Safety and Efficacy of SCH 503034 in Previously Untreated Subjects With Chronic Hepatitis C Infected With Genotype 1 (Study P03523)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00423670

First received: January 17, 2007
Last updated: February 16, 2015
Last verified: February 2015
History of Changes

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Purpose

This was an open-label, randomized safety and efficacy trial in adult, treatment-naïve Chronic Hepatitis C (CHC) participants with genotype 1 infection. The study conducted in 2 parts, compared standard-of-care PegIntron (1.5 µg/kg, once weekly [QW]), plus ribavirin (800 to 1400 mg/day), for 48 weeks to five treatment paradigms containing boceprevir (SCH 503034) 800 mg thrice a day (TID). The five treatments included boceprevir (BOC) plus standard-of-care for 28 or 48 weeks, with and without a 4-week lead-in with PegIntron (PEG) and ribavirin (RBV), and exploration of PegIntron plus low-dose ribavirin (400 to 1000 mg/day) plus boceprevir for 48 weeks.

Condition	Intervention	Phase
Chronic Hepatitis C	Drug: boceprevir (SCH 503034) Drug: peginterferon-alfa 2b (PegIntron) Drug: ribavirin Drug: ribavirin (low-dose)	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Safety and Efficacy Study of SCH 503034 in Previously Untreated Subjects With Chronic Hepatitis C Infected With Genotype 1

Resource links provided by NLM:

MedlinePlus related topics: Hepatitis Hepatitis A Hepatitis C

Drug Information available for: Ribavirin Peginterferon Alfa-2b Boceprevir

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Number of Participants With Sustained Virologic Response (SVR) [Time Frame: From follow-up week (FW) 24 up to end of follow-up (EOF)] [Designated as safety issue: No]

  Participants with undetectable HCV-RNA at FW 24 up to EOF had achieved SVR. Participants missing data at FW 24 were considered to achieve SVR if

  a. he/she had undetectable HCV-RNA at FW 12 or later
  b. he/she returned later to the study center and had undetectable HCV-RNA.

  HCV-RNA in plasma samples was detected with reverse-transcriptase-polymerase chain reaction (RT-PCR) assay, with a lower limit of detection (LLD) of 29 international units/mL (IU/mL). A participant in Arm 2 with undetectable HCV-RNA at FW 24 had detectable HCV-RNA after FW 24. He is not considered to achieve SVR.

Secondary Outcome Measures:

- Number of Participants With SVR Based on a 4-week lead-in Treatment With PegIntron and Ribavirin [Time Frame: From FW 24 up to EOF] [Designated as safety issue: No]

  Number of participants with SVR (undetectable plasma HCV-RNA at FW 24 up to EOF). To assess the effect of lead-in treatment on SVR, participants with (Arm 3 and Arm 5) or without (Arm 2 and Arm 4) lead-in were pooled. Participants missing data at FW 24 were considered to achieve SVR if

  a. he/she had undetectable HCV-RNA at FW 12 or later
  b. he/she returned later to the study center and had undetectable HCV-RNA.

  HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.

- Number of Participants With SVR Based on Duration of Boceprevir Treatment [Time Frame: From FW 24 up to EOF] [Designated as safety issue: No]

  Number of participants with SVR (undetectable plasma HCV-RNA at FW 24 up to EOF). Participants from treatment arms receiving boceprevir for 28-weeks (Arm 2 and Arm 3) were pooled, and those receiving boceprevir for 48-weeks (Arm 4 and Arm 5) were pooled for the analysis. Participants missing data at FW 24 were considered to achieve SVR if

  a. he/she had undetectable HCV-RNA at FW 12 or later
  b. he/she returned later to the study center and had undetectable HCV-RNA.

  HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.

- Number of Participants Negative for HCV-RNA at FW 12 [Time Frame: At FW 12] [Designated as safety issue: No]

  Participants who had undetectable plasma HCV-RNA at FW 12. Also reported are participants for whom the HCV-RNA values were missing. 36 participant who switched over to Arm 8 from Arm 1, are included in the missing values for Arm 1. HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.

- Number of Participants Negative for HCV-RNA at 72 Weeks Post Randomization [Time Frame: 72 weeks post randomization] [Designated as safety issue: No]

  Participants who had undetectable HCV-RNA at 72 weeks post randomization are reported. Participants with missing HCV-RNA values at 72 weeks post randomization are also reported. HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.

- Number of Participants With an Early Virologic Response (EVR) That Achieved SVR [Time Frame: At TW 12, and at FW 24 up to EOF] [Designated as safety issue: No]

  Participants with undetectable HCV-RNA at TW 12 have EVR, and with undetectable HCV-RNA at FW 24 (up to EOF) achieved SVR. Participants missing data at FW 24 were considered to achieve SVR if

  a. he/she had undetectable HCV-RNA at FW 12 or later
  b. if he/she returned later to the study center and had undetectable HCV-RNA.

  HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.

- Number of Participants With a Virologic Response at Follow-up Week 12 That Achieved SVR [Time Frame: At FW 12 and FW 24 up to EOF] [Designated as safety issue: No]

Treatment-naïve adults with CHC genotype 1 were assigned study medication. Participants with undetectable HCV-RNA at FW 12 that achieved SVR (have undetectable HCV-RNA at FW 24 (up to EOF) are reported. Participants missing data at FW 24 were considered to achieve SVR if

a. he/she had undetectable HCV-RNA at FW 12 or later
b. if he/she returned later to the study center and had undetectable HCV-RNA.

HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.

- Number of Participants With a Virologic Response at 72 Weeks Post Randomization That Achieved SVR [Time Frame: At FW 24 up to EOF and at 72 weeks post randomization] [Designated as safety issue: No]

  Participants with undetectable HCV-RNA at 72 weeks post randomization that achieved SVR (have undetectable HCV-RNA at FW 24 up to EOF) are reported. Participants missing data at FW 24 were considered to achieve SVR if

  a. he/she had undetectable HCV-RNA at FW 12 or later
  b. if he/she returned later to the study center and had undetectable HCV-RNA.

  HCV-RNA in plasma samples was detected an the RT-PCR assay. The lower limit of detection (LLD) was 29 IU/mL.

Enrollment:	765
Study Start Date:	January 2007
Study Completion Date:	November 2008
Primary Completion Date:	August 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Arm 1. PEG +RBV for 48 Wks (Part I) Participants treated with PegIntron (1.5 µg/kg, once weekly [QW]) and Ribavirin (800 to 1400 mg/day) for 48 weeks. Participants with detectable HCV-RNA levels after 24 weeks of treatment had the option of crossing over to receive 24 weeks of PegIntron (1.5 µg/kg, QW), Ribavirin (800 to 1400 mg/day), and boceprevir (800 mg three times daily [TID]) for 24 additional weeks. The participants that crossed over to receive boceprevir formed Arm 8. The total treatment duration was up to 54 weeks.	Drug: peginterferon-alfa 2b (PegIntron) 1.5 µg/kg subcutaneously (SC) once weekly (QW) Drug: ribavirin 200 mg capsules in doses of 800 to 1400 mg/day (based on weight) taken orally divided twice daily
Experimental: Arm 2. PEG + RBV + BOC for 28 Wks (Part I) Participants receiving boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 28 weeks.	Drug: boceprevir (SCH 503034) 200 mg capsules taken as 800 mg orally three times daily (TID) Other Name: Boceprevir, Victrelis, SCH 503034 Drug: peginterferon-alfa 2b (PegIntron) 1.5 µg/kg subcutaneously (SC) once weekly (QW) Drug: ribavirin 200 mg capsules in doses of 800 to 1400 mg/day (based on weight) taken orally divided twice daily
Experimental: Arm 3. PEG + RBV + BOC (from Wk 4) for 24 Wks (Part I) Participants receiving a lead-in treatment with PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks, followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 24 weeks.	Drug: boceprevir (SCH 503034) 200 mg capsules taken as 800 mg orally three times daily (TID) Other Name: Boceprevir, Victrelis, SCH 503034 Drug: peginterferon-alfa 2b (PegIntron)

	1.5 µg/kg subcutaneously (SC) once weekly (QW) Drug: ribavirin 200 mg capsules in doses of 800 to 1400 mg/day (based on weight) taken orally divided twice daily
Experimental: Arm 4. PEG +RBV + BOC for 48 Wks (Part I) Participants receiving boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.	Drug: boceprevir (SCH 503034) 200 mg capsules taken as 800 mg orally three times daily (TID) Other Name: Boceprevir, Victrelis, SCH 503034 Drug: peginterferon-alfa 2b (PegIntron) 1.5 µg/kg subcutaneously (SC) once weekly (QW) Drug: ribavirin 200 mg capsules in doses of 800 to 1400 mg/day (based on weight) taken orally divided twice daily
Experimental: Arm 5. PEG + RBV + BOC (from Wk 4) for 44 Wks (Part I) Participants receiving a lead-in treatment with PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks, followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.	Drug: boceprevir (SCH 503034) 200 mg capsules taken as 800 mg orally three times daily (TID) Other Name: Boceprevir, Victrelis, SCH 503034 Drug: peginterferon-alfa 2b (PegIntron) 1.5 µg/kg subcutaneously (SC) once weekly (QW) Drug: ribavirin 200 mg capsules in doses of 800 to 1400 mg/day (based on weight) taken orally divided twice daily
Experimental: Arm 6. PEG + RBV + BOC for 48 Wks (Part II) Participants receiving PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day) and boceprevir (800 mg TID) for up to 48 weeks during Part II of the study. Part II was initiated after participants were fully enrolled for Part I.	Drug: boceprevir (SCH 503034) 200 mg capsules taken as 800 mg orally three times daily (TID) Other Name: Boceprevir, Victrelis, SCH 503034 Drug: peginterferon-alfa 2b (PegIntron) 1.5 µg/kg subcutaneously (SC) once weekly (QW) Drug: ribavirin 200 mg capsules in doses of 800 to 1400 mg/day (based on weight) taken orally divided twice daily
Experimental: Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II) Participants receiving PegIntron (1.5 µg/kg QW), low-dose ribavirin (400 to 1000 mg/day) and boceprevir (800	Drug: boceprevir (SCH 503034)

mg TID) for up to 48 weeks (Arm 7) during Part II of the study. Part II was initiated after participants were fully enrolled for Part I.	200 mg capsules taken as 800 mg orally three times daily (TID) Other Name: Boceprevir, Victrelis, SCH 503034 Drug: peginterferon-alfa 2b (PegIntron) 1.5 µg/kg subcutaneously (SC) once weekly (QW) Drug: ribavirin (low-dose) 200 mg capsules in doses of 400 to 1000 mg/day (based on weight) taken orally divided twice daily
Experimental: Arm 8. PEG + RBV + BOC (from Wk 24) for 48 Wks (Part I) Participants that started in Arm 1 and had detectable HCV-RNA levels after 24 weeks of treatment had the option of receiving boceprevir (800 mg TID) with PegIntron (1.5 µg/kg QW), and ribavirin (800 to 1400 mg/day). Participants that took the option of crossing over to receive PegIntron, ribavirin, and boceprevir (800 mg TID) for 24 additional weeks constitute Arm 8. The total treatment duration was up to 54 weeks.	Drug: boceprevir (SCH 503034) 200 mg capsules taken as 800 mg orally three times daily (TID) Other Name: Boceprevir, Victrelis, SCH 503034 Drug: peginterferon-alfa 2b (PegIntron) 1.5 µg/kg subcutaneously (SC) once weekly (QW) Drug: ribavirin 200 mg capsules in doses of 800 to 1400 mg/day (based on weight) taken orally divided twice daily

Detailed Description:

The study was conducted in 2 parts.

