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., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., 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:

Results analysis stage

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:

General information about the trial

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:

Population of trial subjects

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:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	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 coinfected 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 coinfected 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
Arm title	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

Arm title	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

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

Arm description:

GT1b only participants receive Grazoprevr 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

Arm title	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

Arm title	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

Arm title	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

Arm title	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

Arm title	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	
Arm title	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	
Arm title	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

Arm title	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

Arm title	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

Arm title	B10: NR Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk

Arm 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.

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

Arm title	B11: NR 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

Arm title	B12: TN HIV 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

Arm title	B13: TN HIV NC 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	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

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

Arm 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.

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	
Arm title	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	
Arm title	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	
Arm title	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	

Number of subjects in period 1	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
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	-	-	-

Number of subjects in period 1	B1: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk	B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 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	-

Number of subjects in period 1	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg for 12 wk	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + 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	-	-	-

Number of subjects in period 1	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 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	-	-	-

Number of subjects in period 1	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
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	-	-	-

Number of subjects in period 1	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
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	-	-	-

Number of subjects in period 1	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
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:	
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.	
Reporting group title	A3: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-12 wk
Reporting group description:	
GT1b only participants receive Grazoprevr 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:	
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 weight.	
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	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	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 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
Number of subjects	25	27	13
Age categorical Units: Subjects			
Age Continuous | Units: years			
arithmetic mean	48.7	43.9	43.3
standard deviation	± 12.5	± 12.6	± 13.5

Gender, Male/Female Units: participants			
Female	13	17	6
Male	12	10	7

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

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

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

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

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

Age Continuous | Units: years			
arithmetic mean	58.9	52.2	54.4
standard deviation	± 8	± 8.8	± 9.1
Gender, Male/Female 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 Units: Subjects			
Age Continuous | Units: years			
arithmetic mean	56.2	54.3	46.2
standard deviation	± 10.9	± 12.3	± 8.4
Gender, Male/Female 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 Units: Subjects			
Age Continuous | Units: years			
arithmetic mean	43.5	50.6	55.3
standard deviation	± 10.4	± 10.9	± 10.3
Gender, Male/Female 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 Units: Subjects			
Age Continuous | Units: years			
arithmetic mean	49	42.4	
standard deviation	± 11.5	± 10.8	-
Gender, Male/Female 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:	
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.	
Reporting group title	A3: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-12 wk
Reporting group description:	
GT1b only participants receive Grazoprevr 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:	
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 weight.	
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	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	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.

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

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

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 ≥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.

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	22	24	12	29
Units: percentage of participants				
number (confidence interval 95%)	100 (84.6 to 100)	95.8 (78.9 to 99.9)	100 (73.5 to 100)	82.8 (64.2 to 94.2)

End point values	B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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)

End point values	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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 100)	93.5 (78.6 to 99.2)	100 (88.4 to 100)	90.9 (75.7 to 98.1)

End point values	B10: NR Grazoprevir 100 mg + Elbasvir 50 mg	B11: NR Grazoprevir 100 mg + Elbasvir 50	B12: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg	B13: TN HIV NC Grazoprevir 100 mg + 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 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	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[2]

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 ≥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.

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	25	27[3]	12	30
Units: percentage of participants				
number (confidence interval 95%)	88 (68.8 to 97.5)	85.7 (67.3 to 96)	91.7 (61.5 to 99.8)	90 (73.5 to 97.9)

Notes:

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

End point values	B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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 86.7)	87.1 (70.2 to 96.4)	77.4 (58.9 to 90.4)	65.5 (45.7 to 82.1)

End point values	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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 96.5)	83.9 (66.3 to 94.5)	81.3 (63.6 to 92.8)	78.8 (61.1 to 91)

End point 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	B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 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 99.9)	81.3 (63.6 to 92.8)	65.5 (45.7 to 82.1)	53.3 (34.3 to 71.7)

