                     |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 1 / 30 (3.33%) | 0 / 20 (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          |
| Cholecystitis acute                             |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (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          |
| Psychiatric disorders                           |                |                |                |
| Depression                                      |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (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          |
| Renal and urinary disorders                     |                |                |                |
| Hydronephrosis                                  |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 1 / 30 (3.33%) | 0 / 30 (0.00%) | 0 / 20 (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          |
| <b>Infections and infestations</b>              |                |                |                |
| Bacteraemia                                     |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 1 / 30 (3.33%) | 0 / 20 (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          |
| Scrotal abscess                                 |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Staphylococcal infection                        |                |                |                |
| subjects affected / exposed                     | 1 / 30 (3.33%) | 0 / 30 (0.00%) | 0 / 20 (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          |

|  |  |  |  |
|--|--|--|--|
| <b>Serious adverse events</b>  | <b>C2: TN NC/GT1b<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg-8<br/>wk</b> | <b>D2: TN NC/GT3<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg +<br/>RBV-18 wk</b> |  |
| <b>Total subjects affected by serious adverse events</b>                   |  |  |  |
| subjects affected / exposed  | 0 / 31 (0.00%)   | 2 / 21 (9.52%)   |  |
| number of deaths (all causes)  | 0  | 0  |  |
| number of deaths resulting from adverse events                             | 0  | 0  |  |
| <b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b> |  |  |  |
| Hepatic cancer   |  |  |  |
| subjects affected / exposed  | 0 / 31 (0.00%)   | 0 / 21 (0.00%)   |  |
| occurrences causally related to treatment / all                            | 0 / 0  | 0 / 0  |  |
| deaths causally related to treatment / all                                 | 0 / 0  | 0 / 0  |  |
| Transitional cell carcinoma  |  |  |  |
| subjects affected / exposed  | 0 / 31 (0.00%)   | 0 / 21 (0.00%)   |  |
| occurrences causally related to treatment / all                            | 0 / 0  | 0 / 0  |  |
| deaths causally related to treatment / all                                 | 0 / 0  | 0 / 0  |  |
| <b>Injury, poisoning and procedural complications</b>                      |  |  |  |
| Road traffic accident  |  |  |  |

|  |                |                |  |
|--|----------------|----------------|--|
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Cardiac disorders                                    |                |                |  |
| Atrial fibrillation                                  |                |                |  |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| General disorders and administration site conditions |                |                |  |
| Asthenia   |                |                |  |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Chest pain   |                |                |  |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Gastrointestinal disorders                           |                |                |  |
| Abdominal pain                                       |                |                |  |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Gastritis  |                |                |  |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Nausea   |                |                |  |
| subjects affected / exposed                          | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Hepatobiliary disorders                              |                |                |  |
| Cholangitis  |                |                |  |

|   |                |                |  |
|---|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Cholecystitis acute                             |                |                |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 21 (4.76%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Psychiatric disorders                           |                |                |  |
| Depression                                      |                |                |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 21 (4.76%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Renal and urinary disorders                     |                |                |  |
| Hydronephrosis                                  |                |                |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Infections and infestations                     |                |                |  |
| Bacteraemia                                     |                |                |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Scrotal abscess                                 |                |                |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Staphylococcal infection                        |                |                |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

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

| <b>Non-serious adverse events</b>                           | <b>A1: TN NC<br/>Grazoprevir 100 mg<br/>+ Elbasvir 20 mg +<br/>RBV-12 wk</b> | <b>A2: TN NC<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg +<br/>RBV-12 wk</b> | <b>A3: TN NC/GT1b<br/>Grazoprevir 100 mg<br/>+ Elbasvir 50 mg-12<br/>wk</b> |
|---|--|--|---|
| Total subjects affected by non-serious adverse events       |  |  |   |
| subjects affected / exposed                                 | 19 / 25 (76.00%)   | 24 / 28 (85.71%)   | 11 / 12 (91.67%)  |
| <b>Vascular disorders</b>                                   |  |  |   |
| Flushing  |  |  |   |
| subjects affected / exposed                                 | 1 / 25 (4.00%)   | 0 / 28 (0.00%)   | 0 / 12 (0.00%)  |
| occurrences (all)   | 1  | 0  | 0   |
| Hypertension  |  |  |   |
| subjects affected / exposed                                 | 1 / 25 (4.00%)   | 0 / 28 (0.00%)   | 0 / 12 (0.00%)  |
| occurrences (all)   | 1  | 0  | 0   |
| <b>General disorders and administration site conditions</b> |  |  |   |
| Asthenia  |  |  |   |
| subjects affected / exposed                                 | 0 / 25 (0.00%)   | 0 / 28 (0.00%)   | 0 / 12 (0.00%)  |
| occurrences (all)   | 0  | 0  | 0   |
| Chills  |  |  |   |
| subjects affected / exposed                                 | 1 / 25 (4.00%)   | 0 / 28 (0.00%)   | 0 / 12 (0.00%)  |
| occurrences (all)   | 1  | 0  | 0   |
| Fatigue   |  |  |   |
| subjects affected / exposed                                 | 9 / 25 (36.00%)  | 5 / 28 (17.86%)  | 4 / 12 (33.33%)   |
| occurrences (all)   | 9  | 5  | 4   |
| Influenza like illness                                      |  |  |   |
| subjects affected / exposed                                 | 0 / 25 (0.00%)   | 0 / 28 (0.00%)   | 0 / 12 (0.00%)  |
| occurrences (all)   | 0  | 0  | 0   |
| Malaise   |  |  |   |
| subjects affected / exposed                                 | 2 / 25 (8.00%)   | 0 / 28 (0.00%)   | 0 / 12 (0.00%)  |
| occurrences (all)   | 2  | 0  | 0   |
| Oedema peripheral   |  |  |   |
| subjects affected / exposed                                 | 0 / 25 (0.00%)   | 0 / 28 (0.00%)   | 1 / 12 (8.33%)  |
| occurrences (all)   | 0  | 0  | 1   |
| Pain  |  |  |   |
| subjects affected / exposed                                 | 0 / 25 (0.00%)   | 0 / 28 (0.00%)   | 0 / 12 (0.00%)  |
| occurrences (all)   | 0  | 0  | 0   |
| Peripheral swelling   |  |  |   |
| subjects affected / exposed                                 | 0 / 25 (0.00%)   | 0 / 28 (0.00%)   | 1 / 12 (8.33%)  |
| occurrences (all)   | 0  | 0  | 1   |

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| Respiratory, thoracic and mediastinal disorders |                 |                |                 |
| Cough   |                 |                |                 |
| subjects affected / exposed                     | 1 / 25 (4.00%)  | 2 / 28 (7.14%) | 0 / 12 (0.00%)  |
| occurrences (all)                               | 1               | 2              | 0               |
| Dyspnoea  |                 |                |                 |
| subjects affected / exposed                     | 5 / 25 (20.00%) | 1 / 28 (3.57%) | 0 / 12 (0.00%)  |
| occurrences (all)                               | 5               | 1              | 0               |
| Dyspnoea exertional                             |                 |                |                 |
| subjects affected / exposed                     | 0 / 25 (0.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Epistaxis                                       |                 |                |                 |
| subjects affected / exposed                     | 1 / 25 (4.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                               | 1               | 0              | 0               |
| Oropharyngeal pain                              |                 |                |                 |
| subjects affected / exposed                     | 0 / 25 (0.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Productive cough                                |                 |                |                 |
| subjects affected / exposed                     | 0 / 25 (0.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Rhinorrhoea                                     |                 |                |                 |
| subjects affected / exposed                     | 0 / 25 (0.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Psychiatric disorders                           |                 |                |                 |
| Affect lability                                 |                 |                |                 |
| subjects affected / exposed                     | 1 / 25 (4.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                               | 1               | 0              | 0               |
| Agitation                                       |                 |                |                 |
| subjects affected / exposed                     | 2 / 25 (8.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%)  |
| occurrences (all)                               | 2               | 0              | 0               |
| Anxiety   |                 |                |                 |
| subjects affected / exposed                     | 0 / 25 (0.00%)  | 1 / 28 (3.57%) | 1 / 12 (8.33%)  |
| occurrences (all)                               | 0               | 1              | 1               |
| Depression                                      |                 |                |                 |
| subjects affected / exposed                     | 0 / 25 (0.00%)  | 0 / 28 (0.00%) | 2 / 12 (16.67%) |
| occurrences (all)                               | 0               | 0              | 2               |
| Insomnia  |                 |                |                 |

|  |                 |                |                |
|--|-----------------|----------------|----------------|
| subjects affected / exposed                    | 3 / 25 (12.00%) | 2 / 28 (7.14%) | 1 / 12 (8.33%) |
| occurrences (all)                              | 3               | 2              | 1              |
| Irritability                                   |                 |                |                |
| subjects affected / exposed                    | 2 / 25 (8.00%)  | 1 / 28 (3.57%) | 1 / 12 (8.33%) |
| occurrences (all)                              | 2               | 1              | 1              |
| Mood swings                                    |                 |                |                |
| subjects affected / exposed                    | 0 / 25 (0.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                              | 0               | 0              | 0              |
| Nightmare                                      |                 |                |                |
| subjects affected / exposed                    | 0 / 25 (0.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                              | 0               | 0              | 0              |
| Sleep disorder                                 |                 |                |                |
| subjects affected / exposed                    | 0 / 25 (0.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                              | 0               | 0              | 0              |
| Investigations                                 |                 |                |                |
| Alanine aminotransferase increased             |                 |                |                |
| subjects affected / exposed                    | 0 / 25 (0.00%)  | 2 / 28 (7.14%) | 0 / 12 (0.00%) |
| occurrences (all)                              | 0               | 2              | 0              |
| Amylase increased                              |                 |                |                |
| subjects affected / exposed                    | 0 / 25 (0.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                              | 0               | 0              | 0              |
| Aspartate aminotransferase increased           |                 |                |                |
| subjects affected / exposed                    | 0 / 25 (0.00%)  | 2 / 28 (7.14%) | 0 / 12 (0.00%) |
| occurrences (all)                              | 0               | 2              | 0              |
| Blood creatine phosphokinase increased         |                 |                |                |
| subjects affected / exposed                    | 0 / 25 (0.00%)  | 0 / 28 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all)                              | 0               | 0              | 1              |
| International normalised ratio increased       |                 |                |                |
| subjects affected / exposed                    | 3 / 25 (12.00%) | 0 / 28 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                              | 8               | 0              | 0              |
| Lipase increased                               |                 |                |                |
| subjects affected / exposed                    | 0 / 25 (0.00%)  | 0 / 28 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all)                              | 0               | 0              | 0              |
| Injury, poisoning and procedural complications |                 |                |                |



|  |                      |                      |                      |
|--|----------------------|----------------------|----------------------|
| Accidental overdose<br>subjects affected / exposed<br>occurrences (all)                                  | 1 / 25 (4.00%)<br>1  | 1 / 28 (3.57%)<br>1  | 1 / 12 (8.33%)<br>1  |
| Arthropod sting<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 25 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  |
| Contusion<br>subjects affected / exposed<br>occurrences (all)  | 0 / 25 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  |
| Cardiac disorders<br>Palpitations<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 25 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  |
| Nervous system disorders<br>Disturbance in attention<br>subjects affected / exposed<br>occurrences (all) | 1 / 25 (4.00%)<br>1  | 0 / 28 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)  | 4 / 25 (16.00%)<br>4 | 2 / 28 (7.14%)<br>2  | 1 / 12 (8.33%)<br>1  |
| Dysgeusia<br>subjects affected / exposed<br>occurrences (all)  | 1 / 25 (4.00%)<br>1  | 0 / 28 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Headache<br>subjects affected / exposed<br>occurrences (all)   | 4 / 25 (16.00%)<br>4 | 6 / 28 (21.43%)<br>6 | 5 / 12 (41.67%)<br>5 |
| Somnolence<br>subjects affected / exposed<br>occurrences (all)   | 0 / 25 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  |
| Tremor<br>subjects affected / exposed<br>occurrences (all)   | 0 / 25 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Blood and lymphatic system disorders<br>Anaemia<br>subjects affected / exposed<br>occurrences (all)      | 3 / 25 (12.00%)<br>3 | 2 / 28 (7.14%)<br>2  | 0 / 12 (0.00%)<br>0  |
| Ear and labyrinth disorders  |                      |                      |                      |

|                                  |                 |                 |                |
|----------------------------------|-----------------|-----------------|----------------|
| Ear pain                         |                 |                 |                |
| subjects affected / exposed      | 0 / 25 (0.00%)  | 0 / 28 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                | 0               | 0               | 0              |
| Gastrointestinal disorders       |                 |                 |                |
| Abdominal discomfort             |                 |                 |                |
| subjects affected / exposed      | 0 / 25 (0.00%)  | 0 / 28 (0.00%)  | 1 / 12 (8.33%) |
| occurrences (all)                | 0               | 0               | 1              |
| Abdominal pain                   |                 |                 |                |
| subjects affected / exposed      | 0 / 25 (0.00%)  | 2 / 28 (7.14%)  | 0 / 12 (0.00%) |
| occurrences (all)                | 0               | 2               | 0              |
| Abdominal pain upper             |                 |                 |                |
| subjects affected / exposed      | 5 / 25 (20.00%) | 2 / 28 (7.14%)  | 1 / 12 (8.33%) |
| occurrences (all)                | 5               | 3               | 1              |
| Constipation                     |                 |                 |                |
| subjects affected / exposed      | 1 / 25 (4.00%)  | 0 / 28 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                | 2               | 0               | 0              |
| Diarrhoea                        |                 |                 |                |
| subjects affected / exposed      | 3 / 25 (12.00%) | 5 / 28 (17.86%) | 1 / 12 (8.33%) |
| occurrences (all)                | 3               | 5               | 1              |
| Dry mouth                        |                 |                 |                |
| subjects affected / exposed      | 0 / 25 (0.00%)  | 0 / 28 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                | 0               | 0               | 0              |
| Dyspepsia                        |                 |                 |                |
| subjects affected / exposed      | 3 / 25 (12.00%) | 2 / 28 (7.14%)  | 0 / 12 (0.00%) |
| occurrences (all)                | 4               | 2               | 0              |
| Flatulence                       |                 |                 |                |
| subjects affected / exposed      | 1 / 25 (4.00%)  | 1 / 28 (3.57%)  | 0 / 12 (0.00%) |
| occurrences (all)                | 1               | 1               | 0              |
| Frequent bowel movements         |                 |                 |                |
| subjects affected / exposed      | 0 / 25 (0.00%)  | 0 / 28 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                | 0               | 0               | 0              |
| Gastrooesophageal reflux disease |                 |                 |                |
| subjects affected / exposed      | 1 / 25 (4.00%)  | 0 / 28 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                | 1               | 0               | 0              |
| Nausea                           |                 |                 |                |