Part 1 of the study had 5 arms using weight based ribavirin 800-1400 mg/day and compared:

- PegIntron and ribavirin for 48 weeks (Arm 1 - Control)
- PegIntron, ribavirin, and boceprevir for 28 weeks (Arm 2)
- Lead-in with PegIntron and ribavirin for 4 weeks followed by PegIntron, ribavirin and boceprevir for 24 weeks (Arm 3)
- PegIntron, ribavirin and boceprevir for 48 weeks (Arm 4)
- Lead-in with PegIntron and ribavirin for 4 weeks, followed by PegIntron, ribavirin and boceprevir for 44 weeks (Arm 5)

Participants from Arm 1 receiving PegIntron and ribavirin that were HCV positive after 24 weeks of treatment had the option to receive boceprevir in combination with PegIntron and ribavirin for an additional 24 weeks. All participants from Arm 1 that started boceprevir after Week 24 formed the crossover arm (Arm 8).

Part 2 of the study assessed the safety and efficacy of low dose ribavirin (400-1000 mg/day) and compared:

- PegIntron, ribavirin (800-1400 mg/day) and boceprevir for 48 weeks (Arm 6)
- PegIntron, low-dose ribavirin (400-1000 mg/day) and boceprevir for 48 weeks (Arm 7)

Follow-up for all participants was up to 72 weeks after randomization.

Eligibility

Ages Eligible for Study:	18 Years to 60 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Age between 18 and 60 years;

- Body weight between 45 and 125 kg;
- Documented chronic hepatitis C genotype 1;
- Liver biopsy with histology consistent with chronic hepatitis and no other etiology for chronic liver disease within of 5 years of Day 1;
- Participant and participant's partner(s) must each agree to use acceptable methods of contraception 2 weeks prior to Day 1 and at least 6 months after the last dose of study medication;
- Written informed consent.

Exclusion Criteria:

Include, but are not limited to, the following:

- Prior treatment for hepatitis C;
- Co-infection with HIV or hepatitis B virus (HBsAg positive);
- Evidence of decompensated liver disease;
- Diabetic and hypertensive participants with clinically significant ocular exam findings;
- Pre-existing psychiatric condition, including but not limited to:
  - Current moderate or severe depression;
  - History of depression associated with any of the following:
    - Hospitalization for depression;
    - Electroconvulsive therapy for depression;
    - Depression that resulted in a prolonged absence from work and/or significant disruption of daily functions;
  - Suicidal or homicidal ideation and/or attempt;
  - History of severe psychiatric disorders (including but not limited to schizophrenia, psychosis, bipolar disorder, post-traumatic stress disorder or mania);
  - Past history or current use of lithium;
  - Past history or current use of antipsychotic drugs for listed conditions.
- Substance abuse within protocol specified timeframes;
- Pre-existing medical conditions that could interfere with the participant's participation in and completion of the study, including but not limited to chronic pulmonary disease, cardiac dysfunction or immunologically-mediated disease;
- Active or suspected malignancy or history of malignancy within the past 5 years;
- Participants who are pregnant or nursing; participants who intend to become pregnant during the study period. Male participants with partners who are, or intend to become, pregnant during the study period.
- Treatment with any investigational drug or participation in any clinical trial 30 days within Screening;
- Hemoglobin <12 g/dL for females and <13 g/dL for males;
- Neutrophils <1500 mm^3; Blacks: <1200/mm^3;
- Platelets <100,000/mm^3;
- Other clinically significant laboratory test abnormalities.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Kwo PY, Lawitz EJ, McCone J, Schiff ER, Vierling JM, Pound D, Davis MN, Galati JS, Gordon SC, Ravendhran N, Rossaro L, Anderson FH, Jacobson IM, Rubin R, Koury K, Pedicone LD, Brass CA, Chaudhri E, Albrecht JK; SPRINT-1 investigators. Efficacy of boceprevir, an NS3 protease inhibitor, in combination with peginterferon alfa-2b and ribavirin in treatment-naive patients with genotype 1 hepatitis C infection (SPRINT-1): an open-label, randomised, multicentre phase 2 trial. Lancet. 2010 Aug 28;376(9742):705-16. doi: 10.1016/S0140-6736(10)60934-8. Epub 2010 Aug 6. Erratum in: Lancet. 2010 Oct 9;376(9748):1224. SPRINT-1 investigators [added]; multiple investigator names added.

Responsible Party: Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:	NCT00423670 History of Changes
Other Study ID Numbers:	P03523 EudraCT No. 2006-002543-92
Study First Received:	January 17, 2007
Results First Received:	May 13, 2011
Last Updated:	February 16, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Hepatitis	RNA Virus Infections
Hepatitis A	Virus Diseases
Hepatitis C	Peginterferon alfa-2b
Hepatitis C, Chronic	Ribavirin
Hepatitis, Chronic	Anti-Infective Agents
Digestive System Diseases	Antimetabolites
Enterovirus Infections	Antiviral Agents
Flaviviridae Infections	Molecular Mechanisms of Pharmacological Action
Hepatitis, Viral, Human	Pharmacologic Actions
Liver Diseases	Therapeutic Uses
Picornaviridae Infections	

ClinicalTrials.gov processed this record on May 08, 2016

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First received: January 17, 2007
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History of Changes

Results First Received: May 13, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Chronic Hepatitis C
Interventions:	Drug: boceprevir (SCH 503034) Drug: peginterferon-alfa 2b (PegIntron) Drug: ribavirin Drug: ribavirin (low-dose)

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
765 participants were screened in the study, 598 were randomized of which 3 participants were not treated (Arm 1-7). Participants were assigned to Part I (with standard dosing for ribavirin) or Part II (to explore low-dose ribavirin). All participants that completed or discontinued treatment were scheduled to enter follow-up phase per protocol.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Participants in Arm 1 (Part I) who had detectable Hepatitis C Virus-ribonucleic acid (HCV-RNA) at Treatment Week (TW) 24 were offered boceprevir in addition to PegIntron and ribavirin for an additional 24 weeks of treatment, and switched to a new arm, Arm 8.

Reporting Groups

	Description
Arm 1. PEG +RBV for 48 Wks (Part I)	PegIntron (1.5 µg/kg, once weekly [QW]) plus ribavirin (800 to 1400 mg/day) for 48 weeks. • Participants with detectable HCV-RNA levels after 24 weeks of treatment had the option of crossing over to receive 24 weeks of PegIntron, ribavirin, and boceprevir (800 mg, thrice a day [TID]) for 24 additional weeks. Total treatment duration was up to 54 weeks.
Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 28 weeks.
Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead-in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 24 weeks.
Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.
Arm 5. PEG + RBV + BOC (From Wk 4) for 44 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead-in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.
Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (400 to 1000 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
Arm 8. PEG + RBV + BOC (From Wk 24) for 48 Wks (Part I)	Participants that started in Arm 1 and had detectable HCV-RNA levels after 24 weeks of treatment had the option of receiving boceprevir (800 mg TID) with PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day). Participants that took the option of crossing over to receive 24 weeks of PegIntron, ribavirin, and boceprevir (800 mg TID) for 24 additional weeks constitute Arm 8. The total treatment duration was up to 54 weeks.

Participant Flow for 2 periods

Period 1: Treatment Period

	Arm 1. PEG +RBV for 48 Wks (Part I)	Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Arm 5. PEG + RBV + BOC (From Wk 4) for 44 Wks (Part I)	Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)	Arm 8. PEG + RBV + BOC (From Wk 24) for 48 Wks (Part I)
STARTED	**104**	**107**	**103**	**103**	**103**	**16**	**59**	**36** [1]

COMPLETED	52	77	76	63	76	8	28	15
NOT COMPLETED	52	30	27	40	27	8	31	21
Switched to Arm 8 at TW 24	36	0	0	0	0	0	0	0
Adverse Event	8	12	15	20	9	4	7	2
Protocol-defined clinical event	0	7	4	12	5	4	16	15
Lost to Follow-up	2	1	3	1	6	0	3	1
Subject withdrew (not treatment related)	3	9	4	4	5	0	3	0
Investigator decision	0	0	0	0	0	0	0	1
Non-compliance with protocol	3	1	1	3	2	0	2	2

[1] Arm 8 were Arm 1 participants that were positive for HCV-RNA at TW 24 and had the option to switch.

Period 2: Follow-up Period

	Arm 1. PEG +RBV for 48 Wks (Part I)	Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Arm 5. PEG + RBV + BOC (From Wk 4) for 44 Wks (Part I)	Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)	Arm 8. PEG + RBV + BOC (From Wk 24) for 48 Wks (Part I)
STARTED	97	100	96	96	91	14	50	35
COMPLETED	94	84	85	91	89	14	41	32
NOT COMPLETED	3	16	11	5	2	0	9	3
Lost to Follow-up	0	12	8	3	1	0	5	0

Subject withdrew (not treatment related)	**1**	**4**	**2**	**1**	**1**	**0**	**1**	**1**
Non-compliance with protocol	**2**	**0**	**1**	**1**	**0**	**0**	**3**	**2**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Arm 1. PEG +RBV for 48 Wks (Part I)	PegIntron (1.5 µg/kg QW) plus ribavirin (800 to 1400 mg/day) for 48 weeks. • Participants with detectable HCV-RNA levels after 24 weeks of treatment had to receive 24 weeks of PegIntron, ribavirin and boceprevir (800 mg TID) for 24 additional weeks. Total treatment duration was up to 54 weeks.
Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 28 weeks.
Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 24 weeks.
Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.
Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.
Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (400 to 1000 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
Total	Total of all reporting groups

Baseline Measures

	Arm 1. PEG +RBV	**Arm 2. PEG + RBV + BOC for**	**Arm 3. PEG + RBV + BOC (From Wk 4)**	**Arm 4. PEG +RBV + BOC**	**Arm 5. PEG + RBV+ BOC (From**	**Arm 6. PEG + RBV + BOC for**	**Arm 7. PEG +Low-dose RBV +**	**Total**

	for 48 Wks (Part I)	28 Wks (Part I)	for 24 Wks (Part I)	for 48 Wks (Part I)	Wk 4) for 44 Wks (Part I)	48 Wks (Part II)	BOC for 48 Wks (Part II)	
Number of Participants [units: participants]	104	107	103	103	103	16	59	595
Age [1] [units: years] Mean (Standard Deviation)	48.3 (6.9)	46.4 (8.0)	47.7 (7.4)	46.7 (8.8)	47.6 (8.3)	50.3 (8.5)	48.7 (5.8)	47.5 (7.7)
Gender [2] [units: participants]								
Female	34	44	52	40	45	7	18	240
Male	70	63	51	63	58	9	41	355

[1] Overall age characteristics were displayed for Arm 1 through Arm 7. Participants from Arm 1 (Part I) who had detectable HCV-RNA at TW 24, had the option to switch to a new arm, Arm 8.

[2] Overall gender characteristics were displayed for Arm 1 through Arm 7. Participants from Arm 1 (Part I) who had detectable HCV-RNA TW 24, had the option to switch to a new arm, Arm 8.