End point values	C1: TN NC/GT1b	C2: TN NC/GT1b	D1: TN NC/GT3 Grazoprevir	D2: TN NC/GT3 Grazoprevir

	Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk	Grazoprevir 100 mg + Elbasvir 50 mg-8 wk	100 mg + Elbasvir 50 mg + RBV-12 wk	100 mg + Elbasvir 50 mg + 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 87.7)	54.8 (36 to 72.7)	85 (62.1 to 96.8)	90.5 (69.6 to 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[4]

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 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	25	27[5]	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 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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)

End point values	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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 20.8)	0 (0 to 11.2)	3.1 (0.1 to 16.2)	0 (0 to 10.6)

End point 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	B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 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)

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	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 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 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	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 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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 Grazoprevir 100 mg + Elbasvir 50 mg	B11: NR Grazoprevir 100 mg + Elbasvir 50	B12: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg	B13: TN HIV NC Grazoprevir 100 mg + 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 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	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 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%)	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)

End point values	B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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 38.6)	16.1 (5.5 to 33.7)	6.7 (0.8 to 22.1)	10.3 (2.2 to 27.4)

End point values	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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 43.4)	16.1 (5.5 to 33.7)	12.9 (3.6 to 29.8)	6.1 (0.7 to 20.2)

End point 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	B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 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 20.2)	6.3 (0.8 to 20.8)	37.9 (20.7 to 57.7)	40 (22.7 to 59.4)

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	30	31	20	20
Units: percentage of participants				
number (confidence interval 95%)	46.7 (28.3 to 65.7)	12.9 (3.6 to 29.8)	40 (19.1 to 63.9)	70 (45.7 to 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 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	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 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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)

End point values	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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 86.3)	71 (52 to 85.8)	83.3 (65.3 to 94.4)	68.8 (50 to 83.9)

End point 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	B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 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 84.4)	53.1 (34.7 to 70.9)	75.9 (56.5 to 89.7)	78.6 (59 to 91.7)

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	30	31	20	18
Units: percentage of participants				
number (confidence interval 95%)	86.7 (69.3 to 96.2)	74.2 (55.4 to 88.1)	50 (27.2 to 72.8)	77.8 (52.4 to 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 ≥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 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	22	24	12	0[6]
Units: percentage of participants				
number (confidence interval 95%)	100 (84.6 to 100)	100 (85.8 to 100)	100 (73.5 to 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 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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)	100 (88.8 to 100)	93.3 (77.9 to 99.2)	96.6 (82.2 to 99.9)

End point values	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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 100)	100 (88.8 to 100)	100 (88.4 to 100)	93.8 (79.2 to 99.2)

End point 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	B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 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[7]	0[8]	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)

End point values	B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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 87.7)	77.4 (58.9 to 90.4)	60 (40.6 to 77.3)	79.3 (60.3 to 92)

End point values	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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 90.7)	67.7 (48.6 to 83.3)	77.4 (58.9 to 90.4)	66.7 (48.2 to 82)

End point 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	B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 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 74.5)	62.5 (43.7 to 78.9)	89.7 (72.6 to 97.8)	76.7 (57.7 to 90.1)

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	30	31	20	20
Units: percentage of participants				
number (confidence interval 95%)	76.7 (57.7 to 90.1)	61.3 (42.2 to 78.2)	70 (45.7 to 88.1)	85 (62.1 to 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 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	24	12	30
Units: percentage of participants				
number (confidence interval 95%)	100 (85.2 to 100)	100 (85.8 to 100)	100 (73.5 to 100)	100 (88.4 to 100)

End point values	B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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 100)	100 (88.8 to 100)	90 (73.5 to 97.9)	100 (88.1 to 100)

End point values	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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 100)	90.3 (74.2 to 98)	100 (88.4 to 100)	96.9 (83.8 to 99.9)

End point 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	B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 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 99.9)	93.8 (79.2 to 99.2)	100 (88.1 to 100)	100 (87.7 to 100)