|  |                      |                      |                      |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)   | 5 / 25 (20.00%)<br>5 | 7 / 28 (25.00%)<br>7 | 2 / 12 (16.67%)<br>2 |
| Tooth impacted<br>subjects affected / exposed<br>occurrences (all)                                     | 0 / 25 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)   | 2 / 25 (8.00%)<br>2  | 4 / 28 (14.29%)<br>5 | 0 / 12 (0.00%)<br>0  |
| Hepatobiliary disorders<br>Hyperbilirubinaemia<br>subjects affected / exposed<br>occurrences (all)     | 0 / 25 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Skin and subcutaneous tissue disorders<br>Alopecia<br>subjects affected / exposed<br>occurrences (all) | 2 / 25 (8.00%)<br>2  | 1 / 28 (3.57%)<br>1  | 0 / 12 (0.00%)<br>0  |
| Dermatitis contact<br>subjects affected / exposed<br>occurrences (all)                                 | 2 / 25 (8.00%)<br>2  | 0 / 28 (0.00%)<br>0  | 1 / 12 (8.33%)<br>1  |
| Dry skin<br>subjects affected / exposed<br>occurrences (all)   | 0 / 25 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Eczema<br>subjects affected / exposed<br>occurrences (all)   | 0 / 25 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Pruritus<br>subjects affected / exposed<br>occurrences (all)   | 1 / 25 (4.00%)<br>1  | 2 / 28 (7.14%)<br>2  | 0 / 12 (0.00%)<br>0  |
| Rash<br>subjects affected / exposed<br>occurrences (all)   | 1 / 25 (4.00%)<br>1  | 5 / 28 (17.86%)<br>5 | 1 / 12 (8.33%)<br>1  |
| Rash pruritic<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 25 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0  | 0 / 12 (0.00%)<br>0  |
| Renal and urinary disorders  |                      |                      |                      |

|  |                     |                     |                      |
|--|---------------------|---------------------|----------------------|
| Chromaturia<br>subjects affected / exposed<br>occurrences (all)          | 0 / 25 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Musculoskeletal and connective tissue disorders                          |                     |                     |                      |
| Arthralgia<br>subjects affected / exposed<br>occurrences (all)           | 2 / 25 (8.00%)<br>2 | 1 / 28 (3.57%)<br>1 | 0 / 12 (0.00%)<br>0  |
| Back pain<br>subjects affected / exposed<br>occurrences (all)            | 2 / 25 (8.00%)<br>2 | 0 / 28 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Joint swelling<br>subjects affected / exposed<br>occurrences (all)       | 0 / 25 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Muscle spasms<br>subjects affected / exposed<br>occurrences (all)        | 0 / 25 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Muscular weakness<br>subjects affected / exposed<br>occurrences (all)    | 1 / 25 (4.00%)<br>1 | 0 / 28 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Musculoskeletal pain<br>subjects affected / exposed<br>occurrences (all) | 0 / 25 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Myalgia<br>subjects affected / exposed<br>occurrences (all)              | 2 / 25 (8.00%)<br>2 | 1 / 28 (3.57%)<br>1 | 2 / 12 (16.67%)<br>2 |
| Neck pain<br>subjects affected / exposed<br>occurrences (all)            | 0 / 25 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Infections and infestations  |                     |                     |                      |
| Bronchitis<br>subjects affected / exposed<br>occurrences (all)           | 0 / 25 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Ear infection<br>subjects affected / exposed<br>occurrences (all)        | 0 / 25 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 | 0 / 12 (0.00%)<br>0  |
| Gastroenteritis  |                     |                     |                      |

|                                    |                |                 |                |
|------------------------------------|----------------|-----------------|----------------|
| subjects affected / exposed        | 0 / 25 (0.00%) | 0 / 28 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                  | 0              | 0               | 0              |
| Influenza                          |                |                 |                |
| subjects affected / exposed        | 0 / 25 (0.00%) | 0 / 28 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                  | 0              | 0               | 0              |
| Nasopharyngitis                    |                |                 |                |
| subjects affected / exposed        | 2 / 25 (8.00%) | 0 / 28 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                  | 2              | 0               | 0              |
| Oral herpes                        |                |                 |                |
| subjects affected / exposed        | 1 / 25 (4.00%) | 0 / 28 (0.00%)  | 0 / 12 (0.00%) |
| occurrences (all)                  | 1              | 0               | 0              |
| Sinusitis                          |                |                 |                |
| subjects affected / exposed        | 0 / 25 (0.00%) | 3 / 28 (10.71%) | 0 / 12 (0.00%) |
| occurrences (all)                  | 0              | 3               | 0              |
| Upper respiratory tract infection  |                |                 |                |
| subjects affected / exposed        | 2 / 25 (8.00%) | 1 / 28 (3.57%)  | 0 / 12 (0.00%) |
| occurrences (all)                  | 2              | 1               | 0              |
| Urinary tract infection            |                |                 |                |
| subjects affected / exposed        | 1 / 25 (4.00%) | 2 / 28 (7.14%)  | 0 / 12 (0.00%) |
| occurrences (all)                  | 1              | 2               | 0              |
| Metabolism and nutrition disorders |                |                 |                |
| Decreased appetite                 |                |                 |                |
| subjects affected / exposed        | 1 / 25 (4.00%) | 1 / 28 (3.57%)  | 0 / 12 (0.00%) |
| occurrences (all)                  | 1              | 1               | 0              |

| <b>Non-serious adverse events</b>                        | B1: TN NC/GT1a<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-8 wk | B2: TN NC<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-12 wk | B3: TN NC/GT1a<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg-12<br>wk |
|--|--|--|---|
| Total subjects affected by non-serious<br>adverse events |  |  |   |
| subjects affected / exposed                              | 27 / 30 (90.00%)   | 23 / 33 (69.70%)   | 24 / 31 (77.42%)  |
| Vascular disorders                                       |  |  |   |
| Flushing   |  |  |   |
| subjects affected / exposed                              | 1 / 30 (3.33%)   | 0 / 33 (0.00%)   | 2 / 31 (6.45%)  |
| occurrences (all)  | 1  | 0  | 3   |
| Hypertension   |  |  |   |
| subjects affected / exposed                              | 0 / 30 (0.00%)   | 2 / 33 (6.06%)   | 1 / 31 (3.23%)  |
| occurrences (all)  | 0  | 2  | 1   |
| General disorders and administration                     |  |  |   |

|   |                  |                  |                 |
|---|------------------|------------------|-----------------|
| site conditions                                 |                  |                  |                 |
| Asthenia  |                  |                  |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%)   | 3 / 33 (9.09%)   | 3 / 31 (9.68%)  |
| occurrences (all)                               | 1                | 3                | 3               |
| Chills  |                  |                  |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%)   | 0 / 33 (0.00%)   | 0 / 31 (0.00%)  |
| occurrences (all)                               | 1                | 0                | 0               |
| Fatigue   |                  |                  |                 |
| subjects affected / exposed                     | 15 / 30 (50.00%) | 10 / 33 (30.30%) | 6 / 31 (19.35%) |
| occurrences (all)                               | 15               | 10               | 7               |
| Influenza like illness                          |                  |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 0 / 33 (0.00%)   | 0 / 31 (0.00%)  |
| occurrences (all)                               | 0                | 0                | 0               |
| Malaise   |                  |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 0 / 33 (0.00%)   | 0 / 31 (0.00%)  |
| occurrences (all)                               | 0                | 0                | 0               |
| Oedema peripheral                               |                  |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 0 / 33 (0.00%)   | 0 / 31 (0.00%)  |
| occurrences (all)                               | 0                | 0                | 0               |
| Pain  |                  |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 0 / 33 (0.00%)   | 0 / 31 (0.00%)  |
| occurrences (all)                               | 0                | 0                | 0               |
| Peripheral swelling                             |                  |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 0 / 33 (0.00%)   | 0 / 31 (0.00%)  |
| occurrences (all)                               | 0                | 0                | 0               |
| Respiratory, thoracic and mediastinal disorders |                  |                  |                 |
| Cough   |                  |                  |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%)   | 1 / 33 (3.03%)   | 1 / 31 (3.23%)  |
| occurrences (all)                               | 1                | 1                | 1               |
| Dyspnoea  |                  |                  |                 |
| subjects affected / exposed                     | 4 / 30 (13.33%)  | 0 / 33 (0.00%)   | 1 / 31 (3.23%)  |
| occurrences (all)                               | 4                | 0                | 1               |
| Dyspnoea exertional                             |                  |                  |                 |
| subjects affected / exposed                     | 2 / 30 (6.67%)   | 0 / 33 (0.00%)   | 0 / 31 (0.00%)  |
| occurrences (all)                               | 2                | 0                | 0               |
| Epistaxis                                       |                  |                  |                 |

|                             |                 |                 |                |
|-----------------------------|-----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 30 (0.00%)  | 0 / 33 (0.00%)  | 0 / 31 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Oropharyngeal pain          |                 |                 |                |
| subjects affected / exposed | 1 / 30 (3.33%)  | 1 / 33 (3.03%)  | 2 / 31 (6.45%) |
| occurrences (all)           | 2               | 1               | 2              |
| Productive cough            |                 |                 |                |
| subjects affected / exposed | 1 / 30 (3.33%)  | 0 / 33 (0.00%)  | 0 / 31 (0.00%) |
| occurrences (all)           | 1               | 0               | 0              |
| Rhinorrhoea                 |                 |                 |                |
| subjects affected / exposed | 2 / 30 (6.67%)  | 0 / 33 (0.00%)  | 1 / 31 (3.23%) |
| occurrences (all)           | 2               | 0               | 1              |
| Psychiatric disorders       |                 |                 |                |
| Affect lability             |                 |                 |                |
| subjects affected / exposed | 2 / 30 (6.67%)  | 0 / 33 (0.00%)  | 0 / 31 (0.00%) |
| occurrences (all)           | 2               | 0               | 0              |
| Agitation                   |                 |                 |                |
| subjects affected / exposed | 0 / 30 (0.00%)  | 0 / 33 (0.00%)  | 0 / 31 (0.00%) |
| occurrences (all)           | 0               | 0               | 0              |
| Anxiety                     |                 |                 |                |
| subjects affected / exposed | 0 / 30 (0.00%)  | 3 / 33 (9.09%)  | 2 / 31 (6.45%) |
| occurrences (all)           | 0               | 3               | 2              |
| Depression                  |                 |                 |                |
| subjects affected / exposed | 0 / 30 (0.00%)  | 2 / 33 (6.06%)  | 1 / 31 (3.23%) |
| occurrences (all)           | 0               | 2               | 1              |
| Insomnia                    |                 |                 |                |
| subjects affected / exposed | 3 / 30 (10.00%) | 7 / 33 (21.21%) | 2 / 31 (6.45%) |
| occurrences (all)           | 3               | 8               | 2              |
| Irritability                |                 |                 |                |
| subjects affected / exposed | 2 / 30 (6.67%)  | 2 / 33 (6.06%)  | 0 / 31 (0.00%) |
| occurrences (all)           | 2               | 2               | 0              |
| Mood swings                 |                 |                 |                |
| subjects affected / exposed | 3 / 30 (10.00%) | 0 / 33 (0.00%)  | 1 / 31 (3.23%) |
| occurrences (all)           | 3               | 0               | 1              |
| Nightmare                   |                 |                 |                |
| subjects affected / exposed | 0 / 30 (0.00%)  | 0 / 33 (0.00%)  | 1 / 31 (3.23%) |
| occurrences (all)           | 0               | 0               | 1              |

|  |                      |                      |                     |
|--|----------------------|----------------------|---------------------|
| Sleep disorder<br>subjects affected / exposed<br>occurrences (all)                           | 1 / 30 (3.33%)<br>1  | 2 / 33 (6.06%)<br>2  | 3 / 31 (9.68%)<br>3 |
| Investigations   |                      |                      |                     |
| Alanine aminotransferase increased<br>subjects affected / exposed<br>occurrences (all)       | 0 / 30 (0.00%)<br>0  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0 |
| Amylase increased<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 30 (0.00%)<br>0  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0 |
| Aspartate aminotransferase increased<br>subjects affected / exposed<br>occurrences (all)     | 0 / 30 (0.00%)<br>0  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0 |
| Blood creatine phosphokinase increased<br>subjects affected / exposed<br>occurrences (all)   | 0 / 30 (0.00%)<br>0  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0 |
| International normalised ratio increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 30 (0.00%)<br>0  | 2 / 33 (6.06%)<br>2  | 0 / 31 (0.00%)<br>0 |
| Lipase increased<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 30 (0.00%)<br>0  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0 |
| Injury, poisoning and procedural complications   |                      |                      |                     |
| Accidental overdose<br>subjects affected / exposed<br>occurrences (all)                      | 3 / 30 (10.00%)<br>3 | 4 / 33 (12.12%)<br>5 | 0 / 31 (0.00%)<br>0 |
| Arthropod sting<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 30 (0.00%)<br>0  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0 |
| Contusion<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 30 (0.00%)<br>0  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0 |
| Cardiac disorders  |                      |                      |                     |



|  |                      |                      |                        |
|--|----------------------|----------------------|------------------------|
| Palpitations<br>subjects affected / exposed<br>occurrences (all)             | 1 / 30 (3.33%)<br>1  | 2 / 33 (6.06%)<br>2  | 0 / 31 (0.00%)<br>0    |
| Nervous system disorders   |                      |                      |                        |
| Disturbance in attention<br>subjects affected / exposed<br>occurrences (all) | 3 / 30 (10.00%)<br>3 | 1 / 33 (3.03%)<br>1  | 0 / 31 (0.00%)<br>0    |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                | 3 / 30 (10.00%)<br>3 | 1 / 33 (3.03%)<br>1  | 3 / 31 (9.68%)<br>3    |
| Dysgeusia<br>subjects affected / exposed<br>occurrences (all)                | 1 / 30 (3.33%)<br>1  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0    |
| Headache<br>subjects affected / exposed<br>occurrences (all)                 | 7 / 30 (23.33%)<br>7 | 7 / 33 (21.21%)<br>9 | 10 / 31 (32.26%)<br>11 |
| Somnolence<br>subjects affected / exposed<br>occurrences (all)               | 1 / 30 (3.33%)<br>1  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0    |
| Tremor<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 30 (0.00%)<br>0  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0    |
| Blood and lymphatic system disorders   |                      |                      |                        |
| Anaemia<br>subjects affected / exposed<br>occurrences (all)                  | 1 / 30 (3.33%)<br>1  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0    |
| Ear and labyrinth disorders  |                      |                      |                        |
| Ear pain<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 30 (0.00%)<br>0  | 2 / 33 (6.06%)<br>2  | 0 / 31 (0.00%)<br>0    |
| Gastrointestinal disorders   |                      |                      |                        |
| Abdominal discomfort<br>subjects affected / exposed<br>occurrences (all)     | 0 / 30 (0.00%)<br>0  | 0 / 33 (0.00%)<br>0  | 1 / 31 (3.23%)<br>1    |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all)           | 0 / 30 (0.00%)<br>0  | 2 / 33 (6.06%)<br>2  | 1 / 31 (3.23%)<br>1    |