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Sustained Virologic Response (SVR) [Time Frame: From follow-up week (FW) 24 up to end of follow-up (EOF)]

Measure Type	Primary
Measure Title	Number of Participants With Sustained Virologic Response (SVR)
Measure Description	Participants with undetectable HCV-RNA at FW 24 up to EOF had achieved SVR. Participants missing data at FW 24 were considered to achieve SVR if 1. he/she had undetectable HCV-RNA at FW 12 or later 2. he/she returned later to the study center and had undetectable HCV-RNA. HCV-RNA in plasma samples was detected with reverse-transcriptase-polymerase chain reaction (RT-PCR) assay, with a lower limit of detection (LLD) of 29 international units/mL (IU/mL). A participant in Arm 2 with undetectable HCV-RNA at FW 24 had detectable HCV-RNA after FW 24. He is not considered to achieve SVR.
Time Frame	From follow-up week (FW) 24 up to end of follow-up (EOF)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-Treat (ITT) population: All randomized participants who received at least one dose of any study medication (PegIntron, ribavirin, or boceprevir).

Reporting Groups

	Description
Arm 1. PEG +RBV for 48 Wks (Part I)	PegIntron (1.5 µg/kg QW) plus ribavirin (800 to 1400 mg/day) for 48 weeks. • Participants with detectable HCV-RNA levels after 24 weeks of treatment had to receive 24 weeks of PegIntron, ribavirin and boceprevir (800 mg TID) for 24 additional weeks. Total treatment duration was up to 54 weeks.
Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 28 weeks.
Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 24 weeks.
Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.
Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.
Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (400 to 1000 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.

Measured Values

	Arm 1. PEG +RBV for 48 Wks (Part I)	**Arm 2. PEG + RBV + BOC for 28 Wks (Part I)**	**Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)**	**Arm 4. PEG +RBV + BOC for 48 Wks (Part I)**	**Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)**	**Arm 6. PEG + RBV + BOC for 48 Wks (Part II)**	**Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)**
Number of Participants Analyzed [units: participants]	**104**	**107**	**103**	**103**	**103**	**16**	**59**
Number of Participants With Sustained Virologic Response (SVR) [units: Participants]	**39**	**58**	**58**	**69**	**77**	**8**	**21**

Statistical Analysis 1 for Number of Participants With Sustained Virologic Response (SVR)

Groups [1]	Arm 1. PEG +RBV for 48 Wks (Part I) vs. Arm 2. PEG + RBV + BOC for 28 Wks (Part I)

Method [2]	Cochran-Mantel Haenszel Chi-square test
P Value [3]	0.0126
Percent difference in SVR [4]	16.7
95% Confidence Interval	3.5 to 30

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjusted for baseline stratification factors: black versus non-black, and cirrhosis versus no cirrhosis.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Number of Participants With Sustained Virologic Response (SVR)

Groups [1]	Arm 1. PEG +RBV for 48 Wks (Part I) vs. Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)
Method [2]	Cochran-Mantel Haenszel Chi-square test
P Value [3]	0.0048
Percent difference in SVR [4]	18.8
95% Confidence Interval	5.5 to 32.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjusted for baseline stratification factors: black versus non-black, and cirrhosis versus no cirrhosis.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Number of Participants With Sustained Virologic Response (SVR)

Groups [1]	Arm 1. PEG +RBV for 48 Wks (Part I) vs. Arm 4. PEG +RBV + BOC for 48 Wks (Part I)

Method [2]	Cochran-Mantel Haenszel Chi-square test
P Value [3]	<0.0001
Percent difference in SVR [4]	29.5
95% Confidence Interval	16.5 to 42.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjusted for baseline stratification factors: black versus non-black, and cirrhosis versus no cirrhosis.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Number of Participants With Sustained Virologic Response (SVR)

Groups [1]	Arm 1. PEG +RBV for 48 Wks (Part I) vs. Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)
Method [2]	Cochran-Mantel Haenszel Chi-square test
P Value [3]	<0.0001
Percent difference in SVR [4]	37.3
95% Confidence Interval	24.7 to 49.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjusted for baseline stratification factors: black versus non-black, and cirrhosis versus no cirrhosis.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Number of Participants With SVR Based on a 4-week lead-in Treatment With PegIntron and Ribavirin [Time Frame: From FW 24 up to EOF]

Measure Type	Secondary
Measure Title	Number of Participants With SVR Based on a 4-week lead-in Treatment With PegIntron and Ribavirin
Measure Description	Number of participants with SVR (undetectable plasma HCV-RNA at FW 24 up to EOF). To assess the effect of lead-in treatment on SVR, participants with (Arm 3 and Arm 5) or without (Arm 2 and Arm 4) lead-in were pooled. Participants missing data at FW 24 were considered to achieve SVR if 1. he/she had undetectable HCV-RNA at FW 12 or later 2. he/she returned later to the study center and had undetectable HCV-RNA. HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.
Time Frame	From FW 24 up to EOF
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-Treat (ITT) population: All randomized participants who received at least one dose of any study medication (PegIntron, ribavirin, or boceprevir).

Reporting Groups

	Description
Arm 3 and Arm 5. PEG + RBV + BOC (From Wk 4)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.
Arm 2 and Arm 4. PEG + RBV + BOC	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.

Measured Values

	Arm 3 and Arm 5. PEG + RBV + BOC (From Wk 4)	**Arm 2 and Arm 4. PEG + RBV + BOC**
Number of Participants Analyzed [units: participants]	**206**	**210**
Number of Participants With SVR Based on a 4-week lead-in Treatment With PegIntron and Ribavirin [units: Participants]	**135**	**127**

Statistical Analysis 1 for Number of Participants With SVR Based on a 4-week lead-in Treatment With PegIntron and Ribavirin

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel Chi-Square Test
P Value [3]	0.2864

Percent difference in SVR rates [4]	5.1
95% Confidence Interval	-4.2 to 14.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjusted for baseline stratification factors: black versus non black, and cirrhosis versus no cirrhosis.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Number of Participants With SVR Based on Duration of Boceprevir Treatment [Time Frame: From FW 24 up to EOF]

Measure Type	Secondary
Measure Title	Number of Participants With SVR Based on Duration of Boceprevir Treatment
Measure Description	Number of participants with SVR (undetectable plasma HCV-RNA at FW 24 up to EOF). Participants from treatment arms receiving boceprevir for 28-weeks (Arm 2 and Arm 3) were pooled, and those receiving boceprevir for 48-weeks (Arm 4 and Arm 5) were pooled for the analysis. Participants missing data at FW 24 were considered to achieve SVR if 1. he/she had undetectable HCV-RNA at FW 12 or later 2. he/she returned later to the study center and had undetectable HCV-RNA. HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.
Time Frame	From FW 24 up to EOF
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-Treat (ITT) population: All randomized participants who received at least one dose of any study medication (PegIntron, ribavirin, or boceprevir).

Reporting Groups

	Description
Arm 4 and Arm 5. PEG + RBV + BOC (48 Weeks)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) with or without a 4 weeks lead with boceprevir (800 mg TID) for 48 weeks.

Arm 2 and Arm 3. PEG + RBV + BOC (28 Weeks)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) with or without a 4 weeks lead with boceprevir (800 mg TID) for 28 weeks.

Measured Values

	Arm 4 and Arm 5. PEG + RBV + BOC (48 Weeks)	Arm 2 and Arm 3. PEG + RBV + BOC (28 Weeks)
Number of Participants Analyzed [units: participants]	**206**	**210**
Number of Participants With SVR Based on Duration of Boceprevir Treatment [units: Participants]	**146**	**116**

Statistical Analysis 1 for Number of Participants With SVR Based on Duration of Boceprevir Treatment

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel Chi-Square Test
P Value [3]	0.0009
Percent difference in SVR rates [4]	15.6
95% Confidence Interval	6.5 to 24.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Adjusted for the baseline stratification factors: black versus non black, and cirrhosis versus no cirrhosis.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

4. Secondary: Number of Participants Negative for HCV-RNA at FW 12 [Time Frame: At FW 12]

Measure Type	Secondary
Measure Title	Number of Participants Negative for HCV-RNA at FW 12
Measure Description	Participants who had undetectable plasma HCV-RNA at FW 12. Also reported are participants for whom the HCV-RNA values were missing. 36 participant who switched over to Arm 8 from Arm 1, are included in the missing values for Arm 1.

	HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.
Time Frame	At FW 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-Treat (ITT) population: All randomized participants who received at least one dose of any study medication (PegIntron, ribavirin, or boceprevir).

Reporting Groups

	Description
Arm 1. PEG +RBV for 48 Wks (Part I)	PegIntron (1.5 µg/kg QW) plus ribavirin (800 to 1400 mg/day) for 48 weeks. • Participants with detectable HCV-RNA levels after 24 weeks of treatment had to receive 24 weeks of PegIntron, ribavirin and boceprevir (800 mg TID) for 24 additional weeks. Total treatment duration was up to 54 weeks.
Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 28 weeks.
Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 24 weeks.
Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.
Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.
Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (400 to 1000 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.

Measured Values

	Arm 1. PEG +RBV for 48 Wks (Part I)	**Arm 2. PEG + RBV + BOC for 28 Wks (Part I)**	**Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)**	**Arm 4. PEG +RBV + BOC for 48 Wks (Part I)**	**Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)**	**Arm 6. PEG + RBV + BOC for 48 Wks (Part II)**	**Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)**
Number of Participants Analyzed [units: participants]	**104**	**107**	**103**	**103**	**103**	**16**	**59**
Number of Participants Negative for HCV-RNA at FW 12							

[units: Participants]							
HCV-RNA negative	39	60	59	69	76	8	21
Missing HCV-RNA at FW 12	42	13	11	12	14	2	17

No statistical analysis provided for Number of Participants Negative for HCV-RNA at FW 12

5. Secondary: Number of Participants Negative for HCV-RNA at 72 Weeks Post Randomization [Time Frame: 72 weeks post randomization]

Measure Type	Secondary
Measure Title	Number of Participants Negative for HCV-RNA at 72 Weeks Post Randomization
Measure Description	Participants who had undetectable HCV-RNA at 72 weeks post randomization are reported. Participants with missing HCV-RNA values at 72 weeks post randomization are also reported. HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.
Time Frame	72 weeks post randomization
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Arm 1. PEG +RBV for 48 Wks (Part I)	PegIntron (1.5 µg/kg QW) plus ribavirin (800 to 1400 mg/day) for 48 weeks. • Participants with detectable HCV-RNA levels after 24 weeks of treatment had to receive 24 weeks of PegIntron, ribavirin and boceprevir (800 mg TID) for 24 additional weeks. Total treatment duration was up to 54 weeks.
Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 28 weeks.
Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 24 weeks.
Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.
Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.

Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (400 to 1000 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.

Measured Values

	Arm 1. PEG +RBV for 48 Wks (Part I)	Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)	Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)
Number of Participants Analyzed [units: participants]	**104**	**107**	**103**	**103**	**103**	**16**	**59**
Number of Participants Negative for HCV-RNA at 72 Weeks Post Randomization [units: Participants]							
HCV-RNA negative	**38**	**53**	**56**	**67**	**76**	**8**	**20**
Missing HCV-RNA at 72 weeks post randomization	**45**	**25**	**18**	**17**	**20**	**6**	**22**

No statistical analysis provided for Number of Participants Negative for HCV-RNA at 72 Weeks Post Randomization

6. Secondary: Number of Participants With an Early Virologic Response (EVR) That Achieved SVR [Time Frame: At TW 12, and at FW 24 up to EOF]

Measure Type	Secondary
Measure Title	Number of Participants With an Early Virologic Response (EVR) That Achieved SVR
Measure Description	Participants with undetectable HCV-RNA at TW 12 have EVR, and with undetectable HCV-RNA at FW 24 (up to EOF) achieved SVR. Participants missing data at FW 24 were considered to achieve SVR if 1. he/she had undetectable HCV-RNA at FW 12 or later 2. if he/she returned later to the study center and had undetectable HCV-RNA. HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.
Time Frame	At TW 12, and at FW 24 up to EOF
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Participants with an early virologic response (EVR).