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	30	31	20	18
Units: percentage of participants				
number (confidence interval 95%)	100 (88.4 to 100)	96.8 (83.3 to 99.9)	65 (40.8 to 84.6)	83.3 (58.6 to 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 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	22	24	12	0[9]
Units: percentage of participants				
number (confidence interval 95%)	100 (84.6 to 100)	100 (85.8 to 100)	100 (73.5 to 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 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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)	100 (88.8 to 100)	93.3 (77.9 to 99.2)	100 (88.1 to 100)

End point values	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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 100)	100 (88.8 to 100)	100 (88.4 to 100)	100 (89.1 to 100)

End point values	B10: NR Grazoprevir 100 mg + Elbasvir 50 mg	B11: NR Grazoprevir 100 mg + Elbasvir 50	B12: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 mg	B13: TN HIV NC Grazoprevir 100 mg + 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 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[10]	0[11]	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)

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	22	24	12	30
Units: percentage of participants				
number (confidence interval 95%)	100 (84.6 to 100)	95.8 (78.9 to 99.9)	100 (73.5 to 100)	93.3 (77.9 to 99.2)

End point values	B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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)	96.7 (82.8 to 99.9)	96.6 (82.2 to 99.9)

End point values	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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 100)	96.8 (83.3 to 99.9)	100 (88.4 to 100)	93.9 (79.8 to 99.3)

End point 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	B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 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 100)	96.9 (83.8 to 99.9)	96.6 (82.2 to 99.9)	93.1 (77.2 to 99.2)

End point values	C1: TN NC/GT1b	C2: TN NC/GT1b	D1: TN NC/GT3 Grazoprevir	D2: TN NC/GT3 Grazoprevir

	Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk	Grazoprevir 100 mg + Elbasvir 50 mg-8 wk	100 mg + Elbasvir 50 mg + RBV-12 wk	100 mg + Elbasvir 50 mg + 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 99.2)	96.8 (83.3 to 99.9)	50 (27.2 to 72.8)	61.1 (35.7 to 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 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	20	24	12	28
Units: percentage of participants				
number (confidence interval 95%)	100 (83.2 to 100)	95.8 (78.9 to 99.9)	100 (73.5 to 100)	78.6 (59 to 91.7)

End point values	B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg 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)

End point values	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 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)

End point 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	B13: TN HIV NC Grazoprevir 100 mg + Elbasvir 50 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)

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	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 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 ≥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 Grazoprevr 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

Serious adverse events	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
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
Gastrointestinal disorders			
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
Hepatobiliary disorders			
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
Psychiatric disorders			
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
Renal and urinary disorders			
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
Infections and infestations			
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

Serious adverse events	B1: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk	B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk
Total subjects affected by serious adverse events			
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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
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
Injury, poisoning and procedural complications			
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

Serious adverse events	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg for 12 wk	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + 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

Serious adverse events	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B8: NR Grazoprevir 100 mg + Elbasvir 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

Serious adverse events	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			
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
Injury, poisoning and procedural complications			
Road traffic accident			
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
Cardiac disorders			
Atrial fibrillation			
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
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 33 (0.00%)	1 / 32 (3.13%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
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
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

Serious adverse events	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	D1: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk
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
Infections and infestations			
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

Serious adverse events	C2: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-8 wk	D2: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	
Total subjects affected by serious adverse events			
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	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
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	
Injury, poisoning and procedural complications			
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 %