|  |                      |                      |                      |
|--|----------------------|----------------------|----------------------|
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all)             | 2 / 30 (6.67%)<br>2  | 3 / 33 (9.09%)<br>3  | 0 / 31 (0.00%)<br>0  |
| Constipation<br>subjects affected / exposed<br>occurrences (all)                     | 1 / 30 (3.33%)<br>1  | 0 / 33 (0.00%)<br>0  | 1 / 31 (3.23%)<br>1  |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)                        | 5 / 30 (16.67%)<br>5 | 2 / 33 (6.06%)<br>2  | 4 / 31 (12.90%)<br>5 |
| Dry mouth<br>subjects affected / exposed<br>occurrences (all)                        | 1 / 30 (3.33%)<br>1  | 1 / 33 (3.03%)<br>1  | 1 / 31 (3.23%)<br>1  |
| Dyspepsia<br>subjects affected / exposed<br>occurrences (all)                        | 1 / 30 (3.33%)<br>1  | 1 / 33 (3.03%)<br>1  | 0 / 31 (0.00%)<br>0  |
| Flatulence<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 30 (0.00%)<br>0  | 2 / 33 (6.06%)<br>2  | 0 / 31 (0.00%)<br>0  |
| Frequent bowel movements<br>subjects affected / exposed<br>occurrences (all)         | 0 / 30 (0.00%)<br>0  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0  |
| Gastrooesophageal reflux disease<br>subjects affected / exposed<br>occurrences (all) | 1 / 30 (3.33%)<br>1  | 0 / 33 (0.00%)<br>0  | 1 / 31 (3.23%)<br>1  |
| Nausea<br>subjects affected / exposed<br>occurrences (all)                           | 8 / 30 (26.67%)<br>8 | 6 / 33 (18.18%)<br>6 | 5 / 31 (16.13%)<br>5 |
| Tooth impacted<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 30 (0.00%)<br>0  | 0 / 33 (0.00%)<br>0  | 0 / 31 (0.00%)<br>0  |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)                         | 2 / 30 (6.67%)<br>2  | 2 / 33 (6.06%)<br>2  | 1 / 31 (3.23%)<br>1  |
| Hepatobiliary disorders<br>Hyperbilirubinaemia                                       |                      |                      |                      |

|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all) | 1 / 30 (3.33%)<br>1 | 2 / 33 (6.06%)<br>2 | 0 / 31 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders           |                     |                     |                     |
| Alopecia   |                     |                     |                     |
| subjects affected / exposed                      | 0 / 30 (0.00%)      | 0 / 33 (0.00%)      | 1 / 31 (3.23%)      |
| occurrences (all)                                | 0                   | 0                   | 1                   |
| Dermatitis contact                               |                     |                     |                     |
| subjects affected / exposed                      | 1 / 30 (3.33%)      | 0 / 33 (0.00%)      | 0 / 31 (0.00%)      |
| occurrences (all)                                | 1                   | 0                   | 0                   |
| Dry skin   |                     |                     |                     |
| subjects affected / exposed                      | 2 / 30 (6.67%)      | 0 / 33 (0.00%)      | 0 / 31 (0.00%)      |
| occurrences (all)                                | 2                   | 0                   | 0                   |
| Eczema   |                     |                     |                     |
| subjects affected / exposed                      | 0 / 30 (0.00%)      | 0 / 33 (0.00%)      | 0 / 31 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Pruritus   |                     |                     |                     |
| subjects affected / exposed                      | 6 / 30 (20.00%)     | 4 / 33 (12.12%)     | 0 / 31 (0.00%)      |
| occurrences (all)                                | 6                   | 4                   | 0                   |
| Rash   |                     |                     |                     |
| subjects affected / exposed                      | 0 / 30 (0.00%)      | 3 / 33 (9.09%)      | 1 / 31 (3.23%)      |
| occurrences (all)                                | 0                   | 4                   | 1                   |
| Rash pruritic                                    |                     |                     |                     |
| subjects affected / exposed                      | 2 / 30 (6.67%)      | 0 / 33 (0.00%)      | 0 / 31 (0.00%)      |
| occurrences (all)                                | 2                   | 0                   | 0                   |
| Renal and urinary disorders                      |                     |                     |                     |
| Chromaturia                                      |                     |                     |                     |
| subjects affected / exposed                      | 1 / 30 (3.33%)      | 0 / 33 (0.00%)      | 0 / 31 (0.00%)      |
| occurrences (all)                                | 1                   | 0                   | 0                   |
| Musculoskeletal and connective tissue disorders  |                     |                     |                     |
| Arthralgia                                       |                     |                     |                     |
| subjects affected / exposed                      | 1 / 30 (3.33%)      | 2 / 33 (6.06%)      | 2 / 31 (6.45%)      |
| occurrences (all)                                | 1                   | 3                   | 2                   |
| Back pain  |                     |                     |                     |
| subjects affected / exposed                      | 0 / 30 (0.00%)      | 2 / 33 (6.06%)      | 2 / 31 (6.45%)      |
| occurrences (all)                                | 0                   | 2                   | 2                   |
| Joint swelling                                   |                     |                     |                     |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 2 / 30 (6.67%) | 0 / 33 (0.00%) | 0 / 31 (0.00%) |
| occurrences (all)           | 2              | 0              | 0              |
| Muscle spasms               |                |                |                |
| subjects affected / exposed | 1 / 30 (3.33%) | 2 / 33 (6.06%) | 1 / 31 (3.23%) |
| occurrences (all)           | 1              | 2              | 1              |
| Muscular weakness           |                |                |                |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 33 (0.00%) | 1 / 31 (3.23%) |
| occurrences (all)           | 1              | 0              | 1              |
| Musculoskeletal pain        |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 33 (0.00%) | 1 / 31 (3.23%) |
| occurrences (all)           | 0              | 0              | 1              |
| Myalgia                     |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 1 / 33 (3.03%) | 1 / 31 (3.23%) |
| occurrences (all)           | 0              | 1              | 1              |
| Neck pain                   |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 1 / 33 (3.03%) | 2 / 31 (6.45%) |
| occurrences (all)           | 0              | 1              | 2              |
| Infections and infestations |                |                |                |
| Bronchitis                  |                |                |                |
| subjects affected / exposed | 2 / 30 (6.67%) | 0 / 33 (0.00%) | 0 / 31 (0.00%) |
| occurrences (all)           | 2              | 0              | 0              |
| Ear infection               |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 33 (0.00%) | 0 / 31 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Gastroenteritis             |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 33 (0.00%) | 1 / 31 (3.23%) |
| occurrences (all)           | 0              | 0              | 1              |
| Influenza                   |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 33 (0.00%) | 1 / 31 (3.23%) |
| occurrences (all)           | 0              | 0              | 1              |
| Nasopharyngitis             |                |                |                |
| subjects affected / exposed | 1 / 30 (3.33%) | 3 / 33 (9.09%) | 1 / 31 (3.23%) |
| occurrences (all)           | 1              | 3              | 1              |
| Oral herpes                 |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 1 / 33 (3.03%) | 0 / 31 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |

|                                    |                 |                |                |
|------------------------------------|-----------------|----------------|----------------|
| Sinusitis                          |                 |                |                |
| subjects affected / exposed        | 1 / 30 (3.33%)  | 0 / 33 (0.00%) | 0 / 31 (0.00%) |
| occurrences (all)                  | 1               | 0              | 0              |
| Upper respiratory tract infection  |                 |                |                |
| subjects affected / exposed        | 3 / 30 (10.00%) | 1 / 33 (3.03%) | 0 / 31 (0.00%) |
| occurrences (all)                  | 3               | 1              | 0              |
| Urinary tract infection            |                 |                |                |
| subjects affected / exposed        | 1 / 30 (3.33%)  | 0 / 33 (0.00%) | 0 / 31 (0.00%) |
| occurrences (all)                  | 1               | 0              | 0              |
| Metabolism and nutrition disorders |                 |                |                |
| Decreased appetite                 |                 |                |                |
| subjects affected / exposed        | 4 / 30 (13.33%) | 0 / 33 (0.00%) | 2 / 31 (6.45%) |
| occurrences (all)                  | 5               | 0              | 2              |

| <b>Non-serious adverse events</b>                     | B4: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-12 wk | B5: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg for<br>12 wk | B6: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-18 wk |
|---|---|---|---|
| Total subjects affected by non-serious adverse events |   |   |   |
| subjects affected / exposed                           | 23 / 31 (74.19%)  | 18 / 29 (62.07%)  | 26 / 32 (81.25%)  |
| Vascular disorders                                    |   |   |   |
| Flushing  |   |   |   |
| subjects affected / exposed                           | 1 / 31 (3.23%)  | 0 / 29 (0.00%)  | 0 / 32 (0.00%)  |
| occurrences (all)                                     | 1   | 0   | 0   |
| Hypertension  |   |   |   |
| subjects affected / exposed                           | 0 / 31 (0.00%)  | 1 / 29 (3.45%)  | 1 / 32 (3.13%)  |
| occurrences (all)                                     | 0   | 1   | 1   |
| General disorders and administration site conditions  |   |   |   |
| Asthenia  |   |   |   |
| subjects affected / exposed                           | 2 / 31 (6.45%)  | 1 / 29 (3.45%)  | 5 / 32 (15.63%)   |
| occurrences (all)                                     | 2   | 1   | 6   |
| Chills  |   |   |   |
| subjects affected / exposed                           | 0 / 31 (0.00%)  | 0 / 29 (0.00%)  | 2 / 32 (6.25%)  |
| occurrences (all)                                     | 0   | 0   | 3   |
| Fatigue   |   |   |   |
| subjects affected / exposed                           | 11 / 31 (35.48%)  | 6 / 29 (20.69%)   | 9 / 32 (28.13%)   |
| occurrences (all)                                     | 11  | 6   | 10  |
| Influenza like illness                                |   |   |   |

|   |                |                |                 |
|---|----------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 1 / 32 (3.13%)  |
| occurrences (all)                               | 0              | 0              | 1               |
| Malaise   |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 1 / 32 (3.13%)  |
| occurrences (all)                               | 0              | 0              | 1               |
| Oedema peripheral                               |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 29 (3.45%) | 0 / 32 (0.00%)  |
| occurrences (all)                               | 0              | 1              | 0               |
| Pain  |                |                |                 |
| subjects affected / exposed                     | 1 / 31 (3.23%) | 0 / 29 (0.00%) | 1 / 32 (3.13%)  |
| occurrences (all)                               | 1              | 0              | 1               |
| Peripheral swelling                             |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 29 (3.45%) | 1 / 32 (3.13%)  |
| occurrences (all)                               | 0              | 1              | 1               |
| Respiratory, thoracic and mediastinal disorders |                |                |                 |
| Cough   |                |                |                 |
| subjects affected / exposed                     | 1 / 31 (3.23%) | 2 / 29 (6.90%) | 6 / 32 (18.75%) |
| occurrences (all)                               | 1              | 2              | 6               |
| Dyspnoea  |                |                |                 |
| subjects affected / exposed                     | 1 / 31 (3.23%) | 0 / 29 (0.00%) | 5 / 32 (15.63%) |
| occurrences (all)                               | 1              | 0              | 5               |
| Dyspnoea exertional                             |                |                |                 |
| subjects affected / exposed                     | 1 / 31 (3.23%) | 0 / 29 (0.00%) | 1 / 32 (3.13%)  |
| occurrences (all)                               | 1              | 0              | 1               |
| Epistaxis                                       |                |                |                 |
| subjects affected / exposed                     | 1 / 31 (3.23%) | 0 / 29 (0.00%) | 3 / 32 (9.38%)  |
| occurrences (all)                               | 1              | 0              | 3               |
| Oropharyngeal pain                              |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Productive cough                                |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Rhinorrhoea                                     |                |                |                 |

|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 31 (0.00%)<br>0 | 0 / 29 (0.00%)<br>0 | 0 / 32 (0.00%)<br>0 |
| Psychiatric disorders                            |                     |                     |                     |
| Affect lability                                  |                     |                     |                     |
| subjects affected / exposed                      | 1 / 31 (3.23%)      | 1 / 29 (3.45%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 1                   | 1                   | 0                   |
| Agitation  |                     |                     |                     |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 29 (0.00%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Anxiety  |                     |                     |                     |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 29 (0.00%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Depression                                       |                     |                     |                     |
| subjects affected / exposed                      | 2 / 31 (6.45%)      | 0 / 29 (0.00%)      | 1 / 32 (3.13%)      |
| occurrences (all)                                | 2                   | 0                   | 1                   |
| Insomnia   |                     |                     |                     |
| subjects affected / exposed                      | 5 / 31 (16.13%)     | 2 / 29 (6.90%)      | 4 / 32 (12.50%)     |
| occurrences (all)                                | 5                   | 2                   | 4                   |
| Irritability                                     |                     |                     |                     |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 29 (0.00%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Mood swings                                      |                     |                     |                     |
| subjects affected / exposed                      | 1 / 31 (3.23%)      | 0 / 29 (0.00%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 1                   | 0                   | 0                   |
| Nightmare  |                     |                     |                     |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 29 (0.00%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Sleep disorder                                   |                     |                     |                     |
| subjects affected / exposed                      | 4 / 31 (12.90%)     | 0 / 29 (0.00%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 4                   | 0                   | 0                   |
| Investigations                                   |                     |                     |                     |
| Alanine aminotransferase increased               |                     |                     |                     |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 29 (0.00%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Amylase increased                                |                     |                     |                     |

|  |                 |                |                |
|--|-----------------|----------------|----------------|
| subjects affected / exposed                    | 0 / 31 (0.00%)  | 2 / 29 (6.90%) | 0 / 32 (0.00%) |
| occurrences (all)                              | 0               | 2              | 0              |
| Aspartate aminotransferase increased           |                 |                |                |
| subjects affected / exposed                    | 0 / 31 (0.00%)  | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                              | 0               | 0              | 0              |
| Blood creatine phosphokinase increased         |                 |                |                |
| subjects affected / exposed                    | 0 / 31 (0.00%)  | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                              | 0               | 0              | 0              |
| International normalised ratio increased       |                 |                |                |
| subjects affected / exposed                    | 0 / 31 (0.00%)  | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                              | 0               | 0              | 0              |
| Lipase increased                               |                 |                |                |
| subjects affected / exposed                    | 0 / 31 (0.00%)  | 2 / 29 (6.90%) | 0 / 32 (0.00%) |
| occurrences (all)                              | 0               | 2              | 0              |
| Injury, poisoning and procedural complications |                 |                |                |
| Accidental overdose                            |                 |                |                |
| subjects affected / exposed                    | 5 / 31 (16.13%) | 0 / 29 (0.00%) | 3 / 32 (9.38%) |
| occurrences (all)                              | 6               | 0              | 3              |
| Arthropod sting                                |                 |                |                |
| subjects affected / exposed                    | 0 / 31 (0.00%)  | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                              | 0               | 0              | 0              |
| Contusion                                      |                 |                |                |
| subjects affected / exposed                    | 0 / 31 (0.00%)  | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                              | 0               | 0              | 0              |
| Cardiac disorders                              |                 |                |                |
| Palpitations                                   |                 |                |                |
| subjects affected / exposed                    | 0 / 31 (0.00%)  | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                              | 0               | 0              | 0              |
| Nervous system disorders                       |                 |                |                |
| Disturbance in attention                       |                 |                |                |
| subjects affected / exposed                    | 0 / 31 (0.00%)  | 1 / 29 (3.45%) | 0 / 32 (0.00%) |
| occurrences (all)                              | 0               | 1              | 0              |
| Dizziness                                      |                 |                |                |