Reporting Groups

	Description
Arm 1. PEG +RBV for 48 Wks (Part I)	PegIntron (1.5 µg/kg QW) plus ribavirin (800 to 1400 mg/day) for 48 weeks. • Participants with detectable HCV-RNA levels after 24 weeks of treatment had to receive 24 weeks of PegIntron, ribavirin and boceprevir (800 mg TID) for 24 additional weeks. Total treatment duration was up to 54 weeks.
Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 28 weeks.
Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 24 weeks.
Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.
Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.
Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (400 to 1000 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.

Measured Values

	Arm 1. PEG +RBV for 48 Wks (Part I)	Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)	Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)
Number of Participants Analyzed [units: participants]	**37**	**85**	**85**	**81**	**85**	**11**	**35**
Number of Participants With an Early Virologic Response (EVR) That Achieved SVR [units: Participants]	**32**	**58**	**58**	**68**	**77**	**8**	**21**

No statistical analysis provided for Number of Participants With an Early Virologic Response (EVR) That Achieved SVR

7. Secondary: Number of Participants With a Virologic Response at Follow-up Week 12 That Achieved SVR [Time Frame: At FW 12 and FW 24 up to EOF]

Measure Type	Secondary
Measure Title	Number of Participants With a Virologic Response at Follow-up Week 12 That Achieved SVR

Measure Description	Treatment-naïve adults with CHC genotype 1 were assigned study medication. Participants with undetectable HCV-RNA at FW 12 that achieved SVR (have undetectable HCV-RNA at FW 24 (up to EOF) are reported. Participants missing data at FW 24 were considered to achieve SVR if 1. he/she had undetectable HCV-RNA at FW 12 or later 2. if he/she returned later to the study center and had undetectable HCV-RNA. HCV-RNA in plasma samples was detected with an RT-PCR assay. The LLD for the assay was 29 IU/mL.
Time Frame	At FW 12 and FW 24 up to EOF
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants with undetectable HCV-RNA at FW 12.

Reporting Groups

	Description
Arm 1. PEG +RBV for 48 Wks (Part I)	PegIntron (1.5 µg/kg QW) plus ribavirin (800 to 1400 mg/day) for 48 weeks. • Participants with detectable HCV-RNA levels after 24 weeks of treatment had to receive 24 weeks of PegIntron, ribavirin and boceprevir (800 mg TID) for 24 additional weeks. Total treatment duration was up to 54 weeks.
Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 28 weeks.
Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 24 weeks.
Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.
Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.
Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (400 to 1000 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.

Measured Values

	Arm 1. PEG +RBV for 48 Wks (Part I)	**Arm 2. PEG + RBV + BOC for 28 Wks (Part I)**	**Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)**	**Arm 4. PEG +RBV + BOC for 48 Wks (Part I)**	**Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)**	**Arm 6. PEG + RBV + BOC for 48 Wks (Part II)**	**Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)**
Number of Participants Analyzed [units: participants]	**39**	**60**	**59**	**69**	**76**	**8**	**21**

Number of Participants With a Virologic Response at Follow-up Week 12 That Achieved SVR **[units: Participants]**							
HCV-RNA negative at EOF	**39**	**58**	**58**	**69**	**76**	**8**	**20**
HCV-RNA positive at EOF	**0**	**2**	**1**	**0**	**0**	**0**	**1**
Missing HCV-RNA at EOF	**0**	**0**	**0**	**0**	**0**	**0**	**0**

No statistical analysis provided for Number of Participants With a Virologic Response at Follow-up Week 12 That Achieved SVR

8. Secondary: Number of Participants With a Virologic Response at 72 Weeks Post Randomization That Achieved SVR [Time Frame: At FW 24 up to EOF and at 72 weeks post randomization]

Measure Type	Secondary
Measure Title	Number of Participants With a Virologic Response at 72 Weeks Post Randomization That Achieved SVR
Measure Description	Participants with undetectable HCV-RNA at 72 weeks post randomization that achieved SVR (have undetectable HCV-RNA at FW 24 up to EOF) are reported. Participants missing data at FW 24 were considered to achieve SVR if 1. he/she had undetectable HCV-RNA at FW 12 or later 2. if he/she returned later to the study center and had undetectable HCV-RNA. HCV-RNA in plasma samples was detected an the RT-PCR assay. The lower limit of detection (LLD) was 29 IU/mL.
Time Frame	At FW 24 up to EOF and at 72 weeks post randomization
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who achieved SVR.

Reporting Groups

	Description
Arm 1. PEG +RBV for 48 Wks (Part I)	PegIntron (1.5 µg/kg QW) plus ribavirin (800 to 1400 mg/day) for 48 weeks. • Participants with detectable HCV-RNA levels after 24 weeks of treatment had to receive 24 weeks of PegIntron, ribavirin and boceprevir (800 mg TID) for 24 additional weeks. Total treatment duration was up to 54 weeks.
Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 28

	weeks.
Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 24 weeks.
Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.
Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)	PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.
Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)	PegIntron (1.5 µg/kg QW), ribavirin (400 to 1000 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.

Measured Values

	Arm 1. PEG +RBV for 48 Wks (Part I)	Arm 2. PEG + RBV + BOC for 28 Wks (Part I)	Arm 3. PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	Arm 4. PEG +RBV + BOC for 48 Wks (Part I)	Arm 5. PEG + RBV+ BOC (From Wk 4) for 44 Wks (Part I)	Arm 6. PEG + RBV + BOC for 48 Wks (Part II)	Arm 7. PEG +Low-dose RBV + BOC for 48 Wks (Part II)
Number of Participants Analyzed [units: participants]	**39**	**58**	**58**	**69**	**77**	**8**	**21**
Number of Participants With a Virologic Response at 72 Weeks Post Randomization That Achieved SVR [units: Participants]							
HCV-RNA negative at 72 weeks post randomization	**38**	**53**	**56**	**67**	**76**	**8**	**20**
HCV-RNA positive at FW 24	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Missing HCV-RNA at 72 weeks post randomization	**1**	**5**	**2**	**2**	**1**	**0**	**1**

No statistical analysis provided for Number of Participants With a Virologic Response at 72 Weeks Post Randomization That Achieved SVR

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
PEG +RBV for 48 Wks (Part I)	Arm 1. PegIntron (1.5 µg/kg, once weekly [QW]) plus ribavirin (800 to 1400 mg/day) for 48 weeks. • Participants with detectable HCV-RNA levels after 24 weeks of treatment had the option of crossing over to receive 24 weeks of PegIntron, ribavirin, and boceprevir (800 mg, thrice a day [TID]) for 24 additional weeks. Total treatment duration was up to 54 weeks. Adverse events for 36 participants after they crossed over to Arm 8 are not included.
PEG + RBV + BOC for 28 Wks (Part I)	Arm 2. Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 28 weeks.
PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	Arm 3. PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead-in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 24 weeks.
PEG +RBV + BOC for 48 Wks (Part I)	Arm 4. Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.
PEG + RBV + BOC (From Wk 4) for 44 Wks (Part I)	Arm 5. PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead-in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.
PEG + RBV + BOC for 48 Wks (Part II)	Arm 6. PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
PEG +Low-dose RBV + BOC for 48 Wks (Part II)	Arm 7. PegIntron (1.5 µg/kg QW), ribavirin (400 to 1000 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
PEG + RBV + BOC (From Wk 24) for 48 Wks (Part I)	Arm 8. Participants that started in Arm 1 and had detectable HCV-RNA levels after 24 weeks of treatment had the option of receiving boceprevir (800 mg TID) with PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day). Participants that took the option of crossing over to receive 24 weeks of PegIntron, ribavirin, and boceprevir (800 mg TID) for 24 additional weeks constitute Arm 8. The total treatment duration was up to 54 weeks.

Serious Adverse Events

	PEG +RBV for 48 Wks (Part I)	PEG + RBV + BOC for 28 Wks (Part I)	PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	PEG +RBV + BOC for 48 Wks (Part I)	PEG + RBV + BOC (From Wk 4) for 44 Wks (Part I)	PEG + RBV + BOC for 48 Wks (Part II)	PEG +Low-dose RBV + BOC for 48 Wks (Part II)	PEG + RBV + BOC (From Wk 24) for 48 Wks (Part I)
Total, serious adverse events								
# participants affected / at risk	**8/104 (7.69%)**	**10/107 (9.35%)**	**8/103 (7.77%)**	**10/103 (9.71%)**	**6/103 (5.83%)**	**1/16 (6.25%)**	**3/59 (5.08%)**	**2/36 (5.56%)**
Blood and lymphatic system disorders								
ANAEMIA †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**1/59 (1.69%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**1**	**0**
NEUTROPENIA †								

# participants affected / at risk	0/104 (0.00%)	2/107 (1.87%)	1/103 (0.97%)	0/103 (0.00%)	0/103 (0.00%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	2	1	0	0	1	0	0
Cardiac disorders								
PERICARDITIS †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	0	1	0	0	0
SUPRAVENTRICULAR TACHYCARDIA †								
# participants affected / at risk	0/104 (0.00%)	1/107 (0.93%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	1	0	0	0	0	0	0
Ear and labyrinth disorders								
DEAFNESS UNILATERAL †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	1	0	0	0	0
Eye disorders								
DIPLOPIA †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	0	0	0	0	0	0	0
RETINAL ISCHAEMIA †								
# participants affected / at risk	0/104 (0.00%)	1/107 (0.93%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	1	0	1	0	0	0	0
RETINOPATHY †								
# participants affected / at risk	0/104 (0.00%)	1/107 (0.93%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	1	0	0	0	0	0	0
SCOTOMA †								

# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	1	0	0	0	0
Gastrointestinal disorders								
ABDOMINAL PAIN †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	0	1	0	0	0
ABDOMINAL PAIN UPPER †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	1/103 (0.97%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	1	1	0	0	0	0
HAEMATEMESIS †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	1/59 (1.69%)	0/36 (0.00%)
# events	0	0	0	0	0	0	1	0
INGUINAL HERNIA †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	0	0	0	0	0	0	0
NAUSEA †								
# participants affected / at risk	0/104 (0.00%)	2/107 (1.87%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	2	0	1	0	0	0	0
PANCREATITIS †								
# participants affected / at risk	0/104 (0.00%)	1/107 (0.93%)	0/103 (0.00%)	0/103 (0.00%)	2/103 (1.94%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	1	0	0	7	0	0	0
PERIODONTAL DISEASE †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	1	0	0	0	0

PERITONEAL HAEMORRHAGE †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**
VOMITING †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**1/36 (2.78%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**1**
General disorders								
ASTHENIA †								
# participants affected / at risk	**0/104 (0.00%)**	**2/107 (1.87%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**2**	**0**	**0**	**0**	**0**	**0**	**0**
CHEST PAIN †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**1/59 (1.69%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**
FATIGUE †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**
LOCAL SWELLING †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**1/59 (1.69%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**
MULTI-ORGAN FAILURE †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
PYREXIA †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0**

Infections and infestations								
CELLULITIS †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0**
CORNEAL INFECTION †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**
ERYSIPELAS †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
GASTROENTERITIS †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
LOBAR PNEUMONIA †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
PNEUMONIA †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**0**	**1**	**0**	**0**	**0**
PNEUMONIA STREPTOCOCCAL †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
STAPHYLOCOCCAL SEPSIS †								
# participants		**0/107 (0.00%)**		**0/103 (0.00%)**				

affected / at risk	1/104 (0.96%)		0/103 (0.00%)		0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	0	0	0	0	0	0	0
VULVAL ABSCESS †								
# participants affected / at risk	0/104 (0.00%)	1/107 (0.93%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	1	0	0	0	0	0	0
Injury, poisoning and procedural complications								
ACCIDENTAL OVERDOSE †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	1	0	0	0	0
ANIMAL BITE †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	0	0	0	0	0	0	0
CONTUSION †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	0	0	0	0	0	0	0
DRUG TOXICITY †								
# participants affected / at risk	0/104 (0.00%)	1/107 (0.93%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	1	0	0	0	0	0	0
FALL †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	0	1	0	0	0
HAND FRACTURE †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	0	0	0	0	0	0	0
RIB FRACTURE †								

# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	0	0	0	0	0	0	0
Investigations								
BLOOD AMYLASE INCREASED †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	0	1	0	0	0
LIPASE INCREASED †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	0	1	0	0	0
NEUTROPHIL COUNT DECREASED †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	1	0	0	0	0
Metabolism and nutrition disorders								
DECREASED APPETITE †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	1	0	0	0	0
DEHYDRATION †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	1	0	0	0	0	0
HYPOVOLAEMIA †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	1	0	0	0	0	0
Musculoskeletal and connective tissue disorders								

INTERVERTEBRAL DISC PROTRUSION †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**1/59 (1.69%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**
MUSCLE SPASMS †								
# participants affected / at risk	**1/104 (0.96%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
BASAL CELL CARCINOMA †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**2**	**0**	**0**	**0**	**0**
BREAST CANCER †								
# participants affected / at risk	**1/104 (0.96%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
CERVIX CARCINOMA †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
PARATHYROID TUMOUR BENIGN †								
# participants affected / at risk	**1/104 (0.96%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
RENAL CELL CARCINOMA †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**

Nervous system disorders								
CEREBROVASCULAR ACCIDENT †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
CERVICAL CORD COMPRESSION †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**1/59 (1.69%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**
HEADACHE †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**
HYPOAESTHESIA †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
IIIRD NERVE PARALYSIS †								
# participants affected / at risk	**1/104 (0.96%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
NEUROPATHY PERIPHERAL †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
PARAESTHESIA †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
Psychiatric disorders								
†								

AGGRESSION								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**
ALCOHOLISM †								
# participants affected / at risk	**1/104 (0.96%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
ANXIETY †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**2**	**0**	**0**	**0**	**0**	**0**	**0**
DEPENDENCE †								
# participants affected / at risk	**1/104 (0.96%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
DEPRESSION †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0**
HOMICIDAL IDEATION †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**1**	**1**	**0**	**0**	**0**	**0**
PANIC ATTACK †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**
PARANOIA †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**
SUICIDAL IDEATION †								

# participants affected / at risk	1/104 (0.96%)	1/107 (0.93%)	1/103 (0.97%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	1	1	1	0	0	0	0
SUICIDE ATTEMPT †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	1	0	0	0	0
Respiratory, thoracic and mediastinal disorders								
DYSPNOEA †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	1	0	0	0	0
PULMONARY EMBOLISM †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	1	0	0	0	0
Skin and subcutaneous tissue disorders								
URTICARIA †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	1/59 (1.69%)	0/36 (0.00%)
# events	0	0	0	0	0	0	1	0
Surgical and medical procedures								
UMBILICAL HERNIA REPAIR †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	1/36 (2.78%)
# events	0	0	0	0	0	0	0	1
Vascular disorders								
DEEP VEIN THROMBOSIS †								
# participants	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/16 (0.00%)	0/59 (0.00%)	0/36 (0.00%)

affected / at risk								
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**

† Events were collected by systematic assessment

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
PEG +RBV for 48 Wks (Part I)	Arm 1. PegIntron (1.5 µg/kg, once weekly [QW]) plus ribavirin (800 to 1400 mg/day) for 48 weeks. • Participants with detectable HCV-RNA levels after 24 weeks of treatment had the option of crossing over to receive 24 weeks of PegIntron, ribavirin, and boceprevir (800 mg, thrice a day [TID]) for 24 additional weeks. Total treatment duration was up to 54 weeks. Adverse events for 36 participants after they crossed over to Arm 8 are not included.
PEG + RBV + BOC for 28 Wks (Part I)	Arm 2. Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 28 weeks.
PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	Arm 3. PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead-in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 24 weeks.
PEG +RBV + BOC for 48 Wks (Part I)	Arm 4. Boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 48 weeks.
PEG + RBV + BOC (From Wk 4) for 44 Wks (Part I)	Arm 5. PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for 4 weeks lead-in followed by boceprevir (800 mg TID) plus PegIntron (1.5 µg/kg QW) and ribavirin (800 to 1400 mg/day) for up to 44 weeks.
PEG + RBV + BOC for 48 Wks (Part II)	Arm 6. PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
PEG +Low-dose RBV + BOC for 48 Wks (Part II)	Arm 7. PegIntron (1.5 µg/kg QW), ribavirin (400 to 1000 mg/day) and boceprevir (800 mg TID) for up to 48 weeks.
PEG + RBV + BOC (From Wk 24) for 48 Wks (Part I)	Arm 8. Participants that started in Arm 1 and had detectable HCV-RNA levels after 24 weeks of treatment had the option of receiving boceprevir (800 mg TID) with PegIntron (1.5 µg/kg QW), ribavirin (800 to 1400 mg/day). Participants that took the option of crossing over to receive 24 weeks of PegIntron, ribavirin, and boceprevir (800 mg TID) for 24 additional weeks constitute Arm 8. The total treatment duration was up to 54 weeks.

Other Adverse Events

	PEG +RBV for 48 Wks (Part I)	PEG + RBV + BOC for 28 Wks (Part I)	PEG + RBV + BOC (From Wk 4) for 24 Wks (Part I)	PEG +RBV + BOC for 48 Wks (Part I)	PEG + RBV + BOC (From Wk 4) for 44 Wks (Part I)	PEG + RBV + BOC for 48 Wks (Part II)	PEG +Low-dose RBV + BOC for 48 Wks (Part II)	PEG + RBV + BOC (From Wk 24) for 48 Wks (Part I)
Total, other (not including serious) adverse events								
# participants affected / at risk	102/104 (98.08%)	106/107 (99.07%)	102/103 (99.03%)	103/103 (100.00%)	102/103 (99.03%)	16/16 (100.00%)	59/59 (100.00%)	29/36 (80.56%)
Blood and lymphatic system disorders								
ANAEMIA †								
# participants affected / at risk	35/104 (33.65%)	59/107 (55.14%)	55/103 (53.40%)	54/103 (52.43%)	58/103 (56.31%)	10/16 (62.50%)	14/59 (23.73%)	13/36 (36.11%)
# events	55	96	80	79	88	22	39	13
LEUKOPENIA †								
# participants affected / at risk	6/104 (5.77%)	7/107 (6.54%)	5/103 (4.85%)	5/103 (4.85%)	8/103 (7.77%)	1/16 (6.25%)	9/59 (15.25%)	1/36 (2.78%)
# events	15	37	12	9	12	7	58	2
LYMPHADENOPATHY †								
# participants affected / at risk	0/104 (0.00%)	2/107 (1.87%)	0/103 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	2	0	0	1	1	0	0
NEUTROPENIA †								
# participants affected / at risk	12/104 (11.54%)	23/107 (21.50%)	16/103 (15.53%)	26/103 (25.24%)	31/103 (30.10%)	2/16 (12.50%)	19/59 (32.20%)	8/36 (22.22%)
# events	32	82	30	50	71	11	88	9
PANCYTOPENIA †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/103 (0.00%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	1	0	0	1	0	0
THROMBOCYTOPENIA †								
# participants affected / at risk	0/104 (0.00%)	5/107 (4.67%)	1/103 (0.97%)	1/103 (0.97%)	6/103 (5.83%)	1/16 (6.25%)	5/59 (8.47%)	3/36 (8.33%)
# events	0	7	1	1	9	1	26	3
Cardiac disorders								
PALPITATIONS †								
# participants affected / at risk	2/104 (1.92%)	1/107 (0.93%)	2/103 (1.94%)	3/103 (2.91%)	0/103 (0.00%)	1/16 (6.25%)	1/59 (1.69%)	0/36 (0.00%)

# events	3	1	2	3	0	1	1	0
Ear and labyrinth disorders								
TINNITUS †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	3/103 (2.91%)	7/103 (6.80%)	3/103 (2.91%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	0	3	7	3	1	0	0
Endocrine disorders								
HYPOTHYROIDISM †								
# participants affected / at risk	6/104 (5.77%)	2/107 (1.87%)	3/103 (2.91%)	1/103 (0.97%)	5/103 (4.85%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	6	2	3	1	9	1	0	0
Eye disorders								
CONJUNCTIVAL DISCOLOURATION †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	2/103 (1.94%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	0	2	1	0	0
CONJUNCTIVITIS †								
# participants affected / at risk	1/104 (0.96%)	1/107 (0.93%)	1/103 (0.97%)	1/103 (0.97%)	3/103 (2.91%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	1	1	1	3	1	0	0
DRY EYE †								
# participants affected / at risk	4/104 (3.85%)	1/107 (0.93%)	3/103 (2.91%)	6/103 (5.83%)	4/103 (3.88%)	2/16 (12.50%)	5/59 (8.47%)	0/36 (0.00%)
# events	4	1	4	6	4	2	5	0
EYE IRRITATION †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	1/103 (0.97%)	1/16 (6.25%)	1/59 (1.69%)	0/36 (0.00%)
# events	0	0	1	0	1	1	1	0
RETINAL HAEMORRHAGE †								
# participants affected / at risk	0/104 (0.00%)	1/107 (0.93%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	1	0	0	0	1	0	0
RETINOPATHY †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	0	0	1	0	0
VISION BLURRED †								
# participants affected /								

at risk	7/104 (6.73%)	6/107 (5.61%)	2/103 (1.94%)	8/103 (7.77%)	7/103 (6.80%)	2/16 (12.50%)	3/59 (5.08%)	0/36 (0.00%)
# events	7	6	2	8	7	2	3	0
VISUAL IMPAIRMENT †								
# participants affected / at risk	2/104 (1.92%)	1/107 (0.93%)	5/103 (4.85%)	7/103 (6.80%)	3/103 (2.91%)	0/16 (0.00%)	2/59 (3.39%)	0/36 (0.00%)
# events	2	1	5	7	3	0	2	0
Gastrointestinal disorders								
ABDOMINAL DISCOMFORT †								
# participants affected / at risk	2/104 (1.92%)	0/107 (0.00%)	1/103 (0.97%)	1/103 (0.97%)	1/103 (0.97%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	2	0	1	1	1	1	0	0
ABDOMINAL DISTENSION †								
# participants affected / at risk	1/104 (0.96%)	1/107 (0.93%)	0/103 (0.00%)	2/103 (1.94%)	3/103 (2.91%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	1	0	2	3	1	0	0
ABDOMINAL PAIN †								
# participants affected / at risk	9/104 (8.65%)	4/107 (3.74%)	6/103 (5.83%)	10/103 (9.71%)	6/103 (5.83%)	1/16 (6.25%)	2/59 (3.39%)	2/36 (5.56%)
# events	12	4	6	10	7	1	3	2
ABDOMINAL PAIN UPPER †								
# participants affected / at risk	5/104 (4.81%)	7/107 (6.54%)	5/103 (4.85%)	9/103 (8.74%)	12/103 (11.65%)	2/16 (12.50%)	5/59 (8.47%)	1/36 (2.78%)
# events	5	8	7	9	15	2	6	1
APHTHOUS STOMATITIS †								
# participants affected / at risk	2/104 (1.92%)	2/107 (1.87%)	3/103 (2.91%)	4/103 (3.88%)	4/103 (3.88%)	2/16 (12.50%)	3/59 (5.08%)	0/36 (0.00%)
# events	2	3	4	4	4	2	3	0
CHEILITIS †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	1/103 (0.97%)	2/103 (1.94%)	2/103 (1.94%)	1/16 (6.25%)	0/59 (0.00%)	1/36 (2.78%)
# events	1	0	1	4	2	2	0	1
CONSTIPATION †								
# participants affected / at risk	11/104 (10.58%)	5/107 (4.67%)	14/103 (13.59%)	9/103 (8.74%)	9/103 (8.74%)	1/16 (6.25%)	3/59 (5.08%)	2/36 (5.56%)
# events	13	5	17	10	10	1	3	2
DIARRHOEA †								
# participants affected / at risk	23/104 (22.12%)	28/107 (26.17%)	27/103 (26.21%)	25/103 (24.27%)	29/103 (28.16%)	5/16 (31.25%)	14/59 (23.73%)	2/36 (5.56%)