Non-serious adverse events	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
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 25 (76.00%)	24 / 28 (85.71%)	11 / 12 (91.67%)
Vascular disorders			
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
General disorders and administration site conditions			
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			
subjects affected / exposed	1 / 25 (4.00%)	1 / 28 (3.57%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Arthropod sting			
subjects affected / exposed	0 / 25 (0.00%)	0 / 28 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	0 / 25 (0.00%)	0 / 28 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 25 (0.00%)	0 / 28 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	1 / 25 (4.00%)	0 / 28 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	4 / 25 (16.00%)	2 / 28 (7.14%)	1 / 12 (8.33%)
occurrences (all)	4	2	1
Dysgeusia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 28 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	4 / 25 (16.00%)	6 / 28 (21.43%)	5 / 12 (41.67%)
occurrences (all)	4	6	5
Somnolence			
subjects affected / exposed	0 / 25 (0.00%)	0 / 28 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	0 / 25 (0.00%)	0 / 28 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 25 (12.00%)	2 / 28 (7.14%)	0 / 12 (0.00%)
occurrences (all)	3	2	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	5 / 25 (20.00%)	7 / 28 (25.00%)	2 / 12 (16.67%)
occurrences (all)	5	7	2
Tooth impacted			
subjects affected / exposed	0 / 25 (0.00%)	0 / 28 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	2 / 25 (8.00%)	4 / 28 (14.29%)	0 / 12 (0.00%)
occurrences (all)	2	5	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 28 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	2 / 25 (8.00%)	1 / 28 (3.57%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Dermatitis contact			
subjects affected / exposed	2 / 25 (8.00%)	0 / 28 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Dry skin			
subjects affected / exposed	0 / 25 (0.00%)	0 / 28 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 28 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 25 (4.00%)	2 / 28 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Rash			
subjects affected / exposed	1 / 25 (4.00%)	5 / 28 (17.86%)	1 / 12 (8.33%)
occurrences (all)	1	5	1
Rash pruritic			
subjects affected / exposed	0 / 25 (0.00%)	0 / 28 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

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

Non-serious adverse events	B1: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg + RBV-8 wk	B2: TN NC Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B3: TN NC/GT1a Grazoprevir 100 mg + Elbasvir 50 mg-12 wk
Total subjects affected by non-serious 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			
subjects affected / exposed	1 / 30 (3.33%)	2 / 33 (6.06%)	3 / 31 (9.68%)
occurrences (all)	1	2	3
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 33 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 33 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 33 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 33 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 30 (0.00%)	2 / 33 (6.06%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Lipase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 33 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	3 / 30 (10.00%)	4 / 33 (12.12%)	0 / 31 (0.00%)
occurrences (all)	3	5	0
Arthropod sting			
subjects affected / exposed	0 / 30 (0.00%)	0 / 33 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 33 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

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

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

subjects affected / exposed	1 / 30 (3.33%)	2 / 33 (6.06%)	0 / 31 (0.00%)
occurrences (all)	1	2	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

Non-serious adverse events	B4: TN C Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk	B5: TN C Grazoprevir 100 mg + Elbasvir 50 mg for 12 wk	B6: TN C Grazoprevir 100 mg + Elbasvir 50 mg + 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	0 / 31 (0.00%)	0 / 29 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	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			
subjects affected / exposed	0 / 31 (0.00%)	1 / 29 (3.45%)	0 / 32 (0.00%)
occurrences (all)	0	3	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 31 (3.23%)	2 / 29 (6.90%)	1 / 32 (3.13%)
occurrences (all)	1	2	1