|                                      |                |                 |                  |
|--------------------------------------|----------------|-----------------|------------------|
| subjects affected / exposed          | 2 / 31 (6.45%) | 2 / 29 (6.90%)  | 2 / 32 (6.25%)   |
| occurrences (all)                    | 2              | 2               | 2                |
| Dysgeusia                            |                |                 |                  |
| subjects affected / exposed          | 1 / 31 (3.23%) | 0 / 29 (0.00%)  | 2 / 32 (6.25%)   |
| occurrences (all)                    | 1              | 0               | 2                |
| Headache                             |                |                 |                  |
| subjects affected / exposed          | 2 / 31 (6.45%) | 4 / 29 (13.79%) | 11 / 32 (34.38%) |
| occurrences (all)                    | 3              | 5               | 13               |
| Somnolence                           |                |                 |                  |
| subjects affected / exposed          | 0 / 31 (0.00%) | 0 / 29 (0.00%)  | 0 / 32 (0.00%)   |
| occurrences (all)                    | 0              | 0               | 0                |
| Tremor                               |                |                 |                  |
| subjects affected / exposed          | 0 / 31 (0.00%) | 0 / 29 (0.00%)  | 0 / 32 (0.00%)   |
| occurrences (all)                    | 0              | 0               | 0                |
| Blood and lymphatic system disorders |                |                 |                  |
| Anaemia                              |                |                 |                  |
| subjects affected / exposed          | 1 / 31 (3.23%) | 0 / 29 (0.00%)  | 4 / 32 (12.50%)  |
| occurrences (all)                    | 1              | 0               | 4                |
| Ear and labyrinth disorders          |                |                 |                  |
| Ear pain                             |                |                 |                  |
| subjects affected / exposed          | 0 / 31 (0.00%) | 0 / 29 (0.00%)  | 0 / 32 (0.00%)   |
| occurrences (all)                    | 0              | 0               | 0                |
| Gastrointestinal disorders           |                |                 |                  |
| Abdominal discomfort                 |                |                 |                  |
| subjects affected / exposed          | 0 / 31 (0.00%) | 0 / 29 (0.00%)  | 1 / 32 (3.13%)   |
| occurrences (all)                    | 0              | 0               | 1                |
| Abdominal pain                       |                |                 |                  |
| subjects affected / exposed          | 0 / 31 (0.00%) | 1 / 29 (3.45%)  | 2 / 32 (6.25%)   |
| occurrences (all)                    | 0              | 1               | 2                |
| Abdominal pain upper                 |                |                 |                  |
| subjects affected / exposed          | 3 / 31 (9.68%) | 0 / 29 (0.00%)  | 3 / 32 (9.38%)   |
| occurrences (all)                    | 3              | 0               | 3                |
| Constipation                         |                |                 |                  |
| subjects affected / exposed          | 1 / 31 (3.23%) | 1 / 29 (3.45%)  | 0 / 32 (0.00%)   |
| occurrences (all)                    | 1              | 1               | 0                |
| Diarrhoea                            |                |                 |                  |

|  |                 |                |                 |
|--|-----------------|----------------|-----------------|
| subjects affected / exposed            | 1 / 31 (3.23%)  | 2 / 29 (6.90%) | 4 / 32 (12.50%) |
| occurrences (all)                      | 1               | 2              | 4               |
| Dry mouth                              |                 |                |                 |
| subjects affected / exposed            | 1 / 31 (3.23%)  | 1 / 29 (3.45%) | 1 / 32 (3.13%)  |
| occurrences (all)                      | 1               | 1              | 1               |
| Dyspepsia                              |                 |                |                 |
| subjects affected / exposed            | 0 / 31 (0.00%)  | 0 / 29 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 0               | 0              | 0               |
| Flatulence                             |                 |                |                 |
| subjects affected / exposed            | 0 / 31 (0.00%)  | 0 / 29 (0.00%) | 1 / 32 (3.13%)  |
| occurrences (all)                      | 0               | 0              | 1               |
| Frequent bowel movements               |                 |                |                 |
| subjects affected / exposed            | 1 / 31 (3.23%)  | 0 / 29 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 1               | 0              | 0               |
| Gastrooesophageal reflux disease       |                 |                |                 |
| subjects affected / exposed            | 2 / 31 (6.45%)  | 0 / 29 (0.00%) | 2 / 32 (6.25%)  |
| occurrences (all)                      | 2               | 0              | 2               |
| Nausea                                 |                 |                |                 |
| subjects affected / exposed            | 4 / 31 (12.90%) | 0 / 29 (0.00%) | 4 / 32 (12.50%) |
| occurrences (all)                      | 4               | 0              | 5               |
| Tooth impacted                         |                 |                |                 |
| subjects affected / exposed            | 0 / 31 (0.00%)  | 0 / 29 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 0               | 0              | 0               |
| Vomiting                               |                 |                |                 |
| subjects affected / exposed            | 2 / 31 (6.45%)  | 2 / 29 (6.90%) | 3 / 32 (9.38%)  |
| occurrences (all)                      | 2               | 2              | 5               |
| Hepatobiliary disorders                |                 |                |                 |
| Hyperbilirubinaemia                    |                 |                |                 |
| subjects affected / exposed            | 0 / 31 (0.00%)  | 0 / 29 (0.00%) | 1 / 32 (3.13%)  |
| occurrences (all)                      | 0               | 0              | 1               |
| Skin and subcutaneous tissue disorders |                 |                |                 |
| Alopecia                               |                 |                |                 |
| subjects affected / exposed            | 0 / 31 (0.00%)  | 0 / 29 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 0               | 0              | 0               |
| Dermatitis contact                     |                 |                |                 |

|   |                |                 |                 |
|---|----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%)  | 0 / 32 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0               |
| Dry skin  |                |                 |                 |
| subjects affected / exposed                     | 2 / 31 (6.45%) | 0 / 29 (0.00%)  | 4 / 32 (12.50%) |
| occurrences (all)                               | 2              | 0               | 4               |
| Eczema  |                |                 |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%)  | 2 / 32 (6.25%)  |
| occurrences (all)                               | 0              | 0               | 2               |
| Pruritus  |                |                 |                 |
| subjects affected / exposed                     | 2 / 31 (6.45%) | 1 / 29 (3.45%)  | 5 / 32 (15.63%) |
| occurrences (all)                               | 2              | 1               | 5               |
| Rash  |                |                 |                 |
| subjects affected / exposed                     | 3 / 31 (9.68%) | 0 / 29 (0.00%)  | 7 / 32 (21.88%) |
| occurrences (all)                               | 4              | 0               | 8               |
| Rash pruritic                                   |                |                 |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%)  | 0 / 32 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0               |
| Renal and urinary disorders                     |                |                 |                 |
| Chromaturia                                     |                |                 |                 |
| subjects affected / exposed                     | 2 / 31 (6.45%) | 0 / 29 (0.00%)  | 0 / 32 (0.00%)  |
| occurrences (all)                               | 2              | 0               | 0               |
| Musculoskeletal and connective tissue disorders |                |                 |                 |
| Arthralgia                                      |                |                 |                 |
| subjects affected / exposed                     | 2 / 31 (6.45%) | 3 / 29 (10.34%) | 2 / 32 (6.25%)  |
| occurrences (all)                               | 2              | 4               | 2               |
| Back pain                                       |                |                 |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 2 / 29 (6.90%)  | 4 / 32 (12.50%) |
| occurrences (all)                               | 0              | 2               | 4               |
| Joint swelling                                  |                |                 |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 29 (0.00%)  | 0 / 32 (0.00%)  |
| occurrences (all)                               | 0              | 0               | 0               |
| Muscle spasms                                   |                |                 |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 29 (3.45%)  | 1 / 32 (3.13%)  |
| occurrences (all)                               | 0              | 1               | 1               |
| Muscular weakness                               |                |                 |                 |

|                                   |                |                |                |
|-----------------------------------|----------------|----------------|----------------|
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Musculoskeletal pain              |                |                |                |
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Myalgia                           |                |                |                |
| subjects affected / exposed       | 1 / 31 (3.23%) | 1 / 29 (3.45%) | 0 / 32 (0.00%) |
| occurrences (all)                 | 1              | 1              | 0              |
| Neck pain                         |                |                |                |
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Infections and infestations       |                |                |                |
| Bronchitis                        |                |                |                |
| subjects affected / exposed       | 1 / 31 (3.23%) | 0 / 29 (0.00%) | 2 / 32 (6.25%) |
| occurrences (all)                 | 1              | 0              | 2              |
| Ear infection                     |                |                |                |
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all)                 | 0              | 0              | 1              |
| Gastroenteritis                   |                |                |                |
| subjects affected / exposed       | 1 / 31 (3.23%) | 0 / 29 (0.00%) | 2 / 32 (6.25%) |
| occurrences (all)                 | 1              | 0              | 2              |
| Influenza                         |                |                |                |
| subjects affected / exposed       | 1 / 31 (3.23%) | 1 / 29 (3.45%) | 0 / 32 (0.00%) |
| occurrences (all)                 | 1              | 1              | 0              |
| Nasopharyngitis                   |                |                |                |
| subjects affected / exposed       | 2 / 31 (6.45%) | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                 | 2              | 0              | 0              |
| Oral herpes                       |                |                |                |
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all)                 | 0              | 0              | 1              |
| Sinusitis                         |                |                |                |
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 29 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                 | 0              | 0              | 0              |
| Upper respiratory tract infection |                |                |                |
| subjects affected / exposed       | 0 / 31 (0.00%) | 2 / 29 (6.90%) | 3 / 32 (9.38%) |
| occurrences (all)                 | 0              | 2              | 3              |

|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)                                  | 0 / 31 (0.00%)<br>0 | 1 / 29 (3.45%)<br>3 | 0 / 32 (0.00%)<br>0 |
| Metabolism and nutrition disorders<br>Decreased appetite<br>subjects affected / exposed<br>occurrences (all) | 1 / 31 (3.23%)<br>1 | 2 / 29 (6.90%)<br>2 | 1 / 32 (3.13%)<br>1 |

| <b>Non-serious adverse events</b>   | B7: TN C<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg-18<br>wk | B9: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg-12 wk | B8: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg +RBV-12 wk |
|---|---|--|---|
| Total subjects affected by non-serious<br>adverse events<br>subjects affected / exposed                                 | 24 / 31 (77.42%)  | 25 / 33 (75.76%)                                       | 24 / 32 (75.00%)  |
| Vascular disorders<br>Flushing<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 31 (0.00%)<br>0   | 0 / 33 (0.00%)<br>0                                    | 0 / 32 (0.00%)<br>0   |
| Hypertension<br>subjects affected / exposed<br>occurrences (all)  | 0 / 31 (0.00%)<br>0   | 0 / 33 (0.00%)<br>0                                    | 1 / 32 (3.13%)<br>1   |
| General disorders and administration<br>site conditions<br>Asthenia<br>subjects affected / exposed<br>occurrences (all) | 2 / 31 (6.45%)<br>2   | 5 / 33 (15.15%)<br>7                                   | 7 / 32 (21.88%)<br>7  |
| Chills<br>subjects affected / exposed<br>occurrences (all)  | 2 / 31 (6.45%)<br>2   | 1 / 33 (3.03%)<br>1                                    | 0 / 32 (0.00%)<br>0   |
| Fatigue<br>subjects affected / exposed<br>occurrences (all)   | 6 / 31 (19.35%)<br>7  | 10 / 33 (30.30%)<br>12                                 | 6 / 32 (18.75%)<br>6  |
| Influenza like illness<br>subjects affected / exposed<br>occurrences (all)  | 0 / 31 (0.00%)<br>0   | 0 / 33 (0.00%)<br>0                                    | 1 / 32 (3.13%)<br>1   |
| Malaise<br>subjects affected / exposed<br>occurrences (all)   | 0 / 31 (0.00%)<br>0   | 0 / 33 (0.00%)<br>0                                    | 1 / 32 (3.13%)<br>1   |
| Oedema peripheral   |   |  |   |

|   |                |                |                 |
|---|----------------|----------------|-----------------|
| subjects affected / exposed                     | 1 / 31 (3.23%) | 0 / 33 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0               |
| Pain  |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 33 (3.03%) | 1 / 32 (3.13%)  |
| occurrences (all)                               | 0              | 1              | 1               |
| Peripheral swelling                             |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Respiratory, thoracic and mediastinal disorders |                |                |                 |
| Cough   |                |                |                 |
| subjects affected / exposed                     | 1 / 31 (3.23%) | 1 / 33 (3.03%) | 5 / 32 (15.63%) |
| occurrences (all)                               | 1              | 1              | 5               |
| Dyspnoea  |                |                |                 |
| subjects affected / exposed                     | 1 / 31 (3.23%) | 2 / 33 (6.06%) | 1 / 32 (3.13%)  |
| occurrences (all)                               | 1              | 2              | 1               |
| Dyspnoea exertional                             |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 1 / 32 (3.13%)  |
| occurrences (all)                               | 0              | 0              | 1               |
| Epistaxis                                       |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Oropharyngeal pain                              |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 33 (3.03%) | 1 / 32 (3.13%)  |
| occurrences (all)                               | 0              | 1              | 1               |
| Productive cough                                |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Rhinorrhoea                                     |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 1 / 32 (3.13%)  |
| occurrences (all)                               | 0              | 0              | 1               |
| Psychiatric disorders                           |                |                |                 |
| Affect lability                                 |                |                |                 |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Agitation                                       |                |                |                 |

|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed            | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Anxiety                                |                |                |                |
| subjects affected / exposed            | 0 / 31 (0.00%) | 1 / 33 (3.03%) | 1 / 32 (3.13%) |
| occurrences (all)                      | 0              | 1              | 1              |
| Depression                             |                |                |                |
| subjects affected / exposed            | 1 / 31 (3.23%) | 0 / 33 (0.00%) | 2 / 32 (6.25%) |
| occurrences (all)                      | 2              | 0              | 2              |
| Insomnia                               |                |                |                |
| subjects affected / exposed            | 0 / 31 (0.00%) | 3 / 33 (9.09%) | 2 / 32 (6.25%) |
| occurrences (all)                      | 0              | 3              | 3              |
| Irritability                           |                |                |                |
| subjects affected / exposed            | 2 / 31 (6.45%) | 1 / 33 (3.03%) | 2 / 32 (6.25%) |
| occurrences (all)                      | 2              | 1              | 2              |
| Mood swings                            |                |                |                |
| subjects affected / exposed            | 1 / 31 (3.23%) | 0 / 33 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all)                      | 1              | 0              | 1              |
| Nightmare                              |                |                |                |
| subjects affected / exposed            | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 2 / 32 (6.25%) |
| occurrences (all)                      | 0              | 0              | 2              |
| Sleep disorder                         |                |                |                |
| subjects affected / exposed            | 1 / 31 (3.23%) | 1 / 33 (3.03%) | 0 / 32 (0.00%) |
| occurrences (all)                      | 1              | 1              | 0              |
| Investigations                         |                |                |                |
| Alanine aminotransferase increased     |                |                |                |
| subjects affected / exposed            | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Amylase increased                      |                |                |                |
| subjects affected / exposed            | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Aspartate aminotransferase increased   |                |                |                |
| subjects affected / exposed            | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                      | 0              | 0              | 0              |
| Blood creatine phosphokinase increased |                |                |                |