# events	31	40	29	30	36	5	18	2
DRY MOUTH †								
# participants affected / at risk	5/104 (4.81%)	14/107 (13.08%)	8/103 (7.77%)	12/103 (11.65%)	10/103 (9.71%)	2/16 (12.50%)	5/59 (8.47%)	2/36 (5.56%)
# events	5	15	8	15	10	2	7	3
DYSPEPSIA †								
# participants affected / at risk	8/104 (7.69%)	6/107 (5.61%)	8/103 (7.77%)	9/103 (8.74%)	8/103 (7.77%)	1/16 (6.25%)	0/59 (0.00%)	1/36 (2.78%)
# events	9	8	8	10	8	1	0	1
GASTROOESOPHAGEAL REFLUX DISEASE †								
# participants affected / at risk	5/104 (4.81%)	11/107 (10.28%)	3/103 (2.91%)	8/103 (7.77%)	10/103 (9.71%)	1/16 (6.25%)	2/59 (3.39%)	1/36 (2.78%)
# events	5	12	4	9	11	2	2	1
GINGIVAL PAIN †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	2/103 (1.94%)	0/103 (0.00%)	3/103 (2.91%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	2	0	4	1	0	0
HAEMORRHOIDS †								
# participants affected / at risk	7/104 (6.73%)	5/107 (4.67%)	2/103 (1.94%)	3/103 (2.91%)	1/103 (0.97%)	3/16 (18.75%)	0/59 (0.00%)	0/36 (0.00%)
# events	7	6	2	3	1	3	0	0
NAUSEA †								
# participants affected / at risk	45/104 (43.27%)	41/107 (38.32%)	42/103 (40.78%)	55/103 (53.40%)	48/103 (46.60%)	10/16 (62.50%)	35/59 (59.32%)	4/36 (11.11%)
# events	52	50	53	80	87	13	40	4
ORAL PAIN †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	4/103 (3.88%)	1/16 (6.25%)	1/59 (1.69%)	1/36 (2.78%)
# events	1	0	0	1	4	1	1	1
PROCTALGIA †								
# participants affected / at risk	0/104 (0.00%)	1/107 (0.93%)	1/103 (0.97%)	1/103 (0.97%)	0/103 (0.00%)	1/16 (6.25%)	1/59 (1.69%)	0/36 (0.00%)
# events	0	1	1	1	0	1	1	0
RECTAL HAEMORRHAGE †								
# participants affected / at risk	3/104 (2.88%)	2/107 (1.87%)	2/103 (1.94%)	0/103 (0.00%)	2/103 (1.94%)	0/16 (0.00%)	0/59 (0.00%)	2/36 (5.56%)
# events	3	2	2	0	2	0	0	2
SALIVARY HYPERSECRETION †								
# participants affected /								

at risk	0/104 (0.00%)	0/107 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	0/103 (0.00%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	1	0	0	1	0	0
STOMACH DISCOMFORT †								
# participants affected / at risk	3/104 (2.88%)	1/107 (0.93%)	0/103 (0.00%)	3/103 (2.91%)	0/103 (0.00%)	1/16 (6.25%)	3/59 (5.08%)	0/36 (0.00%)
# events	4	1	0	3	0	1	3	0
STOMATITIS †								
# participants affected / at risk	2/104 (1.92%)	7/107 (6.54%)	5/103 (4.85%)	5/103 (4.85%)	4/103 (3.88%)	0/16 (0.00%)	0/59 (0.00%)	1/36 (2.78%)
# events	2	8	5	7	5	0	0	1
TOOTHACHE †								
# participants affected / at risk	2/104 (1.92%)	3/107 (2.80%)	1/103 (0.97%)	0/103 (0.00%)	2/103 (1.94%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	2	3	1	0	2	1	0	0
VOMITING †								
# participants affected / at risk	5/104 (4.81%)	24/107 (22.43%)	15/103 (14.56%)	25/103 (24.27%)	17/103 (16.50%)	7/16 (43.75%)	11/59 (18.64%)	2/36 (5.56%)
# events	7	27	21	28	23	8	14	2
General disorders								
ASTHENIA †								
# participants affected / at risk	14/104 (13.46%)	9/107 (8.41%)	9/103 (8.74%)	20/103 (19.42%)	15/103 (14.56%)	1/16 (6.25%)	3/59 (5.08%)	3/36 (8.33%)
# events	18	12	18	27	26	2	3	4
CHEST DISCOMFORT †								
# participants affected / at risk	3/104 (2.88%)	0/107 (0.00%)	1/103 (0.97%)	2/103 (1.94%)	0/103 (0.00%)	1/16 (6.25%)	2/59 (3.39%)	0/36 (0.00%)
# events	3	0	1	2	0	1	3	0
CHILLS †								
# participants affected / at risk	35/104 (33.65%)	31/107 (28.97%)	31/103 (30.10%)	33/103 (32.04%)	35/103 (33.98%)	5/16 (31.25%)	26/59 (44.07%)	0/36 (0.00%)
# events	38	39	34	37	39	6	29	0
FATIGUE †								
# participants affected / at risk	57/104 (54.81%)	65/107 (60.75%)	70/103 (67.96%)	51/103 (49.51%)	73/103 (70.87%)	11/16 (68.75%)	40/59 (67.80%)	5/36 (13.89%)
# events	62	78	80	69	95	14	55	5
IMPAIRED HEALING †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	0/103 (0.00%)	1/16 (6.25%)	1/59 (1.69%)	0/36 (0.00%)
# events	0	0	0	1	0	1	1	0
INFLUENZA LIKE ILLNESS								

†								
# participants affected / at risk	25/104 (24.04%)	24/107 (22.43%)	21/103 (20.39%)	19/103 (18.45%)	15/103 (14.56%)	6/16 (37.50%)	11/59 (18.64%)	0/36 (0.00%)
# events	37	26	22	20	27	6	11	0
INJECTION SITE ERYTHEMA †								
# participants affected / at risk	13/104 (12.50%)	9/107 (8.41%)	14/103 (13.59%)	7/103 (6.80%)	13/103 (12.62%)	1/16 (6.25%)	4/59 (6.78%)	1/36 (2.78%)
# events	13	9	14	7	13	1	4	1
INJECTION SITE RASH †								
# participants affected / at risk	6/104 (5.77%)	3/107 (2.80%)	0/103 (0.00%)	3/103 (2.91%)	6/103 (5.83%)	1/16 (6.25%)	1/59 (1.69%)	0/36 (0.00%)
# events	6	3	0	3	6	1	1	0
INJECTION SITE REACTION †								
# participants affected / at risk	10/104 (9.62%)	9/107 (8.41%)	5/103 (4.85%)	9/103 (8.74%)	11/103 (10.68%)	4/16 (25.00%)	21/59 (35.59%)	1/36 (2.78%)
# events	12	9	5	9	11	4	21	1
IRRITABILITY †								
# participants affected / at risk	23/104 (22.12%)	25/107 (23.36%)	24/103 (23.30%)	15/103 (14.56%)	27/103 (26.21%)	3/16 (18.75%)	9/59 (15.25%)	0/36 (0.00%)
# events	23	26	27	21	32	3	11	0
NON-CARDIAC CHEST PAIN †								
# participants affected / at risk	1/104 (0.96%)	2/107 (1.87%)	0/103 (0.00%)	2/103 (1.94%)	1/103 (0.97%)	2/16 (12.50%)	1/59 (1.69%)	0/36 (0.00%)
# events	1	2	0	2	1	3	1	0
PAIN †								
# participants affected / at risk	8/104 (7.69%)	11/107 (10.28%)	9/103 (8.74%)	11/103 (10.68%)	5/103 (4.85%)	1/16 (6.25%)	11/59 (18.64%)	0/36 (0.00%)
# events	8	11	10	12	5	1	12	0
PYREXIA †								
# participants affected / at risk	35/104 (33.65%)	27/107 (25.23%)	27/103 (26.21%)	40/103 (38.83%)	35/103 (33.98%)	7/16 (43.75%)	26/59 (44.07%)	0/36 (0.00%)
# events	55	35	34	51	53	10	31	0
TEMPERATURE INTOLERANCE †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	1/16 (6.25%)	1/59 (1.69%)	0/36 (0.00%)
# events	1	0	0	0	1	2	1	0
Infections and infestations								

BRONCHITIS †								
# participants affected / at risk	**3/104 (2.88%)**	**4/107 (3.74%)**	**1/103 (0.97%)**	**2/103 (1.94%)**	**1/103 (0.97%)**	**1/16 (6.25%)**	**1/59 (1.69%)**	**0/36 (0.00%)**
# events	**3**	**6**	**1**	**2**	**2**	**1**	**1**	**0**
EAR INFECTION †								
# participants affected / at risk	**1/104 (0.96%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**1/103 (0.97%)**	**1/103 (0.97%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**1**	**0**	**1**	**3**	**1**	**1**	**0**	**0**
EYE INFECTION †								
# participants affected / at risk	**1/104 (0.96%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**1/36 (2.78%)**
# events	**2**	**0**	**0**	**0**	**0**	**1**	**0**	**1**
INFLUENZA †								
# participants affected / at risk	**1/104 (0.96%)**	**3/107 (2.80%)**	**0/103 (0.00%)**	**3/103 (2.91%)**	**3/103 (2.91%)**	**1/16 (6.25%)**	**1/59 (1.69%)**	**0/36 (0.00%)**
# events	**1**	**4**	**0**	**4**	**3**	**1**	**1**	**0**
LARYNGITIS †								
# participants affected / at risk	**1/104 (0.96%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**1**	**0**	**0**	**1**	**0**	**1**	**0**	**0**
ORAL CANDIDIASIS †								
# participants affected / at risk	**1/104 (0.96%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**2/103 (1.94%)**	**1/103 (0.97%)**	**1/16 (6.25%)**	**3/59 (5.08%)**	**0/36 (0.00%)**
# events	**1**	**1**	**0**	**2**	**1**	**1**	**5**	**0**
PHARYNGITIS †								
# participants affected / at risk	**1/104 (0.96%)**	**0/107 (0.00%)**	**2/103 (1.94%)**	**1/103 (0.97%)**	**1/103 (0.97%)**	**1/16 (6.25%)**	**1/59 (1.69%)**	**1/36 (2.78%)**
# events	**1**	**0**	**2**	**1**	**3**	**1**	**1**	**1**
PHARYNGITIS STREPTOCOCCAL †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**2**	**0**	**0**
RECTAL ABSCESS †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
SINUSITIS †								
# participants affected / at risk	**3/104 (2.88%)**	**3/107 (2.80%)**	**3/103 (2.91%)**	**5/103 (4.85%)**	**5/103 (4.85%)**	**2/16 (12.50%)**	**1/59 (1.69%)**	**2/36 (5.56%)**
# events	**3**	**4**	**3**	**7**	**5**	**3**	**1**	**2**