Non-serious adverse events	B7: TN C Grazoprevir 100 mg + Elbasvir 50 mg-18 wk	B9: NR Grazoprevir 100 mg + Elbasvir 50 mg-12 wk	B8: NR Grazoprevir 100 mg + Elbasvir 50 mg +RBV-12 wk
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 31 (77.42%)	25 / 33 (75.76%)	24 / 32 (75.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 31 (6.45%)	5 / 33 (15.15%)	7 / 32 (21.88%)
occurrences (all)	2	7	7
Chills			
subjects affected / exposed	2 / 31 (6.45%)	1 / 33 (3.03%)	0 / 32 (0.00%)
occurrences (all)	2	1	0
Fatigue			
subjects affected / exposed	6 / 31 (19.35%)	10 / 33 (30.30%)	6 / 32 (18.75%)
occurrences (all)	7	12	6
Influenza like illness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	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	0 / 31 (0.00%)	0 / 33 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
International normalised ratio increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 31 (0.00%)	1 / 33 (3.03%)	1 / 32 (3.13%)
occurrences (all)	0	1	1
Dizziness			
subjects affected / exposed	4 / 31 (12.90%)	1 / 33 (3.03%)	2 / 32 (6.25%)
occurrences (all)	4	1	2
Dysgeusia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	10 / 31 (32.26%)	6 / 33 (18.18%)	10 / 32 (31.25%)
occurrences (all)	12	6	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	2 / 31 (6.45%)	2 / 33 (6.06%)	1 / 32 (3.13%)
occurrences (all)	2	2	1
Rash			
subjects affected / exposed	0 / 31 (0.00%)	3 / 33 (9.09%)	3 / 32 (9.38%)
occurrences (all)	0	3	4
Rash pruritic			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 31 (6.45%)	0 / 33 (0.00%)	2 / 32 (6.25%)
occurrences (all)	2	0	2
Back pain			
subjects affected / exposed	2 / 31 (6.45%)	0 / 33 (0.00%)	3 / 32 (9.38%)
occurrences (all)	2	0	4
Joint swelling			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Musculoskeletal pain			
subjects affected / exposed	1 / 31 (3.23%)	1 / 33 (3.03%)	1 / 32 (3.13%)
occurrences (all)	1	1	1
Myalgia			
subjects affected / exposed	1 / 31 (3.23%)	6 / 33 (18.18%)	1 / 32 (3.13%)
occurrences (all)	1	8	1
Neck pain			

subjects affected / exposed	0 / 31 (0.00%)	0 / 33 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Infections and infestations			
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
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 31 (6.45%)	2 / 33 (6.06%)	1 / 32 (3.13%)
occurrences (all)	2	2	1

Non-serious adverse events	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 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			
subjects affected / exposed	2 / 33 (6.06%)	0 / 32 (0.00%)	1 / 29 (3.45%)
occurrences (all)	5	0	1
Arthropod sting			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 33 (3.03%)	1 / 32 (3.13%)	0 / 29 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	2 / 33 (6.06%)	0 / 32 (0.00%)	1 / 29 (3.45%)
occurrences (all)	2	0	1
Dysgeusia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	6 / 33 (18.18%)	10 / 32 (31.25%)	4 / 29 (13.79%)
occurrences (all)	7	10	5
Somnolence			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	2 / 33 (6.06%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 33 (15.15%)	0 / 32 (0.00%)	2 / 29 (6.90%)
occurrences (all)	5	0	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	5 / 33 (15.15%)	1 / 32 (3.13%)	0 / 29 (0.00%)
occurrences (all)	6	1	0
Tooth impacted			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 33 (9.09%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	3	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	4 / 33 (12.12%)	0 / 32 (0.00%)	1 / 29 (3.45%)
occurrences (all)	4	0	1
Eczema			
subjects affected / exposed	1 / 33 (3.03%)	1 / 32 (3.13%)	0 / 29 (0.00%)
occurrences (all)	1	1	0
Pruritus			
subjects affected / exposed	10 / 33 (30.30%)	1 / 32 (3.13%)	3 / 29 (10.34%)
occurrences (all)	10	1	3
Rash			
subjects affected / exposed	3 / 33 (9.09%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	3	0	0
Rash pruritic			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

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

Non-serious adverse events	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	D1: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-12 wk
Total subjects affected by non-serious 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			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	3 / 20 (15.00%)
occurrences (all)	0	2	4
Arthropod sting			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

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

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

subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	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

Non-serious adverse events	C2: TN NC/GT1b Grazoprevir 100 mg + Elbasvir 50 mg-8 wk	D2: TN NC/GT3 Grazoprevir 100 mg + Elbasvir 50 mg + RBV-18 wk	
Total subjects affected by non-serious 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 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	0 / 31 (0.00%)	0 / 21 (0.00%)	
occurrences (all)	0	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 subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 21 (0.00%) 0	
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 31 (0.00%) 0	0 / 21 (0.00%) 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