|  |                        |                      |                        |
|--|------------------------|----------------------|------------------------|
| subjects affected / exposed<br>occurrences (all)   | 0 / 31 (0.00%)<br>0    | 0 / 33 (0.00%)<br>0  | 1 / 32 (3.13%)<br>1    |
| International normalised ratio<br>increased<br>subjects affected / exposed<br>occurrences (all)                              | 0 / 31 (0.00%)<br>0    | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0    |
| Lipase increased<br>subjects affected / exposed<br>occurrences (all)   | 0 / 31 (0.00%)<br>0    | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0    |
| Injury, poisoning and procedural<br>complications<br>Accidental overdose<br>subjects affected / exposed<br>occurrences (all) | 0 / 31 (0.00%)<br>0    | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0    |
| Arthropod sting<br>subjects affected / exposed<br>occurrences (all)  | 0 / 31 (0.00%)<br>0    | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0    |
| Contusion<br>subjects affected / exposed<br>occurrences (all)  | 0 / 31 (0.00%)<br>0    | 0 / 33 (0.00%)<br>0  | 1 / 32 (3.13%)<br>1    |
| Cardiac disorders<br>Palpitations<br>subjects affected / exposed<br>occurrences (all)  | 0 / 31 (0.00%)<br>0    | 0 / 33 (0.00%)<br>0  | 1 / 32 (3.13%)<br>1    |
| Nervous system disorders<br>Disturbance in attention<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 31 (0.00%)<br>0    | 1 / 33 (3.03%)<br>1  | 1 / 32 (3.13%)<br>1    |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)  | 4 / 31 (12.90%)<br>4   | 1 / 33 (3.03%)<br>1  | 2 / 32 (6.25%)<br>2    |
| Dysgeusia<br>subjects affected / exposed<br>occurrences (all)  | 0 / 31 (0.00%)<br>0    | 0 / 33 (0.00%)<br>0  | 1 / 32 (3.13%)<br>1    |
| Headache<br>subjects affected / exposed<br>occurrences (all)   | 10 / 31 (32.26%)<br>12 | 6 / 33 (18.18%)<br>6 | 10 / 32 (31.25%)<br>12 |
| Somnolence   |                        |                      |                        |



|                                      |                |                |                |
|--------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed          | 0 / 31 (0.00%) | 2 / 33 (6.06%) | 1 / 32 (3.13%) |
| occurrences (all)                    | 0              | 2              | 1              |
| Tremor                               |                |                |                |
| subjects affected / exposed          | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                    | 0              | 0              | 0              |
| Blood and lymphatic system disorders |                |                |                |
| Anaemia                              |                |                |                |
| subjects affected / exposed          | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 2 / 32 (6.25%) |
| occurrences (all)                    | 0              | 0              | 2              |
| Ear and labyrinth disorders          |                |                |                |
| Ear pain                             |                |                |                |
| subjects affected / exposed          | 0 / 31 (0.00%) | 0 / 33 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                    | 0              | 0              | 0              |
| Gastrointestinal disorders           |                |                |                |
| Abdominal discomfort                 |                |                |                |
| subjects affected / exposed          | 2 / 31 (6.45%) | 0 / 33 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                    | 2              | 0              | 0              |
| Abdominal pain                       |                |                |                |
| subjects affected / exposed          | 1 / 31 (3.23%) | 1 / 33 (3.03%) | 1 / 32 (3.13%) |
| occurrences (all)                    | 1              | 1              | 1              |
| Abdominal pain upper                 |                |                |                |
| subjects affected / exposed          | 0 / 31 (0.00%) | 2 / 33 (6.06%) | 1 / 32 (3.13%) |
| occurrences (all)                    | 0              | 2              | 1              |
| Constipation                         |                |                |                |
| subjects affected / exposed          | 0 / 31 (0.00%) | 3 / 33 (9.09%) | 0 / 32 (0.00%) |
| occurrences (all)                    | 0              | 4              | 0              |
| Diarrhoea                            |                |                |                |
| subjects affected / exposed          | 1 / 31 (3.23%) | 0 / 33 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all)                    | 1              | 0              | 0              |
| Dry mouth                            |                |                |                |
| subjects affected / exposed          | 1 / 31 (3.23%) | 0 / 33 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all)                    | 1              | 0              | 1              |
| Dyspepsia                            |                |                |                |
| subjects affected / exposed          | 0 / 31 (0.00%) | 1 / 33 (3.03%) | 1 / 32 (3.13%) |
| occurrences (all)                    | 0              | 1              | 1              |
| Flatulence                           |                |                |                |

|  |                 |                |                 |
|--|-----------------|----------------|-----------------|
| subjects affected / exposed            | 1 / 31 (3.23%)  | 1 / 33 (3.03%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 1               | 1              | 0               |
| Frequent bowel movements               |                 |                |                 |
| subjects affected / exposed            | 0 / 31 (0.00%)  | 0 / 33 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 0               | 0              | 0               |
| Gastrooesophageal reflux disease       |                 |                |                 |
| subjects affected / exposed            | 1 / 31 (3.23%)  | 0 / 33 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 1               | 0              | 0               |
| Nausea                                 |                 |                |                 |
| subjects affected / exposed            | 4 / 31 (12.90%) | 2 / 33 (6.06%) | 4 / 32 (12.50%) |
| occurrences (all)                      | 5               | 2              | 4               |
| Tooth impacted                         |                 |                |                 |
| subjects affected / exposed            | 0 / 31 (0.00%)  | 0 / 33 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 0               | 0              | 0               |
| Vomiting                               |                 |                |                 |
| subjects affected / exposed            | 2 / 31 (6.45%)  | 2 / 33 (6.06%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 2               | 3              | 0               |
| Hepatobiliary disorders                |                 |                |                 |
| Hyperbilirubinaemia                    |                 |                |                 |
| subjects affected / exposed            | 0 / 31 (0.00%)  | 0 / 33 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 0               | 0              | 0               |
| Skin and subcutaneous tissue disorders |                 |                |                 |
| Alopecia                               |                 |                |                 |
| subjects affected / exposed            | 0 / 31 (0.00%)  | 0 / 33 (0.00%) | 2 / 32 (6.25%)  |
| occurrences (all)                      | 0               | 0              | 2               |
| Dermatitis contact                     |                 |                |                 |
| subjects affected / exposed            | 0 / 31 (0.00%)  | 0 / 33 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 0               | 0              | 0               |
| Dry skin                               |                 |                |                 |
| subjects affected / exposed            | 1 / 31 (3.23%)  | 0 / 33 (0.00%) | 1 / 32 (3.13%)  |
| occurrences (all)                      | 1               | 0              | 1               |
| Eczema                                 |                 |                |                 |
| subjects affected / exposed            | 0 / 31 (0.00%)  | 0 / 33 (0.00%) | 0 / 32 (0.00%)  |
| occurrences (all)                      | 0               | 0              | 0               |
| Pruritus                               |                 |                |                 |

|   |                     |                      |                     |
|---|---------------------|----------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)  | 2 / 31 (6.45%)<br>2 | 2 / 33 (6.06%)<br>2  | 1 / 32 (3.13%)<br>1 |
| Rash<br>subjects affected / exposed<br>occurrences (all)  | 0 / 31 (0.00%)<br>0 | 3 / 33 (9.09%)<br>3  | 3 / 32 (9.38%)<br>4 |
| Rash pruritic<br>subjects affected / exposed<br>occurrences (all)   | 0 / 31 (0.00%)<br>0 | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0 |
| Renal and urinary disorders<br>Chromaturia<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 31 (0.00%)<br>0 | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0 |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 2 / 31 (6.45%)<br>2 | 0 / 33 (0.00%)<br>0  | 2 / 32 (6.25%)<br>2 |
| Back pain<br>subjects affected / exposed<br>occurrences (all)   | 2 / 31 (6.45%)<br>2 | 0 / 33 (0.00%)<br>0  | 3 / 32 (9.38%)<br>4 |
| Joint swelling<br>subjects affected / exposed<br>occurrences (all)  | 0 / 31 (0.00%)<br>0 | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0 |
| Muscle spasms<br>subjects affected / exposed<br>occurrences (all)   | 0 / 31 (0.00%)<br>0 | 0 / 33 (0.00%)<br>0  | 1 / 32 (3.13%)<br>1 |
| Muscular weakness<br>subjects affected / exposed<br>occurrences (all)   | 0 / 31 (0.00%)<br>0 | 0 / 33 (0.00%)<br>0  | 2 / 32 (6.25%)<br>2 |
| Musculoskeletal pain<br>subjects affected / exposed<br>occurrences (all)  | 1 / 31 (3.23%)<br>1 | 1 / 33 (3.03%)<br>1  | 1 / 32 (3.13%)<br>1 |
| Myalgia<br>subjects affected / exposed<br>occurrences (all)   | 1 / 31 (3.23%)<br>1 | 6 / 33 (18.18%)<br>8 | 1 / 32 (3.13%)<br>1 |
| Neck pain   |                     |                      |                     |

|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 31 (0.00%)<br>0 | 0 / 33 (0.00%)<br>0 | 1 / 32 (3.13%)<br>1 |
| <b>Infections and infestations</b>               |                     |                     |                     |
| Bronchitis                                       |                     |                     |                     |
| subjects affected / exposed                      | 1 / 31 (3.23%)      | 1 / 33 (3.03%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 2                   | 1                   | 0                   |
| Ear infection                                    |                     |                     |                     |
| subjects affected / exposed                      | 2 / 31 (6.45%)      | 0 / 33 (0.00%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 2                   | 0                   | 0                   |
| Gastroenteritis                                  |                     |                     |                     |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 33 (0.00%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Influenza  |                     |                     |                     |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 2 / 33 (6.06%)      | 1 / 32 (3.13%)      |
| occurrences (all)                                | 0                   | 2                   | 1                   |
| Nasopharyngitis                                  |                     |                     |                     |
| subjects affected / exposed                      | 4 / 31 (12.90%)     | 1 / 33 (3.03%)      | 3 / 32 (9.38%)      |
| occurrences (all)                                | 5                   | 1                   | 3                   |
| Oral herpes                                      |                     |                     |                     |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 33 (0.00%)      | 1 / 32 (3.13%)      |
| occurrences (all)                                | 0                   | 0                   | 1                   |
| Sinusitis  |                     |                     |                     |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 33 (0.00%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Upper respiratory tract infection                |                     |                     |                     |
| subjects affected / exposed                      | 1 / 31 (3.23%)      | 1 / 33 (3.03%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 1                   | 1                   | 0                   |
| Urinary tract infection                          |                     |                     |                     |
| subjects affected / exposed                      | 1 / 31 (3.23%)      | 0 / 33 (0.00%)      | 0 / 32 (0.00%)      |
| occurrences (all)                                | 1                   | 0                   | 0                   |
| <b>Metabolism and nutrition disorders</b>        |                     |                     |                     |
| Decreased appetite                               |                     |                     |                     |
| subjects affected / exposed                      | 2 / 31 (6.45%)      | 2 / 33 (6.06%)      | 1 / 32 (3.13%)      |
| occurrences (all)                                | 2                   | 2                   | 1                   |

|                                   |  |   |  |
|-----------------------------------|--|---|--|
| <b>Non-serious adverse events</b> | B10: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg + RBV-8 wk | B11: NR Grazoprevir<br>100 mg + Elbasvir<br>50 mg-18 wk | B12: TN HIV NC<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg + |
|-----------------------------------|--|---|--|

|   |                  |                  | RBV-12 wk        |
|---|------------------|------------------|------------------|
| Total subjects affected by non-serious adverse events |                  |                  |                  |
| subjects affected / exposed                           | 32 / 33 (96.97%) | 25 / 32 (78.13%) | 18 / 29 (62.07%) |
| Vascular disorders                                    |                  |                  |                  |
| Flushing  |                  |                  |                  |
| subjects affected / exposed                           | 0 / 33 (0.00%)   | 0 / 32 (0.00%)   | 0 / 29 (0.00%)   |
| occurrences (all)                                     | 0                | 0                | 0                |
| Hypertension  |                  |                  |                  |
| subjects affected / exposed                           | 0 / 33 (0.00%)   | 1 / 32 (3.13%)   | 0 / 29 (0.00%)   |
| occurrences (all)                                     | 0                | 1                | 0                |
| General disorders and administration site conditions  |                  |                  |                  |
| Asthenia  |                  |                  |                  |
| subjects affected / exposed                           | 6 / 33 (18.18%)  | 7 / 32 (21.88%)  | 4 / 29 (13.79%)  |
| occurrences (all)                                     | 6                | 7                | 5                |
| Chills  |                  |                  |                  |
| subjects affected / exposed                           | 1 / 33 (3.03%)   | 0 / 32 (0.00%)   | 0 / 29 (0.00%)   |
| occurrences (all)                                     | 1                | 0                | 0                |
| Fatigue   |                  |                  |                  |
| subjects affected / exposed                           | 15 / 33 (45.45%) | 8 / 32 (25.00%)  | 2 / 29 (6.90%)   |
| occurrences (all)                                     | 16               | 8                | 2                |
| Influenza like illness                                |                  |                  |                  |
| subjects affected / exposed                           | 2 / 33 (6.06%)   | 1 / 32 (3.13%)   | 1 / 29 (3.45%)   |
| occurrences (all)                                     | 2                | 1                | 1                |
| Malaise   |                  |                  |                  |
| subjects affected / exposed                           | 1 / 33 (3.03%)   | 0 / 32 (0.00%)   | 0 / 29 (0.00%)   |
| occurrences (all)                                     | 1                | 0                | 0                |
| Oedema peripheral                                     |                  |                  |                  |
| subjects affected / exposed                           | 0 / 33 (0.00%)   | 1 / 32 (3.13%)   | 0 / 29 (0.00%)   |
| occurrences (all)                                     | 0                | 1                | 0                |
| Pain  |                  |                  |                  |
| subjects affected / exposed                           | 0 / 33 (0.00%)   | 2 / 32 (6.25%)   | 0 / 29 (0.00%)   |
| occurrences (all)                                     | 0                | 2                | 0                |
| Peripheral swelling                                   |                  |                  |                  |
| subjects affected / exposed                           | 0 / 33 (0.00%)   | 0 / 32 (0.00%)   | 0 / 29 (0.00%)   |
| occurrences (all)                                     | 0                | 0                | 0                |
| Respiratory, thoracic and mediastinal disorders       |                  |                  |                  |