TINEA VERSICOLOUR †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
UPPER RESPIRATORY TRACT INFECTION †								
# participants affected / at risk	**3/104 (2.88%)**	**7/107 (6.54%)**	**1/103 (0.97%)**	**4/103 (3.88%)**	**7/103 (6.80%)**	**1/16 (6.25%)**	**6/59 (10.17%)**	**0/36 (0.00%)**
# events	**3**	**7**	**1**	**4**	**8**	**1**	**7**	**0**
URINARY TRACT INFECTION †								
# participants affected / at risk	**3/104 (2.88%)**	**3/107 (2.80%)**	**3/103 (2.91%)**	**2/103 (1.94%)**	**1/103 (0.97%)**	**1/16 (6.25%)**	**2/59 (3.39%)**	**0/36 (0.00%)**
# events	**4**	**3**	**3**	**2**	**2**	**1**	**2**	**0**
Investigations								
BLOOD URIC ACID INCREASED †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/16 (0.00%)**	**3/59 (5.08%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**5**	**0**
HEART RATE INCREASED †								
# participants affected / at risk	**1/104 (0.96%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**1/59 (1.69%)**	**0/36 (0.00%)**
# events	**1**	**0**	**0**	**1**	**0**	**1**	**1**	**0**
WEIGHT DECREASED †								
# participants affected / at risk	**9/104 (8.65%)**	**6/107 (5.61%)**	**8/103 (7.77%)**	**6/103 (5.83%)**	**9/103 (8.74%)**	**2/16 (12.50%)**	**8/59 (13.56%)**	**1/36 (2.78%)**
# events	**9**	**6**	**8**	**8**	**10**	**2**	**8**	**1**
Metabolism and nutrition disorders								
ANOREXIA †								
# participants affected / at risk	**10/104 (9.62%)**	**10/107 (9.35%)**	**8/103 (7.77%)**	**13/103 (12.62%)**	**11/103 (10.68%)**	**2/16 (12.50%)**	**4/59 (6.78%)**	**0/36 (0.00%)**
# events	**11**	**10**	**8**	**18**	**15**	**2**	**5**	**0**
DECREASED APPETITE †								
# participants affected / at risk	**12/104 (11.54%)**	**7/107 (6.54%)**	**14/103 (13.59%)**	**16/103 (15.53%)**	**12/103 (11.65%)**	**6/16 (37.50%)**	**16/59 (27.12%)**	**1/36 (2.78%)**
# events	**13**	**7**	**15**	**18**	**12**	**6**	**17**	**1**
HYPERAMYLASAEMIA †								
# participants affected /	**1/104 (0.96%)**	**3/107 (2.80%)**	**1/103 (0.97%)**	**1/103 (0.97%)**	**1/103 (0.97%)**	**0/16 (0.00%)**	**3/59 (5.08%)**	**0/36 (0.00%)**

at risk								
# events	2	4	1	1	2	0	3	0
HYPERTRIGLYCERIDAEMIA †								
# participants affected / at risk	0/104 (0.00%)	1/107 (0.93%)	3/103 (2.91%)	1/103 (0.97%)	3/103 (2.91%)	0/16 (0.00%)	3/59 (5.08%)	0/36 (0.00%)
# events	0	1	3	1	3	0	3	0
HYPERURICAEMIA †								
# participants affected / at risk	3/104 (2.88%)	1/107 (0.93%)	1/103 (0.97%)	0/103 (0.00%)	2/103 (1.94%)	1/16 (6.25%)	1/59 (1.69%)	0/36 (0.00%)
# events	3	1	1	0	3	1	1	0
Musculoskeletal and connective tissue disorders								
ARTHRALGIA †								
# participants affected / at risk	21/104 (20.19%)	14/107 (13.08%)	22/103 (21.36%)	21/103 (20.39%)	19/103 (18.45%)	5/16 (31.25%)	11/59 (18.64%)	1/36 (2.78%)
# events	24	20	26	25	21	7	13	1
BACK PAIN †								
# participants affected / at risk	5/104 (4.81%)	5/107 (4.67%)	7/103 (6.80%)	10/103 (9.71%)	9/103 (8.74%)	3/16 (18.75%)	5/59 (8.47%)	0/36 (0.00%)
# events	5	5	7	13	11	3	5	0
JOINT SWELLING †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	1/103 (0.97%)	1/103 (0.97%)	1/103 (0.97%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	0	1	1	1	1	0	0
MUSCLE SPASMS †								
# participants affected / at risk	5/104 (4.81%)	4/107 (3.74%)	4/103 (3.88%)	6/103 (5.83%)	1/103 (0.97%)	0/16 (0.00%)	3/59 (5.08%)	2/36 (5.56%)
# events	7	4	4	6	1	0	3	2
MUSCLE TIGHTNESS †								
# participants affected / at risk	1/104 (0.96%)	1/107 (0.93%)	0/103 (0.00%)	0/103 (0.00%)	2/103 (1.94%)	1/16 (6.25%)	1/59 (1.69%)	0/36 (0.00%)
# events	1	1	0	0	2	1	1	0
MUSCULAR WEAKNESS †								
# participants affected / at risk	4/104 (3.85%)	4/107 (3.74%)	0/103 (0.00%)	1/103 (0.97%)	1/103 (0.97%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	4	5	0	1	1	2	0	0
MUSCULOSKELETAL PAIN †								
# participants affected / at risk	5/104 (4.81%)	4/107 (3.74%)	0/103 (0.00%)	1/103 (0.97%)	1/103 (0.97%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)

# events	6	5	0	1	1	1	0	0
MYALGIA †								
# participants affected / at risk	17/104 (16.35%)	31/107 (28.97%)	20/103 (19.42%)	21/103 (20.39%)	27/103 (26.21%)	4/16 (25.00%)	12/59 (20.34%)	2/36 (5.56%)
# events	17	34	20	30	33	5	15	2
PAIN IN EXTREMITY †								
# participants affected / at risk	4/104 (3.85%)	4/107 (3.74%)	0/103 (0.00%)	6/103 (5.83%)	4/103 (3.88%)	0/16 (0.00%)	2/59 (3.39%)	0/36 (0.00%)
# events	5	4	0	7	5	0	2	0
Nervous system disorders								
AMNESIA †								
# participants affected / at risk	1/104 (0.96%)	1/107 (0.93%)	2/103 (1.94%)	5/103 (4.85%)	1/103 (0.97%)	2/16 (12.50%)	1/59 (1.69%)	0/36 (0.00%)
# events	1	1	3	6	1	2	1	0
DISTURBANCE IN ATTENTION †								
# participants affected / at risk	4/104 (3.85%)	7/107 (6.54%)	9/103 (8.74%)	7/103 (6.80%)	10/103 (9.71%)	0/16 (0.00%)	3/59 (5.08%)	0/36 (0.00%)
# events	5	7	9	8	11	0	4	0
DIZZINESS †								
# participants affected / at risk	16/104 (15.38%)	19/107 (17.76%)	16/103 (15.53%)	21/103 (20.39%)	14/103 (13.59%)	7/16 (43.75%)	11/59 (18.64%)	2/36 (5.56%)
# events	18	23	18	21	18	8	16	2
DYSGEUSIA †								
# participants affected / at risk	9/104 (8.65%)	23/107 (21.50%)	27/103 (26.21%)	33/103 (32.04%)	28/103 (27.18%)	7/16 (43.75%)	18/59 (30.51%)	7/36 (19.44%)
# events	10	25	28	38	31	9	20	7
HEADACHE †								
# participants affected / at risk	45/104 (43.27%)	51/107 (47.66%)	41/103 (39.81%)	44/103 (42.72%)	54/103 (52.43%)	13/16 (81.25%)	29/59 (49.15%)	2/36 (5.56%)
# events	60	66	46	52	67	13	35	2
MEMORY IMPAIRMENT †								
# participants affected / at risk	3/104 (2.88%)	2/107 (1.87%)	2/103 (1.94%)	3/103 (2.91%)	2/103 (1.94%)	1/16 (6.25%)	5/59 (8.47%)	1/36 (2.78%)
# events	3	2	2	3	2	1	5	1
MIGRAINE †								
# participants affected / at risk	2/104 (1.92%)	1/107 (0.93%)	2/103 (1.94%)	5/103 (4.85%)	3/103 (2.91%)	4/16 (25.00%)	1/59 (1.69%)	1/36 (2.78%)
# events	3	1	2	5	3	6	1	1
PARAESTHESIA †								

# participants affected / at risk	3/104 (2.88%)	5/107 (4.67%)	4/103 (3.88%)	6/103 (5.83%)	2/103 (1.94%)	1/16 (6.25%)	3/59 (5.08%)	0/36 (0.00%)
# events	4	6	4	6	2	2	3	0
SCIATICA †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	0	0	0	1	2	0	0
SOMNOLENCE †								
# participants affected / at risk	1/104 (0.96%)	0/107 (0.00%)	0/103 (0.00%)	2/103 (1.94%)	0/103 (0.00%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	1	0	0	2	0	1	0	0
TREMOR †								
# participants affected / at risk	3/104 (2.88%)	3/107 (2.80%)	1/103 (0.97%)	3/103 (2.91%)	1/103 (0.97%)	2/16 (12.50%)	4/59 (6.78%)	0/36 (0.00%)
# events	3	3	1	3	1	3	4	0
TRIGEMINAL NEURALGIA †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	0	0	0	1	0	0
Psychiatric disorders								
ANXIETY †								
# participants affected / at risk	18/104 (17.31%)	16/107 (14.95%)	9/103 (8.74%)	15/103 (14.56%)	17/103 (16.50%)	1/16 (6.25%)	8/59 (13.56%)	0/36 (0.00%)
# events	21	19	10	17	20	1	11	0
CONFUSIONAL STATE †								
# participants affected / at risk	0/104 (0.00%)	1/107 (0.93%)	2/103 (1.94%)	0/103 (0.00%)	3/103 (2.91%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	1	2	0	3	2	0	0
DEPRESSION †								
# participants affected / at risk	22/104 (21.15%)	22/107 (20.56%)	20/103 (19.42%)	29/103 (28.16%)	20/103 (19.42%)	1/16 (6.25%)	14/59 (23.73%)	4/36 (11.11%)
# events	25	29	23	34	26	1	17	5
INSOMNIA †								
# participants affected / at risk	40/104 (38.46%)	36/107 (33.64%)	29/103 (28.16%)	40/103 (38.83%)	41/103 (39.81%)	7/16 (43.75%)	23/59 (38.98%)	7/36 (19.44%)
# events	50	40	37	46	48	7	27	7
MOOD SWINGS †								
# participants affected / at risk	2/104 (1.92%)	1/107 (0.93%)	1/103 (0.97%)	3/103 (2.91%)	1/103 (0.97%)	1/16 (6.25%)	2/59 (3.39%)	0/36 (0.00%)
# events	3	1	1	4	1	1	2	0