|                             |                 |                |                |
|-----------------------------|-----------------|----------------|----------------|
| Cough                       |                 |                |                |
| subjects affected / exposed | 5 / 33 (15.15%) | 1 / 32 (3.13%) | 2 / 29 (6.90%) |
| occurrences (all)           | 6               | 1              | 3              |
| Dyspnoea                    |                 |                |                |
| subjects affected / exposed | 6 / 33 (18.18%) | 0 / 32 (0.00%) | 1 / 29 (3.45%) |
| occurrences (all)           | 7               | 0              | 1              |
| Dyspnoea exertional         |                 |                |                |
| subjects affected / exposed | 3 / 33 (9.09%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)           | 3               | 0              | 0              |
| Epistaxis                   |                 |                |                |
| subjects affected / exposed | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)           | 0               | 0              | 0              |
| Oropharyngeal pain          |                 |                |                |
| subjects affected / exposed | 2 / 33 (6.06%)  | 2 / 32 (6.25%) | 0 / 29 (0.00%) |
| occurrences (all)           | 2               | 2              | 0              |
| Productive cough            |                 |                |                |
| subjects affected / exposed | 2 / 33 (6.06%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)           | 2               | 0              | 0              |
| Rhinorrhoea                 |                 |                |                |
| subjects affected / exposed | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)           | 0               | 0              | 0              |
| Psychiatric disorders       |                 |                |                |
| Affect lability             |                 |                |                |
| subjects affected / exposed | 2 / 33 (6.06%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)           | 3               | 0              | 0              |
| Agitation                   |                 |                |                |
| subjects affected / exposed | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)           | 0               | 0              | 0              |
| Anxiety                     |                 |                |                |
| subjects affected / exposed | 3 / 33 (9.09%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)           | 3               | 0              | 0              |
| Depression                  |                 |                |                |
| subjects affected / exposed | 1 / 33 (3.03%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)           | 1               | 0              | 0              |
| Insomnia                    |                 |                |                |

|  |                 |                |                 |
|--|-----------------|----------------|-----------------|
| subjects affected / exposed                    | 6 / 33 (18.18%) | 1 / 32 (3.13%) | 2 / 29 (6.90%)  |
| occurrences (all)                              | 6               | 1              | 3               |
| Irritability                                   |                 |                |                 |
| subjects affected / exposed                    | 2 / 33 (6.06%)  | 1 / 32 (3.13%) | 1 / 29 (3.45%)  |
| occurrences (all)                              | 2               | 1              | 1               |
| Mood swings                                    |                 |                |                 |
| subjects affected / exposed                    | 1 / 33 (3.03%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%)  |
| occurrences (all)                              | 1               | 0              | 0               |
| Nightmare                                      |                 |                |                 |
| subjects affected / exposed                    | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%)  |
| occurrences (all)                              | 0               | 0              | 0               |
| Sleep disorder                                 |                 |                |                 |
| subjects affected / exposed                    | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 4 / 29 (13.79%) |
| occurrences (all)                              | 0               | 0              | 4               |
| Investigations                                 |                 |                |                 |
| Alanine aminotransferase increased             |                 |                |                 |
| subjects affected / exposed                    | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%)  |
| occurrences (all)                              | 0               | 0              | 0               |
| Amylase increased                              |                 |                |                 |
| subjects affected / exposed                    | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%)  |
| occurrences (all)                              | 0               | 0              | 0               |
| Aspartate aminotransferase increased           |                 |                |                 |
| subjects affected / exposed                    | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%)  |
| occurrences (all)                              | 0               | 0              | 0               |
| Blood creatine phosphokinase increased         |                 |                |                 |
| subjects affected / exposed                    | 0 / 33 (0.00%)  | 1 / 32 (3.13%) | 1 / 29 (3.45%)  |
| occurrences (all)                              | 0               | 1              | 1               |
| International normalised ratio increased       |                 |                |                 |
| subjects affected / exposed                    | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%)  |
| occurrences (all)                              | 0               | 0              | 0               |
| Lipase increased                               |                 |                |                 |
| subjects affected / exposed                    | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%)  |
| occurrences (all)                              | 0               | 0              | 0               |
| Injury, poisoning and procedural complications |                 |                |                 |

|  |                      |                        |                      |
|--|----------------------|------------------------|----------------------|
| Accidental overdose<br>subjects affected / exposed<br>occurrences (all)                                  | 2 / 33 (6.06%)<br>5  | 0 / 32 (0.00%)<br>0    | 1 / 29 (3.45%)<br>1  |
| Arthropod sting<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0    | 0 / 29 (0.00%)<br>0  |
| Contusion<br>subjects affected / exposed<br>occurrences (all)  | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0    | 0 / 29 (0.00%)<br>0  |
| Cardiac disorders<br>Palpitations<br>subjects affected / exposed<br>occurrences (all)                    | 1 / 33 (3.03%)<br>1  | 1 / 32 (3.13%)<br>1    | 0 / 29 (0.00%)<br>0  |
| Nervous system disorders<br>Disturbance in attention<br>subjects affected / exposed<br>occurrences (all) | 1 / 33 (3.03%)<br>1  | 0 / 32 (0.00%)<br>0    | 0 / 29 (0.00%)<br>0  |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)  | 2 / 33 (6.06%)<br>2  | 0 / 32 (0.00%)<br>0    | 1 / 29 (3.45%)<br>1  |
| Dysgeusia<br>subjects affected / exposed<br>occurrences (all)  | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0    | 0 / 29 (0.00%)<br>0  |
| Headache<br>subjects affected / exposed<br>occurrences (all)   | 6 / 33 (18.18%)<br>7 | 10 / 32 (31.25%)<br>10 | 4 / 29 (13.79%)<br>5 |
| Somnolence<br>subjects affected / exposed<br>occurrences (all)   | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0    | 0 / 29 (0.00%)<br>0  |
| Tremor<br>subjects affected / exposed<br>occurrences (all)   | 2 / 33 (6.06%)<br>2  | 0 / 32 (0.00%)<br>0    | 0 / 29 (0.00%)<br>0  |
| Blood and lymphatic system disorders<br>Anaemia<br>subjects affected / exposed<br>occurrences (all)      | 5 / 33 (15.15%)<br>5 | 0 / 32 (0.00%)<br>0    | 2 / 29 (6.90%)<br>2  |
| Ear and labyrinth disorders  |                      |                        |                      |



|                                  |                 |                 |                |
|----------------------------------|-----------------|-----------------|----------------|
| Ear pain                         |                 |                 |                |
| subjects affected / exposed      | 0 / 33 (0.00%)  | 0 / 32 (0.00%)  | 0 / 29 (0.00%) |
| occurrences (all)                | 0               | 0               | 0              |
| Gastrointestinal disorders       |                 |                 |                |
| Abdominal discomfort             |                 |                 |                |
| subjects affected / exposed      | 0 / 33 (0.00%)  | 1 / 32 (3.13%)  | 1 / 29 (3.45%) |
| occurrences (all)                | 0               | 1               | 1              |
| Abdominal pain                   |                 |                 |                |
| subjects affected / exposed      | 2 / 33 (6.06%)  | 1 / 32 (3.13%)  | 1 / 29 (3.45%) |
| occurrences (all)                | 4               | 3               | 1              |
| Abdominal pain upper             |                 |                 |                |
| subjects affected / exposed      | 3 / 33 (9.09%)  | 5 / 32 (15.63%) | 0 / 29 (0.00%) |
| occurrences (all)                | 4               | 5               | 0              |
| Constipation                     |                 |                 |                |
| subjects affected / exposed      | 4 / 33 (12.12%) | 2 / 32 (6.25%)  | 0 / 29 (0.00%) |
| occurrences (all)                | 5               | 2               | 0              |
| Diarrhoea                        |                 |                 |                |
| subjects affected / exposed      | 3 / 33 (9.09%)  | 7 / 32 (21.88%) | 1 / 29 (3.45%) |
| occurrences (all)                | 3               | 7               | 1              |
| Dry mouth                        |                 |                 |                |
| subjects affected / exposed      | 2 / 33 (6.06%)  | 1 / 32 (3.13%)  | 1 / 29 (3.45%) |
| occurrences (all)                | 2               | 1               | 1              |
| Dyspepsia                        |                 |                 |                |
| subjects affected / exposed      | 3 / 33 (9.09%)  | 1 / 32 (3.13%)  | 0 / 29 (0.00%) |
| occurrences (all)                | 3               | 1               | 0              |
| Flatulence                       |                 |                 |                |
| subjects affected / exposed      | 1 / 33 (3.03%)  | 1 / 32 (3.13%)  | 1 / 29 (3.45%) |
| occurrences (all)                | 1               | 1               | 1              |
| Frequent bowel movements         |                 |                 |                |
| subjects affected / exposed      | 0 / 33 (0.00%)  | 2 / 32 (6.25%)  | 0 / 29 (0.00%) |
| occurrences (all)                | 0               | 2               | 0              |
| Gastrooesophageal reflux disease |                 |                 |                |
| subjects affected / exposed      | 1 / 33 (3.03%)  | 1 / 32 (3.13%)  | 0 / 29 (0.00%) |
| occurrences (all)                | 1               | 1               | 0              |
| Nausea                           |                 |                 |                |

|  |                        |                     |                      |
|--|------------------------|---------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)   | 5 / 33 (15.15%)<br>6   | 1 / 32 (3.13%)<br>1 | 0 / 29 (0.00%)<br>0  |
| Tooth impacted<br>subjects affected / exposed<br>occurrences (all)                                     | 0 / 33 (0.00%)<br>0    | 0 / 32 (0.00%)<br>0 | 0 / 29 (0.00%)<br>0  |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)   | 3 / 33 (9.09%)<br>3    | 0 / 32 (0.00%)<br>0 | 0 / 29 (0.00%)<br>0  |
| Hepatobiliary disorders<br>Hyperbilirubinaemia<br>subjects affected / exposed<br>occurrences (all)     | 0 / 33 (0.00%)<br>0    | 0 / 32 (0.00%)<br>0 | 0 / 29 (0.00%)<br>0  |
| Skin and subcutaneous tissue disorders<br>Alopecia<br>subjects affected / exposed<br>occurrences (all) | 1 / 33 (3.03%)<br>1    | 0 / 32 (0.00%)<br>0 | 0 / 29 (0.00%)<br>0  |
| Dermatitis contact<br>subjects affected / exposed<br>occurrences (all)                                 | 0 / 33 (0.00%)<br>0    | 0 / 32 (0.00%)<br>0 | 0 / 29 (0.00%)<br>0  |
| Dry skin<br>subjects affected / exposed<br>occurrences (all)   | 4 / 33 (12.12%)<br>4   | 0 / 32 (0.00%)<br>0 | 1 / 29 (3.45%)<br>1  |
| Eczema<br>subjects affected / exposed<br>occurrences (all)   | 1 / 33 (3.03%)<br>1    | 1 / 32 (3.13%)<br>1 | 0 / 29 (0.00%)<br>0  |
| Pruritus<br>subjects affected / exposed<br>occurrences (all)   | 10 / 33 (30.30%)<br>10 | 1 / 32 (3.13%)<br>1 | 3 / 29 (10.34%)<br>3 |
| Rash<br>subjects affected / exposed<br>occurrences (all)   | 3 / 33 (9.09%)<br>3    | 0 / 32 (0.00%)<br>0 | 0 / 29 (0.00%)<br>0  |
| Rash pruritic<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 33 (0.00%)<br>0    | 0 / 32 (0.00%)<br>0 | 0 / 29 (0.00%)<br>0  |
| Renal and urinary disorders  |                        |                     |                      |

|  |                      |                      |                     |
|--|----------------------|----------------------|---------------------|
| Chromaturia<br>subjects affected / exposed<br>occurrences (all)          | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0 |
| Musculoskeletal and connective tissue disorders                          |                      |                      |                     |
| Arthralgia<br>subjects affected / exposed<br>occurrences (all)           | 4 / 33 (12.12%)<br>4 | 4 / 32 (12.50%)<br>4 | 0 / 29 (0.00%)<br>0 |
| Back pain<br>subjects affected / exposed<br>occurrences (all)            | 1 / 33 (3.03%)<br>1  | 5 / 32 (15.63%)<br>5 | 1 / 29 (3.45%)<br>1 |
| Joint swelling<br>subjects affected / exposed<br>occurrences (all)       | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0 |
| Muscle spasms<br>subjects affected / exposed<br>occurrences (all)        | 2 / 33 (6.06%)<br>2  | 2 / 32 (6.25%)<br>2  | 0 / 29 (0.00%)<br>0 |
| Muscular weakness<br>subjects affected / exposed<br>occurrences (all)    | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0 |
| Musculoskeletal pain<br>subjects affected / exposed<br>occurrences (all) | 1 / 33 (3.03%)<br>1  | 2 / 32 (6.25%)<br>2  | 0 / 29 (0.00%)<br>0 |
| Myalgia<br>subjects affected / exposed<br>occurrences (all)              | 6 / 33 (18.18%)<br>6 | 4 / 32 (12.50%)<br>4 | 1 / 29 (3.45%)<br>1 |
| Neck pain<br>subjects affected / exposed<br>occurrences (all)            | 2 / 33 (6.06%)<br>2  | 0 / 32 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0 |
| Infections and infestations  |                      |                      |                     |
| Bronchitis<br>subjects affected / exposed<br>occurrences (all)           | 4 / 33 (12.12%)<br>4 | 0 / 32 (0.00%)<br>0  | 1 / 29 (3.45%)<br>1 |
| Ear infection<br>subjects affected / exposed<br>occurrences (all)        | 0 / 33 (0.00%)<br>0  | 0 / 32 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0 |
| Gastroenteritis  |                      |                      |                     |

|                                    |                 |                |                |
|------------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed        | 1 / 33 (3.03%)  | 1 / 32 (3.13%) | 0 / 29 (0.00%) |
| occurrences (all)                  | 1               | 1              | 0              |
| Influenza                          |                 |                |                |
| subjects affected / exposed        | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)                  | 0               | 0              | 0              |
| Nasopharyngitis                    |                 |                |                |
| subjects affected / exposed        | 5 / 33 (15.15%) | 0 / 32 (0.00%) | 1 / 29 (3.45%) |
| occurrences (all)                  | 6               | 0              | 1              |
| Oral herpes                        |                 |                |                |
| subjects affected / exposed        | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)                  | 0               | 0              | 0              |
| Sinusitis                          |                 |                |                |
| subjects affected / exposed        | 2 / 33 (6.06%)  | 0 / 32 (0.00%) | 2 / 29 (6.90%) |
| occurrences (all)                  | 2               | 0              | 2              |
| Upper respiratory tract infection  |                 |                |                |
| subjects affected / exposed        | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)                  | 0               | 0              | 0              |
| Urinary tract infection            |                 |                |                |
| subjects affected / exposed        | 0 / 33 (0.00%)  | 0 / 32 (0.00%) | 0 / 29 (0.00%) |
| occurrences (all)                  | 0               | 0              | 0              |
| Metabolism and nutrition disorders |                 |                |                |
| Decreased appetite                 |                 |                |                |
| subjects affected / exposed        | 2 / 33 (6.06%)  | 1 / 32 (3.13%) | 0 / 29 (0.00%) |
| occurrences (all)                  | 2               | 1              | 0              |

| <b>Non-serious adverse events</b>                        | B13: TN HIV NC<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg-12<br>wk | C1: TN NC/GT1b<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-8 wk | D1: TN NC/GT3<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-12 wk |
|--|---|--|--|
| Total subjects affected by non-serious<br>adverse events |   |  |  |
| subjects affected / exposed                              | 14 / 30 (46.67%)  | 22 / 30 (73.33%)   | 16 / 20 (80.00%)   |
| Vascular disorders                                       |   |  |  |
| Flushing   |   |  |  |
| subjects affected / exposed                              | 0 / 30 (0.00%)  | 0 / 30 (0.00%)   | 0 / 20 (0.00%)   |
| occurrences (all)  | 0   | 0  | 0  |
| Hypertension   |   |  |  |
| subjects affected / exposed                              | 1 / 30 (3.33%)  | 0 / 30 (0.00%)   | 0 / 20 (0.00%)   |
| occurrences (all)  | 1   | 0  | 0  |
| General disorders and administration                     |   |  |  |

|   |                |                  |                 |
|---|----------------|------------------|-----------------|
| site conditions                                 |                |                  |                 |
| Asthenia  |                |                  |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%) | 1 / 30 (3.33%)   | 2 / 20 (10.00%) |
| occurrences (all)                               | 1              | 1                | 2               |
| Chills  |                |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%)   | 0 / 20 (0.00%)  |
| occurrences (all)                               | 0              | 0                | 0               |
| Fatigue   |                |                  |                 |
| subjects affected / exposed                     | 2 / 30 (6.67%) | 11 / 30 (36.67%) | 2 / 20 (10.00%) |
| occurrences (all)                               | 2              | 11               | 2               |
| Influenza like illness                          |                |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%)   | 0 / 20 (0.00%)  |
| occurrences (all)                               | 0              | 0                | 0               |
| Malaise   |                |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 1 / 30 (3.33%)   | 0 / 20 (0.00%)  |
| occurrences (all)                               | 0              | 1                | 0               |
| Oedema peripheral                               |                |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%)   | 0 / 20 (0.00%)  |
| occurrences (all)                               | 0              | 0                | 0               |
| Pain  |                |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%)   | 0 / 20 (0.00%)  |
| occurrences (all)                               | 0              | 0                | 0               |
| Peripheral swelling                             |                |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%)   | 0 / 20 (0.00%)  |
| occurrences (all)                               | 0              | 0                | 0               |
| Respiratory, thoracic and mediastinal disorders |                |                  |                 |
| Cough   |                |                  |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%) | 0 / 30 (0.00%)   | 1 / 20 (5.00%)  |
| occurrences (all)                               | 1              | 0                | 1               |
| Dyspnoea  |                |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 2 / 30 (6.67%)   | 0 / 20 (0.00%)  |
| occurrences (all)                               | 0              | 2                | 0               |
| Dyspnoea exertional                             |                |                  |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 1 / 30 (3.33%)   | 0 / 20 (0.00%)  |
| occurrences (all)                               | 0              | 1                | 0               |
| Epistaxis                                       |                |                  |                 |

|                             |                |                 |                 |
|-----------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%)  | 0 / 20 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Oropharyngeal pain          |                |                 |                 |
| subjects affected / exposed | 0 / 30 (0.00%) | 1 / 30 (3.33%)  | 0 / 20 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0               |
| Productive cough            |                |                 |                 |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%)  | 0 / 20 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Rhinorrhoea                 |                |                 |                 |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%)  | 0 / 20 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Psychiatric disorders       |                |                 |                 |
| Affect lability             |                |                 |                 |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%)  | 0 / 20 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Agitation                   |                |                 |                 |
| subjects affected / exposed | 0 / 30 (0.00%) | 1 / 30 (3.33%)  | 0 / 20 (0.00%)  |
| occurrences (all)           | 0              | 1               | 0               |
| Anxiety                     |                |                 |                 |
| subjects affected / exposed | 1 / 30 (3.33%) | 1 / 30 (3.33%)  | 1 / 20 (5.00%)  |
| occurrences (all)           | 1              | 1               | 1               |
| Depression                  |                |                 |                 |
| subjects affected / exposed | 0 / 30 (0.00%) | 3 / 30 (10.00%) | 0 / 20 (0.00%)  |
| occurrences (all)           | 0              | 3               | 0               |
| Insomnia                    |                |                 |                 |
| subjects affected / exposed | 0 / 30 (0.00%) | 1 / 30 (3.33%)  | 3 / 20 (15.00%) |
| occurrences (all)           | 0              | 1               | 3               |
| Irritability                |                |                 |                 |
| subjects affected / exposed | 0 / 30 (0.00%) | 2 / 30 (6.67%)  | 0 / 20 (0.00%)  |
| occurrences (all)           | 0              | 2               | 0               |
| Mood swings                 |                |                 |                 |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%)  | 0 / 20 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |
| Nightmare                   |                |                 |                 |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%)  | 0 / 20 (0.00%)  |
| occurrences (all)           | 0              | 0               | 0               |

|  |                     |                     |                      |
|--|---------------------|---------------------|----------------------|
| Sleep disorder<br>subjects affected / exposed<br>occurrences (all)                           | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0  |
| Investigations   |                     |                     |                      |
| Alanine aminotransferase increased<br>subjects affected / exposed<br>occurrences (all)       | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0  |
| Amylase increased<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0  |
| Aspartate aminotransferase increased<br>subjects affected / exposed<br>occurrences (all)     | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0  |
| Blood creatine phosphokinase increased<br>subjects affected / exposed<br>occurrences (all)   | 0 / 30 (0.00%)<br>0 | 1 / 30 (3.33%)<br>1 | 0 / 20 (0.00%)<br>0  |
| International normalised ratio increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0  |
| Lipase increased<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0  |
| Injury, poisoning and procedural complications   |                     |                     |                      |
| Accidental overdose<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 30 (0.00%)<br>0 | 2 / 30 (6.67%)<br>2 | 3 / 20 (15.00%)<br>4 |
| Arthropod sting<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0  |
| Contusion<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0  |
| Cardiac disorders  |                     |                     |                      |

|  |                     |                      |                      |
|--|---------------------|----------------------|----------------------|
| Palpitations<br>subjects affected / exposed<br>occurrences (all)             | 1 / 30 (3.33%)<br>1 | 0 / 30 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1  |
| Nervous system disorders   |                     |                      |                      |
| Disturbance in attention<br>subjects affected / exposed<br>occurrences (all) | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                | 0 / 30 (0.00%)<br>0 | 2 / 30 (6.67%)<br>2  | 1 / 20 (5.00%)<br>1  |
| Dysgeusia<br>subjects affected / exposed<br>occurrences (all)                | 0 / 30 (0.00%)<br>0 | 1 / 30 (3.33%)<br>1  | 0 / 20 (0.00%)<br>0  |
| Headache<br>subjects affected / exposed<br>occurrences (all)                 | 2 / 30 (6.67%)<br>2 | 6 / 30 (20.00%)<br>6 | 5 / 20 (25.00%)<br>5 |
| Somnolence<br>subjects affected / exposed<br>occurrences (all)               | 1 / 30 (3.33%)<br>1 | 0 / 30 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |
| Tremor<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 30 (0.00%)<br>0 | 1 / 30 (3.33%)<br>1  | 0 / 20 (0.00%)<br>0  |
| Blood and lymphatic system disorders   |                     |                      |                      |
| Anaemia<br>subjects affected / exposed<br>occurrences (all)                  | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0  | 3 / 20 (15.00%)<br>3 |
| Ear and labyrinth disorders  |                     |                      |                      |
| Ear pain<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |
| Gastrointestinal disorders   |                     |                      |                      |
| Abdominal discomfort<br>subjects affected / exposed<br>occurrences (all)     | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all)           | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0  | 1 / 20 (5.00%)<br>1  |



|  |                     |                      |                      |
|--|---------------------|----------------------|----------------------|
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all)             | 1 / 30 (3.33%)<br>1 | 1 / 30 (3.33%)<br>1  | 1 / 20 (5.00%)<br>1  |
| Constipation<br>subjects affected / exposed<br>occurrences (all)                     | 1 / 30 (3.33%)<br>1 | 1 / 30 (3.33%)<br>1  | 0 / 20 (0.00%)<br>0  |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 30 (0.00%)<br>0 | 1 / 30 (3.33%)<br>1  | 1 / 20 (5.00%)<br>1  |
| Dry mouth<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 30 (0.00%)<br>0 | 2 / 30 (6.67%)<br>2  | 1 / 20 (5.00%)<br>1  |
| Dyspepsia<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |
| Flatulence<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 30 (0.00%)<br>0 | 1 / 30 (3.33%)<br>1  | 0 / 20 (0.00%)<br>0  |
| Frequent bowel movements<br>subjects affected / exposed<br>occurrences (all)         | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |
| Gastrooesophageal reflux disease<br>subjects affected / exposed<br>occurrences (all) | 0 / 30 (0.00%)<br>0 | 1 / 30 (3.33%)<br>1  | 1 / 20 (5.00%)<br>1  |
| Nausea<br>subjects affected / exposed<br>occurrences (all)                           | 1 / 30 (3.33%)<br>1 | 6 / 30 (20.00%)<br>6 | 3 / 20 (15.00%)<br>3 |
| Tooth impacted<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0  | 0 / 20 (0.00%)<br>0  |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)                         | 1 / 30 (3.33%)<br>1 | 1 / 30 (3.33%)<br>1  | 0 / 20 (0.00%)<br>0  |
| Hepatobiliary disorders<br>Hyperbilirubinaemia                                       |                     |                      |                      |

|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0 | 0 / 20 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders           |                     |                     |                     |
| Alopecia   |                     |                     |                     |
| subjects affected / exposed                      | 0 / 30 (0.00%)      | 0 / 30 (0.00%)      | 0 / 20 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Dermatitis contact                               |                     |                     |                     |
| subjects affected / exposed                      | 0 / 30 (0.00%)      | 0 / 30 (0.00%)      | 0 / 20 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Dry skin   |                     |                     |                     |
| subjects affected / exposed                      | 1 / 30 (3.33%)      | 1 / 30 (3.33%)      | 0 / 20 (0.00%)      |
| occurrences (all)                                | 1                   | 1                   | 0                   |
| Eczema   |                     |                     |                     |
| subjects affected / exposed                      | 0 / 30 (0.00%)      | 0 / 30 (0.00%)      | 1 / 20 (5.00%)      |
| occurrences (all)                                | 0                   | 0                   | 1                   |
| Pruritus   |                     |                     |                     |
| subjects affected / exposed                      | 0 / 30 (0.00%)      | 4 / 30 (13.33%)     | 1 / 20 (5.00%)      |
| occurrences (all)                                | 0                   | 4                   | 1                   |
| Rash   |                     |                     |                     |
| subjects affected / exposed                      | 0 / 30 (0.00%)      | 3 / 30 (10.00%)     | 3 / 20 (15.00%)     |
| occurrences (all)                                | 0                   | 3                   | 6                   |
| Rash pruritic                                    |                     |                     |                     |
| subjects affected / exposed                      | 0 / 30 (0.00%)      | 0 / 30 (0.00%)      | 0 / 20 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Renal and urinary disorders                      |                     |                     |                     |
| Chromaturia                                      |                     |                     |                     |
| subjects affected / exposed                      | 0 / 30 (0.00%)      | 0 / 30 (0.00%)      | 0 / 20 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                   |
| Musculoskeletal and connective tissue disorders  |                     |                     |                     |
| Arthralgia                                       |                     |                     |                     |
| subjects affected / exposed                      | 1 / 30 (3.33%)      | 1 / 30 (3.33%)      | 0 / 20 (0.00%)      |
| occurrences (all)                                | 2                   | 1                   | 0                   |
| Back pain  |                     |                     |                     |
| subjects affected / exposed                      | 1 / 30 (3.33%)      | 0 / 30 (0.00%)      | 1 / 20 (5.00%)      |
| occurrences (all)                                | 1                   | 0                   | 1                   |
| Joint swelling                                   |                     |                     |                     |

|                             |                |                |                |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Muscle spasms               |                |                |                |
| subjects affected / exposed | 1 / 30 (3.33%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all)           | 1              | 0              | 0              |
| Muscular weakness           |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Musculoskeletal pain        |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Myalgia                     |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 1 / 30 (3.33%) | 0 / 20 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Neck pain                   |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Infections and infestations |                |                |                |
| Bronchitis                  |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Ear infection               |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Gastroenteritis             |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 1 / 30 (3.33%) | 0 / 20 (0.00%) |
| occurrences (all)           | 0              | 1              | 0              |
| Influenza                   |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Nasopharyngitis             |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |
| Oral herpes                 |                |                |                |
| subjects affected / exposed | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%) |
| occurrences (all)           | 0              | 0              | 0              |

|                                    |                |                |                 |
|------------------------------------|----------------|----------------|-----------------|
| Sinusitis                          |                |                |                 |
| subjects affected / exposed        | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 20 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0               |
| Upper respiratory tract infection  |                |                |                 |
| subjects affected / exposed        | 1 / 30 (3.33%) | 0 / 30 (0.00%) | 3 / 20 (15.00%) |
| occurrences (all)                  | 1              | 0              | 3               |
| Urinary tract infection            |                |                |                 |
| subjects affected / exposed        | 1 / 30 (3.33%) | 0 / 30 (0.00%) | 0 / 20 (0.00%)  |
| occurrences (all)                  | 1              | 0              | 0               |
| Metabolism and nutrition disorders |                |                |                 |
| Decreased appetite                 |                |                |                 |
| subjects affected / exposed        | 1 / 30 (3.33%) | 1 / 30 (3.33%) | 1 / 20 (5.00%)  |
| occurrences (all)                  | 1              | 1              | 1               |