Renal and urinary disorders								
CHROMATURIA †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**0**
HAEMATURIA †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**1/103 (0.97%)**	**1/103 (0.97%)**	**1/103 (0.97%)**	**1/16 (6.25%)**	**1/59 (1.69%)**	**1/36 (2.78%)**
# events	**0**	**0**	**1**	**1**	**1**	**1**	**1**	**1**
NOCTURIA †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**2/103 (1.94%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**2**	**0**	**1**	**0**	**0**
POLLAKIURIA †								
# participants affected / at risk	**1/104 (0.96%)**	**4/107 (3.74%)**	**6/103 (5.83%)**	**3/103 (2.91%)**	**6/103 (5.83%)**	**2/16 (12.50%)**	**5/59 (8.47%)**	**0/36 (0.00%)**
# events	**1**	**4**	**6**	**3**	**6**	**2**	**5**	**0**
URETHRAL OBSTRUCTION †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
URINARY RETENTION †								
# participants affected / at risk	**0/104 (0.00%)**	**0/107 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**
Reproductive system and breast disorders								
ERECTILE DYSFUNCTION †								
# participants affected / at risk	**2/104 (1.92%)**	**2/107 (1.87%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**2/103 (1.94%)**	**1/16 (6.25%)**	**5/59 (8.47%)**	**0/36 (0.00%)**
# events	**2**	**2**	**0**	**0**	**2**	**1**	**5**	**0**
VULVOVAGINAL PRURITUS †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**0/103 (0.00%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**1**	**0**	**0**
Respiratory, thoracic and mediastinal disorders								
COUGH †								

# participants affected / at risk	20/104 (19.23%)	18/107 (16.82%)	22/103 (21.36%)	17/103 (16.50%)	19/103 (18.45%)	2/16 (12.50%)	8/59 (13.56%)	2/36 (5.56%)
# events	26	27	25	21	25	2	9	2
DYSPNOEA †								
# participants affected / at risk	15/104 (14.42%)	18/107 (16.82%)	12/103 (11.65%)	16/103 (15.53%)	20/103 (19.42%)	4/16 (25.00%)	10/59 (16.95%)	2/36 (5.56%)
# events	20	23	12	21	25	4	14	2
DYSPNOEA EXERTIONAL †								
# participants affected / at risk	6/104 (5.77%)	6/107 (5.61%)	2/103 (1.94%)	5/103 (4.85%)	11/103 (10.68%)	1/16 (6.25%)	4/59 (6.78%)	0/36 (0.00%)
# events	6	6	2	6	14	1	4	0
EPISTAXIS †								
# participants affected / at risk	3/104 (2.88%)	3/107 (2.80%)	2/103 (1.94%)	6/103 (5.83%)	3/103 (2.91%)	0/16 (0.00%)	2/59 (3.39%)	0/36 (0.00%)
# events	3	4	2	7	3	0	2	0
INCREASED UPPER AIRWAY SECRETION †								
# participants affected / at risk	0/104 (0.00%)	0/107 (0.00%)	3/103 (2.91%)	2/103 (1.94%)	2/103 (1.94%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	0	3	2	2	1	0	0
OROPHARYNGEAL PAIN †								
# participants affected / at risk	3/104 (2.88%)	2/107 (1.87%)	11/103 (10.68%)	9/103 (8.74%)	5/103 (4.85%)	2/16 (12.50%)	2/59 (3.39%)	1/36 (2.78%)
# events	3	2	12	10	5	2	2	1
PARANASAL SINUS HYPERSECRETION †								
# participants affected / at risk	0/104 (0.00%)	1/107 (0.93%)	0/103 (0.00%)	1/103 (0.97%)	1/103 (0.97%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	1	0	1	1	1	0	0
POSTNASAL DRIP †								
# participants affected / at risk	1/104 (0.96%)	2/107 (1.87%)	0/103 (0.00%)	0/103 (0.00%)	0/103 (0.00%)	1/16 (6.25%)	1/59 (1.69%)	0/36 (0.00%)
# events	1	2	0	0	0	1	1	0
PRODUCTIVE COUGH †								
# participants affected / at risk	5/104 (4.81%)	2/107 (1.87%)	0/103 (0.00%)	2/103 (1.94%)	4/103 (3.88%)	0/16 (0.00%)	3/59 (5.08%)	0/36 (0.00%)
# events	5	2	0	2	5	0	5	0
SINUS CONGESTION †								
# participants affected / at risk	2/104 (1.92%)	1/107 (0.93%)	3/103 (2.91%)	3/103 (2.91%)	4/103 (3.88%)	1/16 (6.25%)	2/59 (3.39%)	0/36 (0.00%)
# events	3	1	3	3	4	1	2	0

Skin and subcutaneous tissue disorders								
ALOPECIA †								
# participants affected / at risk	**27/104 (25.96%)**	**36/107 (33.64%)**	**30/103 (29.13%)**	**30/103 (29.13%)**	**35/103 (33.98%)**	**5/16 (31.25%)**	**19/59 (32.20%)**	**2/36 (5.56%)**
# events	**28**	**41**	**34**	**31**	**38**	**5**	**19**	**2**
DERMATITIS †								
# participants affected / at risk	**4/104 (3.85%)**	**1/107 (0.93%)**	**1/103 (0.97%)**	**4/103 (3.88%)**	**1/103 (0.97%)**	**2/16 (12.50%)**	**2/59 (3.39%)**	**0/36 (0.00%)**
# events	**5**	**1**	**1**	**5**	**1**	**4**	**2**	**0**
DRY SKIN †								
# participants affected / at risk	**17/104 (16.35%)**	**12/107 (11.21%)**	**9/103 (8.74%)**	**22/103 (21.36%)**	**17/103 (16.50%)**	**3/16 (18.75%)**	**9/59 (15.25%)**	**4/36 (11.11%)**
# events	**17**	**14**	**10**	**24**	**18**	**3**	**13**	**4**
ECZEMA †								
# participants affected / at risk	**4/104 (3.85%)**	**2/107 (1.87%)**	**7/103 (6.80%)**	**3/103 (2.91%)**	**4/103 (3.88%)**	**2/16 (12.50%)**	**2/59 (3.39%)**	**0/36 (0.00%)**
# events	**7**	**2**	**8**	**4**	**4**	**2**	**2**	**0**
ERYTHEMA †								
# participants affected / at risk	**3/104 (2.88%)**	**4/107 (3.74%)**	**6/103 (5.83%)**	**3/103 (2.91%)**	**2/103 (1.94%)**	**0/16 (0.00%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**3**	**4**	**6**	**3**	**2**	**0**	**0**	**0**
INCREASED TENDENCY TO BRUISE †								
# participants affected / at risk	**0/104 (0.00%)**	**1/107 (0.93%)**	**1/103 (0.97%)**	**0/103 (0.00%)**	**1/103 (0.97%)**	**1/16 (6.25%)**	**0/59 (0.00%)**	**0/36 (0.00%)**
# events	**0**	**1**	**1**	**0**	**1**	**1**	**0**	**0**
PRURITUS †								
# participants affected / at risk	**16/104 (15.38%)**	**19/107 (17.76%)**	**19/103 (18.45%)**	**23/103 (22.33%)**	**19/103 (18.45%)**	**1/16 (6.25%)**	**11/59 (18.64%)**	**3/36 (8.33%)**
# events	**20**	**23**	**28**	**35**	**24**	**1**	**17**	**3**
RASH †								
# participants affected / at risk	**6/104 (5.77%)**	**3/107 (2.80%)**	**6/103 (5.83%)**	**9/103 (8.74%)**	**9/103 (8.74%)**	**1/16 (6.25%)**	**1/59 (1.69%)**	**2/36 (5.56%)**
# events	**7**	**5**	**6**	**12**	**9**	**1**	**1**	**2**
RASH ERYTHEMATOUS †								
# participants affected / at risk	**2/104 (1.92%)**	**7/107 (6.54%)**	**5/103 (4.85%)**	**4/103 (3.88%)**	**3/103 (2.91%)**	**0/16 (0.00%)**	**2/59 (3.39%)**	**0/36 (0.00%)**
# events	**3**	**9**	**6**	**9**	**3**	**0**	**3**	**0**
RASH MACULAR †								
# participants affected /								

at risk	0/104 (0.00%)	2/107 (1.87%)	3/103 (2.91%)	6/103 (5.83%)	6/103 (5.83%)	0/16 (0.00%)	2/59 (3.39%)	0/36 (0.00%)
# events	0	2	3	9	7	0	3	0
RASH MACULO-PAPULAR †								
# participants affected / at risk	5/104 (4.81%)	6/107 (5.61%)	1/103 (0.97%)	5/103 (4.85%)	4/103 (3.88%)	1/16 (6.25%)	8/59 (13.56%)	0/36 (0.00%)
# events	7	7	1	5	5	1	9	0
RASH PAPULAR †								
# participants affected / at risk	8/104 (7.69%)	9/107 (8.41%)	8/103 (7.77%)	17/103 (16.50%)	14/103 (13.59%)	1/16 (6.25%)	4/59 (6.78%)	0/36 (0.00%)
# events	10	9	9	23	17	1	6	0
RASH PRURITIC †								
# participants affected / at risk	4/104 (3.85%)	1/107 (0.93%)	4/103 (3.88%)	1/103 (0.97%)	5/103 (4.85%)	1/16 (6.25%)	5/59 (8.47%)	1/36 (2.78%)
# events	5	1	4	1	6	1	7	1
SKIN LESION †								
# participants affected / at risk	4/104 (3.85%)	4/107 (3.74%)	1/103 (0.97%)	1/103 (0.97%)	2/103 (1.94%)	0/16 (0.00%)	1/59 (1.69%)	2/36 (5.56%)
# events	4	4	1	1	4	0	1	2
URTICARIA †								
# participants affected / at risk	2/104 (1.92%)	3/107 (2.80%)	0/103 (0.00%)	0/103 (0.00%)	1/103 (0.97%)	2/16 (12.50%)	0/59 (0.00%)	0/36 (0.00%)
# events	2	3	0	0	1	2	0	0
Vascular disorders								
HYPERTENSION †								
# participants affected / at risk	6/104 (5.77%)	2/107 (1.87%)	4/103 (3.88%)	1/103 (0.97%)	5/103 (4.85%)	0/16 (0.00%)	3/59 (5.08%)	0/36 (0.00%)
# events	6	2	4	1	5	0	4	0
HYPOTENSION †								
# participants affected / at risk	0/104 (0.00%)	3/107 (2.80%)	1/103 (0.97%)	1/103 (0.97%)	3/103 (2.91%)	1/16 (6.25%)	0/59 (0.00%)	0/36 (0.00%)
# events	0	4	1	1	3	1	0	0

† Events were collected by systematic assessment

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: The Principal Investigator agrees to provide to the sponsor thirty (30) days prior to submission for publication or presentation, review copies of abstracts or manuscripts for publication (including slides and texts of oral or other public presentations and texts of any transmission through any electronic media) that report any results of the study.

Results Point of Contact:

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Kwo PY, Lawitz EJ, McCone J, Schiff ER, Vierling JM, Pound D, Davis MN, Galati JS, Gordon SC, Ravendhran N, Rossaro L, Anderson FH, Jacobson IM, Rubin R, Koury K, Pedicone LD, Brass CA, Chaudhri E, Albrecht JK; SPRINT-1 investigators. Efficacy of boceprevir, an NS3 protease inhibitor, in combination with peginterferon alfa-2b and ribavirin in treatment-naive patients with genotype 1 hepatitis C infection (SPRINT-1): an open-label, randomised, multicentre phase 2 trial. Lancet. 2010 Aug 28;376(9742):705-16. doi: 10.1016/S0140-6736(10)60934-8. Epub 2010 Aug 6. Erratum in: Lancet. 2010 Oct 9;376(9748):1224. SPRINT-1 investigators [added]; multiple investigator names added.

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