| <b>Non-serious adverse events</b>                        | C2: TN NC/GT1b<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg-8<br>wk | D2: TN NC/GT3<br>Grazoprevir 100 mg<br>+ Elbasvir 50 mg +<br>RBV-18 wk |  |
|--|--|--|--|
| Total subjects affected by non-serious<br>adverse events |  |  |  |
| subjects affected / exposed                              | 14 / 31 (45.16%)   | 20 / 21 (95.24%)   |  |
| Vascular disorders                                       |  |  |  |
| Flushing   |  |  |  |
| subjects affected / exposed                              | 0 / 31 (0.00%)   | 0 / 21 (0.00%)   |  |
| occurrences (all)  | 0  | 0  |  |
| Hypertension   |  |  |  |
| subjects affected / exposed                              | 0 / 31 (0.00%)   | 0 / 21 (0.00%)   |  |
| occurrences (all)  | 0  | 0  |  |
| General disorders and administration<br>site conditions  |  |  |  |
| Asthenia   |  |  |  |
| subjects affected / exposed                              | 2 / 31 (6.45%)   | 3 / 21 (14.29%)  |  |
| occurrences (all)  | 2  | 3  |  |
| Chills   |  |  |  |
| subjects affected / exposed                              | 1 / 31 (3.23%)   | 0 / 21 (0.00%)   |  |
| occurrences (all)  | 2  | 0  |  |
| Fatigue  |  |  |  |
| subjects affected / exposed                              | 3 / 31 (9.68%)   | 3 / 21 (14.29%)  |  |
| occurrences (all)  | 3  | 3  |  |
| Influenza like illness                                   |  |  |  |

|   |                |                 |  |
|---|----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                               | 0              | 0               |  |
| Malaise   |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                               | 0              | 0               |  |
| Oedema peripheral                               |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                               | 0              | 0               |  |
| Pain  |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 21 (4.76%)  |  |
| occurrences (all)                               | 0              | 1               |  |
| Peripheral swelling                             |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                               | 0              | 0               |  |
| Respiratory, thoracic and mediastinal disorders |                |                 |  |
| Cough   |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 21 (4.76%)  |  |
| occurrences (all)                               | 0              | 1               |  |
| Dyspnoea  |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 3 / 21 (14.29%) |  |
| occurrences (all)                               | 0              | 3               |  |
| Dyspnoea exertional                             |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 21 (4.76%)  |  |
| occurrences (all)                               | 0              | 1               |  |
| Epistaxis                                       |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                               | 0              | 0               |  |
| Oropharyngeal pain                              |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 21 (4.76%)  |  |
| occurrences (all)                               | 0              | 1               |  |
| Productive cough                                |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 2 / 21 (9.52%)  |  |
| occurrences (all)                               | 0              | 2               |  |
| Rhinorrhoea                                     |                |                 |  |

|  |                     |                     |  |
|--|---------------------|---------------------|--|
| subjects affected / exposed<br>occurrences (all) | 0 / 31 (0.00%)<br>0 | 0 / 21 (0.00%)<br>0 |  |
| Psychiatric disorders                            |                     |                     |  |
| Affect lability                                  |                     |                     |  |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 1 / 21 (4.76%)      |  |
| occurrences (all)                                | 0                   | 1                   |  |
| Agitation  |                     |                     |  |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 21 (0.00%)      |  |
| occurrences (all)                                | 0                   | 0                   |  |
| Anxiety  |                     |                     |  |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 1 / 21 (4.76%)      |  |
| occurrences (all)                                | 0                   | 1                   |  |
| Depression                                       |                     |                     |  |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 1 / 21 (4.76%)      |  |
| occurrences (all)                                | 0                   | 1                   |  |
| Insomnia   |                     |                     |  |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 3 / 21 (14.29%)     |  |
| occurrences (all)                                | 0                   | 3                   |  |
| Irritability                                     |                     |                     |  |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 21 (0.00%)      |  |
| occurrences (all)                                | 0                   | 0                   |  |
| Mood swings                                      |                     |                     |  |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 21 (0.00%)      |  |
| occurrences (all)                                | 0                   | 0                   |  |
| Nightmare  |                     |                     |  |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 21 (0.00%)      |  |
| occurrences (all)                                | 0                   | 0                   |  |
| Sleep disorder                                   |                     |                     |  |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 1 / 21 (4.76%)      |  |
| occurrences (all)                                | 0                   | 1                   |  |
| Investigations                                   |                     |                     |  |
| Alanine aminotransferase increased               |                     |                     |  |
| subjects affected / exposed                      | 0 / 31 (0.00%)      | 0 / 21 (0.00%)      |  |
| occurrences (all)                                | 0                   | 0                   |  |
| Amylase increased                                |                     |                     |  |

|  |                |                |  |
|--|----------------|----------------|--|
| subjects affected / exposed                    | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences (all)                              | 0              | 0              |  |
| Aspartate aminotransferase increased           |                |                |  |
| subjects affected / exposed                    | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences (all)                              | 0              | 0              |  |
| Blood creatine phosphokinase increased         |                |                |  |
| subjects affected / exposed                    | 1 / 31 (3.23%) | 1 / 21 (4.76%) |  |
| occurrences (all)                              | 1              | 1              |  |
| International normalised ratio increased       |                |                |  |
| subjects affected / exposed                    | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences (all)                              | 0              | 0              |  |
| Lipase increased                               |                |                |  |
| subjects affected / exposed                    | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences (all)                              | 0              | 0              |  |
| Injury, poisoning and procedural complications |                |                |  |
| Accidental overdose                            |                |                |  |
| subjects affected / exposed                    | 0 / 31 (0.00%) | 2 / 21 (9.52%) |  |
| occurrences (all)                              | 0              | 4              |  |
| Arthropod sting                                |                |                |  |
| subjects affected / exposed                    | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences (all)                              | 0              | 0              |  |
| Contusion                                      |                |                |  |
| subjects affected / exposed                    | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences (all)                              | 0              | 0              |  |
| Cardiac disorders                              |                |                |  |
| Palpitations                                   |                |                |  |
| subjects affected / exposed                    | 0 / 31 (0.00%) | 1 / 21 (4.76%) |  |
| occurrences (all)                              | 0              | 1              |  |
| Nervous system disorders                       |                |                |  |
| Disturbance in attention                       |                |                |  |
| subjects affected / exposed                    | 0 / 31 (0.00%) | 0 / 21 (0.00%) |  |
| occurrences (all)                              | 0              | 0              |  |
| Dizziness                                      |                |                |  |

|                                      |                 |                 |  |
|--------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed          | 0 / 31 (0.00%)  | 1 / 21 (4.76%)  |  |
| occurrences (all)                    | 0               | 1               |  |
| Dysgeusia                            |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 1 / 21 (4.76%)  |  |
| occurrences (all)                    | 0               | 1               |  |
| Headache                             |                 |                 |  |
| subjects affected / exposed          | 5 / 31 (16.13%) | 5 / 21 (23.81%) |  |
| occurrences (all)                    | 6               | 5               |  |
| Somnolence                           |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 0 / 21 (0.00%)  |  |
| occurrences (all)                    | 0               | 0               |  |
| Tremor                               |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 0 / 21 (0.00%)  |  |
| occurrences (all)                    | 0               | 0               |  |
| Blood and lymphatic system disorders |                 |                 |  |
| Anaemia                              |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 0 / 21 (0.00%)  |  |
| occurrences (all)                    | 0               | 0               |  |
| Ear and labyrinth disorders          |                 |                 |  |
| Ear pain                             |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 1 / 21 (4.76%)  |  |
| occurrences (all)                    | 0               | 1               |  |
| Gastrointestinal disorders           |                 |                 |  |
| Abdominal discomfort                 |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 0 / 21 (0.00%)  |  |
| occurrences (all)                    | 0               | 0               |  |
| Abdominal pain                       |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 3 / 21 (14.29%) |  |
| occurrences (all)                    | 0               | 3               |  |
| Abdominal pain upper                 |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 2 / 21 (9.52%)  |  |
| occurrences (all)                    | 0               | 2               |  |
| Constipation                         |                 |                 |  |
| subjects affected / exposed          | 0 / 31 (0.00%)  | 0 / 21 (0.00%)  |  |
| occurrences (all)                    | 0               | 0               |  |
| Diarrhoea                            |                 |                 |  |



|  |                |                 |  |
|--|----------------|-----------------|--|
| subjects affected / exposed            | 2 / 31 (6.45%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                      | 3              | 0               |  |
| Dry mouth                              |                |                 |  |
| subjects affected / exposed            | 0 / 31 (0.00%) | 1 / 21 (4.76%)  |  |
| occurrences (all)                      | 0              | 1               |  |
| Dyspepsia                              |                |                 |  |
| subjects affected / exposed            | 1 / 31 (3.23%) | 3 / 21 (14.29%) |  |
| occurrences (all)                      | 1              | 3               |  |
| Flatulence                             |                |                 |  |
| subjects affected / exposed            | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                      | 0              | 0               |  |
| Frequent bowel movements               |                |                 |  |
| subjects affected / exposed            | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                      | 0              | 0               |  |
| Gastrooesophageal reflux disease       |                |                 |  |
| subjects affected / exposed            | 0 / 31 (0.00%) | 1 / 21 (4.76%)  |  |
| occurrences (all)                      | 0              | 1               |  |
| Nausea                                 |                |                 |  |
| subjects affected / exposed            | 3 / 31 (9.68%) | 6 / 21 (28.57%) |  |
| occurrences (all)                      | 3              | 7               |  |
| Tooth impacted                         |                |                 |  |
| subjects affected / exposed            | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                      | 0              | 0               |  |
| Vomiting                               |                |                 |  |
| subjects affected / exposed            | 0 / 31 (0.00%) | 3 / 21 (14.29%) |  |
| occurrences (all)                      | 0              | 3               |  |
| Hepatobiliary disorders                |                |                 |  |
| Hyperbilirubinaemia                    |                |                 |  |
| subjects affected / exposed            | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                      | 0              | 0               |  |
| Skin and subcutaneous tissue disorders |                |                 |  |
| Alopecia                               |                |                 |  |
| subjects affected / exposed            | 0 / 31 (0.00%) | 1 / 21 (4.76%)  |  |
| occurrences (all)                      | 0              | 1               |  |
| Dermatitis contact                     |                |                 |  |

|   |                |                 |  |
|---|----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 31 (0.00%) | 1 / 21 (4.76%)  |  |
| occurrences (all)                               | 0              | 1               |  |
| Dry skin  |                |                 |  |
| subjects affected / exposed                     | 1 / 31 (3.23%) | 1 / 21 (4.76%)  |  |
| occurrences (all)                               | 1              | 1               |  |
| Eczema  |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 2 / 21 (9.52%)  |  |
| occurrences (all)                               | 0              | 3               |  |
| Pruritus  |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 3 / 21 (14.29%) |  |
| occurrences (all)                               | 0              | 3               |  |
| Rash  |                |                 |  |
| subjects affected / exposed                     | 1 / 31 (3.23%) | 2 / 21 (9.52%)  |  |
| occurrences (all)                               | 1              | 2               |  |
| Rash pruritic                                   |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                               | 0              | 0               |  |
| Renal and urinary disorders                     |                |                 |  |
| Chromaturia                                     |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                               | 0              | 0               |  |
| Musculoskeletal and connective tissue disorders |                |                 |  |
| Arthralgia                                      |                |                 |  |
| subjects affected / exposed                     | 1 / 31 (3.23%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                               | 1              | 0               |  |
| Back pain                                       |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                               | 0              | 0               |  |
| Joint swelling                                  |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                               | 0              | 0               |  |
| Muscle spasms                                   |                |                 |  |
| subjects affected / exposed                     | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                               | 0              | 0               |  |
| Muscular weakness                               |                |                 |  |

|                                   |                |                 |  |
|-----------------------------------|----------------|-----------------|--|
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                 | 0              | 0               |  |
| Musculoskeletal pain              |                |                 |  |
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                 | 0              | 0               |  |
| Myalgia                           |                |                 |  |
| subjects affected / exposed       | 3 / 31 (9.68%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                 | 4              | 0               |  |
| Neck pain                         |                |                 |  |
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                 | 0              | 0               |  |
| Infections and infestations       |                |                 |  |
| Bronchitis                        |                |                 |  |
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                 | 0              | 0               |  |
| Ear infection                     |                |                 |  |
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                 | 0              | 0               |  |
| Gastroenteritis                   |                |                 |  |
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                 | 0              | 0               |  |
| Influenza                         |                |                 |  |
| subjects affected / exposed       | 0 / 31 (0.00%) | 1 / 21 (4.76%)  |  |
| occurrences (all)                 | 0              | 1               |  |
| Nasopharyngitis                   |                |                 |  |
| subjects affected / exposed       | 0 / 31 (0.00%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                 | 0              | 0               |  |
| Oral herpes                       |                |                 |  |
| subjects affected / exposed       | 0 / 31 (0.00%) | 2 / 21 (9.52%)  |  |
| occurrences (all)                 | 0              | 2               |  |
| Sinusitis                         |                |                 |  |
| subjects affected / exposed       | 2 / 31 (6.45%) | 0 / 21 (0.00%)  |  |
| occurrences (all)                 | 2              | 0               |  |
| Upper respiratory tract infection |                |                 |  |
| subjects affected / exposed       | 0 / 31 (0.00%) | 5 / 21 (23.81%) |  |
| occurrences (all)                 | 0              | 5               |  |

|  |                     |                     |  |
|--|---------------------|---------------------|--|
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)                                  | 0 / 31 (0.00%)<br>0 | 0 / 21 (0.00%)<br>0 |  |
| Metabolism and nutrition disorders<br>Decreased appetite<br>subjects affected / exposed<br>occurrences (all) | 0 / 31 (0.00%)<br>0 | 0 / 21 (0.00%)<br>0 |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment  |
|------------------|--|
| 28 June 2013     | The primary reason for protocol amendment 1 (AM1) was to add Part B which included 4 participant populations in 13 treatment arms, comprising an additional 390 subjects. Participants were randomized to treatment with 100 mg of grazoprevir in combination with 50 mg of elbasvir plus/minus RBV. Two study objectives were added, which were applicable only to study Part B within the HIV co-infected participant population.  |
| 15 August 2013   | The primary changes in AM2 were to revise/update the following: stopping rules for early trial termination due to failure criteria, Part B eligibility criteria, list of prohibited concomitant medications, and the definition for treatment naïve, non-cirrhotic HIV co-infection participants. Discontinuation criteria were also added for the HIV-coinfected arm.   |
| 25 November 2013 | AM3 added a Week 8 Follow-Up Visit to the protocol, removed the futility rule at Treatment Week 4 for Part B, revised the list of prohibited medications, and clarified events of clinical interest.   |
| 10 January 2014  | The primary reason for AM4 was to add 2 additional study arms to Part B: Arm 1.5 in treatment-naïve (noncirrhotic) participants treated with grazoprevir 100 mg + elbasvir 50 mg for 8 weeks (n=30), and Arm 14 in treatment-naïve (non-cirrhotic) participants co-infected with HIV treated with grazoprevir 100 mg + elbasvir 50 mg for 8 weeks (n=30). Enrollment was canceled for study Arms 1.5 and 14 of Part B in Protocol Amendment No. 5 after data became available for treatment of participants with HCV GT1a for 8 weeks. |
| 21 February 2014 | AM5 added Part C to include 2 arms studying 8-week durations in treatment-naïve noncirrhotic, HCV GT1b-infected participants. In addition, enrollment was canceled for study Arms 1.5 and 14 of Part B.  |
| 03 April 2014    | AM6 added Part D to include 2 arms studying 12- and 18-week treatment durations in treatment-naïve, non-cirrhotic, HCV GT3-infected populations.   |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported