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Safety and Efficacy of Vaniprevir (MK7009) Administered With Pegylated-Interferon and Ribavirin (MK-7009-007)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00704184

First received: June 23, 2008
Last updated: December 23, 2015
Last verified: December 2015
History of Changes

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Purpose

A study to evaluate how effective different levels of Vaniprevir (MK-7009), when administered with Pegylated-Interferon (Peg-IFN) and Ribavirin, are at achieving rapid viral response (RVR) i.e., undetectable hepatitis C virus [HCV] viral ribonucleic acid [RNA] at Week 4 in participants with chronic HCV infection. The primary hypothesis was that the proportion of participants in one or more of the Vaniprevir treatment groups achieving RVR would be greater than the proportion of placebo participants achieving RVR when Vaniprevir and placebo were co-administered with Peg-IFN/Ribavirin.

Condition	Intervention	Phase
Hepatitis C	Drug: Comparator: Vaniprevir Drug: Comparator: Pegylated-Interferon (Peg-IFN) Drug: Comparator: Ribavirin Drug: Comparator: placebo	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Phase II, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of MK7009 Administered Concomitantly With Pegylated-Interferon and Ribavirin for 28 Days in Treatment-Naive Patients With Chronic Hepatitis C Infection

Resource links provided by NLM:

MedlinePlus related topics: Hepatitis Hepatitis A Hepatitis C

Drug Information available for: Interferon Ribavirin

U.S. FDA Resources

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

Primary Outcome Measures:

- Percentage of Participants Achieving RVR [Time Frame: Week 4] [Designated as safety issue: No]

  Rapid Viral Response (RVR) was declared if Hepatitis C Virus (HCV) ribonucleic acid (RNA) was undetectable at Week 4.

- Number of Participants Experiencing an Adverse Event (AE) [Time Frame: Up to Day 42] [Designated as safety issue: Yes]

  The number of participants experiencing AEs in each treatment group was monitored during the Vaniprevir/Placebo treatment (Day 1 to Day 28) and safety follow-up (Day 29 to Day 42) periods.

- Number of Participants Discontinuing From Study Therapy Due to AEs [Time Frame: Day 1 to Day 28] [Designated as safety issue: Yes]

  An AE was defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of study therapy, whether or not considered related to the use of the product.

Secondary Outcome Measures:

- Number of Participants With ≥2-log10 Decrease in HCV RNA [Time Frame: Baseline and Week 4] [Designated as safety issue: No]

  The number of participants with at least a 2-log10 decrease from baseline in HCV RNA following 4 weeks of treatment with Placebo or Vaniprevir.

- Number of Participants With ≥3-log10 Decrease in HCV RNA [Time Frame: Baseline and Week 4] [Designated as safety issue: No]

  The number of participants with at least a 3-log10 decrease from baseline in HCV RNA following 4 weeks of treatment with Placebo or Vaniprevir.

- Mean Log Change From Baseline in HCV RNA [Time Frame: Baseline and Week 4] [Designated as safety issue: No]

  The mean changes from baseline in log10 HCV RNA in each vaniprevir group was compared against control treatment at Week 4.

Enrollment:	95
Study Start Date:	July 2008
Study Completion Date:	April 2010
Primary Completion Date:	December 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: Placebo + Peg-IFN/Ribavirin Participants took double-blind Placebo + Peg-IFN/Ribavirin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavirin from Week 5 to Week 48.	Drug: Comparator: Pegylated-Interferon (Peg-IFN) Peg-IFN 180 mcg once-weekly subcutaneous injection; duration of treatment: 48 weeks Drug: Comparator: Ribavirin Ribavirin 200 mg tablet b.i.d. (dose based on body weight); duration of treatment: 48 weeks
Experimental: Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin Participants took double-blind Vaniprevir 300 mg twice daily (b.i.d.) + Peg-IFN/Ribavirin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavirin from Week 5 to Week 48.	Drug: Comparator: Vaniprevir Vaniprevir 300 mg b.i.d., 600 mg b.i.d., 600 mg q.d., or 800 mg q.d.; duration of treatment: 28 days Other Name: MK-7009 Drug: Comparator: Pegylated-Interferon (Peg-IFN) Peg-IFN 180 mcg once-weekly subcutaneous injection; duration of treatment: 48 weeks Drug: Comparator: Ribavirin Ribavirin 200 mg tablet b.i.d. (dose based on body weight); duration of treatment: 48 weeks

Experimental: Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin Participants took double-blind Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavirin from Week 5 to Week 48.	Drug: Comparator: Vaniprevir Vaniprevir 300 mg b.i.d., 600 mg b.i.d., 600 mg q.d., or 800 mg q.d.; duration of treatment: 28 days Other Name: MK-7009 Drug: Comparator: Pegylated-Interferon (Peg-IFN) Peg-IFN 180 mcg once-weekly subcutaneous injection; duration of treatment: 48 weeks Drug: Comparator: Ribavirin Ribavirin 200 mg tablet b.i.d. (dose based on body weight); duration of treatment: 48 weeks
Experimental: Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin Participants took double-blind Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavirin from Week 5 to Week 48.	Drug: Comparator: Vaniprevir Vaniprevir 300 mg b.i.d., 600 mg b.i.d., 600 mg q.d., or 800 mg q.d.; duration of treatment: 28 days Other Name: MK-7009 Drug: Comparator: Pegylated-Interferon (Peg-IFN) Peg-IFN 180 mcg once-weekly subcutaneous injection; duration of treatment: 48 weeks Drug: Comparator: Ribavirin Ribavirin 200 mg tablet b.i.d. (dose based on body weight); duration of treatment: 48 weeks
Experimental: Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin Participants took double-blind Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavirin from Week 5 to Week 48.	Drug: Comparator: Vaniprevir Vaniprevir 300 mg b.i.d., 600 mg b.i.d., 600 mg q.d., or 800 mg q.d.; duration of treatment: 28 days Other Name: MK-7009 Drug: Comparator: Pegylated-Interferon (Peg-IFN) Peg-IFN 180 mcg once-weekly subcutaneous injection; duration of treatment: 48 weeks Drug: Comparator: Ribavirin Ribavirin 200 mg tablet b.i.d. (dose based on body weight); duration of treatment: 48 weeks Drug: Comparator: placebo Matching placebo to vaniprevir; duration of treatment: 28 days

Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Patient has chronic Genotype 1 Hepatitis C infection

Exclusion Criteria:

- Subject has been previously treated for HCV
- Has Human Immunodeficiency Virus (HIV)
- Has Hepatitis B
- Has a history of clinically significant medical condition that may interfere with the study (e.g., stroke or chronic seizures or major neurological disorder) or is contraindicated for treatment with peg-IFN and Ribavirin

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.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00704184

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

Publications:

Manns MP, Gane E, Rodriguez-Torres M, Stoehr A, Yeh CT, Marcellin P, Wiedmann RT, Hwang PM, Caro L, Barnard RJ, Lee AW; MK-7009 Protocol 007 Study Group. Vaniprevir with pegylated interferon alpha-2a and ribavirin in treatment-naïve patients with chronic hepatitis C: a randomized phase II study. Hepatology. 2012 Sep;56(3):884-93. doi: 10.1002/hep.25743. Epub 2012 Jul 17.

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

Lawitz E, Sulkowski M, Jacobson I, Kraft WK, Maliakkal B, Al-Ibrahim M, Gordon SC, Kwo P, Rockstroh JK, Panorchan P, Miller M, Caro L, Barnard R, Hwang PM, Gress J, Quirk E, Mobashery N. Characterization of vaniprevir, a hepatitis C virus NS3/4A protease inhibitor, in patients with HCV genotype 1 infection: safety, antiviral activity, resistance, and pharmacokinetics. Antiviral Res. 2013 Sep;99(3):214-20. doi: 10.1016/j.antiviral.2013.05.015. Epub 2013 Jun 7.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00704184 History of Changes
Other Study ID Numbers:	**7009-007** MK**7009-007** 2007_658
Study First Received:	June 23, 2008
Results First Received:	September 26, 2014
Last Updated:	December 23, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Hepatitis	Ribavirin
Hepatitis C	Anti-Infective Agents
Digestive System Diseases	Antimetabolites
Flaviviridae Infections	Antineoplastic Agents
Hepatitis, Viral, Human	Antiviral Agents
Liver Diseases	Molecular Mechanisms of Pharmacological Action
RNA Virus Infections	Pharmacologic Actions
Virus Diseases	Therapeutic Uses
Interferons	

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Safety and Efficacy of Vaniprevir (MK7009) Administered With Pegylated-Interferon and Ribavirin (MK-7009-007)

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First received: June 23, 2008
Last updated: December 23, 2015
Last verified: December 2015
History of Changes

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Results First Received: September 26, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Hepatitis C
Interventions:	Drug: Comparator: Vaniprevir Drug: Comparator: Pegylated-Interferon (Peg-IFN) Drug: Comparator: Ribavirin Drug: Comparator: placebo

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

No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

During the double-blind phase (Day 1 to Day 28), participants took Vaniprevir or Placebo in combination with Pegylated Interferon (Peg-IFN)/Ribavirin. During the open-label phase (Day 29 to Week 48), participants took Peg-IFN/Ribavirin only.

Reporting Groups

	Description
Placebo + Peg-IFN/Ribavirin	Participants took double-blind Placebo + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 800 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.

Participant Flow for 2 periods

Period 1: Double-Blind Treatment

	Placebo + Peg-IFN/Ribavirin	Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
STARTED	20	18	20	18	19
Treated	19 [1]	18	20	18	19
COMPLETED	19	18	20	18	19
NOT COMPLETED	1	0	0	0	0
Withdrawal by Subject	1	0	0	0	0

[1] One participant was randomized to placebo but withdrew prior to receiving study medication.

Period 2: Open-Label Treatment

	Placebo + Peg-IFN/Ribavirin	Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
STARTED	19	18	20	18	19
COMPLETED	18	16	16	13	16
NOT COMPLETED	1	2	4	5	3
Adverse Event	0	0	2	0	1
Lack of Efficacy	0	2	2	2	1
Physician Decision	0	0	0	0	1

Withdrawal by Subject	**1**	**0**	**0**	**3**	**0**

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.
The baseline population consists of all participants treated with study medication. One participant was randomized to the placebo group but withdrew from the study prior to taking any study medication.

Reporting Groups

	Description
Placebo + Peg-IFN/Ribavirin	Participants took double-blind Placebo + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 800 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Total	Total of all reporting groups

Baseline Measures

	Placebo + Peg-IFN/Ribavirin	**Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin**	**Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin**	**Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin**	**Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin**	**Total**
Number of Participants [units: participants]	**19**	**18**	**20**	**18**	**19**	**94**
Age [units: Years] Mean (Standard Deviation)	**47.8 (10.1)**	**46.7 (10.2)**	**42.0 (10.7)**	**50.1 (8.4)**	**45.1 (12.0)**	**46.2 (10.5)**
Gender [units: Participants]						
Female	**8**	**4**	**9**	**11**	**7**	**39**
Male	**11**	**14**	**11**	**7**	**12**	**55**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants Achieving RVR [Time Frame: Week 4]

Measure Type	Primary
Measure Title	Percentage of Participants Achieving RVR
Measure Description	Rapid Viral Response (RVR) was declared if Hepatitis C Virus (HCV) ribonucleic acid (RNA) was undetectable at Week 4.
Time Frame	Week 4
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.
The Per Protocol population included all participants who did not have clinically important deviations from protocol-specified criteria. Only participants with an HCV RNA result at the Week 4 time point were included in the analysis.

Reporting Groups

	Description
Placebo + Peg-IFN/Ribavirin	Participants took double-blind Placebo + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 800 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.

Measured Values

	Placebo + Peg-IFN/Ribavirin	**Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin**	**Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin**	**Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin**	**Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin**
Number of Participants Analyzed [units: participants]	**18**	**16**	**19**	**16**	**18**
Percentage of Participants Achieving RVR [units: Percentage of Participants]	**5.6**	**75.0**	**78.9**	**68.8**	**83.3**

Statistical Analysis 1 for Percentage of Participants Achieving RVR

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin
Method [2]	Miettinen and Nurminen method
P Value [3]	<0.001
Adjusted difference in % [4]	69.3

95% Confidence Interval	40.3 to 86.7

[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:
	No text entered.
[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:
	Adjusted difference subtracts the percentage of placebo responders (5.3%) and stratifies by HCV genotype (1a vs. non-1a).

Statistical Analysis 2 for Percentage of Participants Achieving RVR

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin
Method [2]	Miettinen and Nurminen method
P Value [3]	<0.001
Adjusted difference in % [4]	73.6
95% Confidence Interval	46.0 to 88.6

[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:
	No text entered.
[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:
	Adjusted difference subtracts the percentage of placebo responders (5.3%) and stratifies by HCV genotype (1a vs. non-1a).

Statistical Analysis 3 for Percentage of Participants Achieving RVR

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin
Method [2]	Miettinen and Nurminen method
P Value [3]	<0.001
Adjusted difference in % [4]	63.3
95% Confidence Interval	32.8 to 82.7

[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:
	No text entered.

[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:
	Adjusted difference subtracts the percentage of placebo responders (5.3%) and stratifies by HCV genotype (1a vs. non-1a).

Statistical Analysis 4 for Percentage of Participants Achieving RVR

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
Method [2]	Miettinen and Nurminen method
P Value [3]	<0.001
Adjusted difference in % [4]	77.8
95% Confidence Interval	49.2 to 91.3

[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:
	No text entered.
[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:
	Adjusted difference subtracts the percentage of placebo responders (5.3) and stratifies by HCV genotype (1a vs. non-1a).

2. Primary: Number of Participants Experiencing an Adverse Event (AE) [Time Frame: Up to Day 42]

Measure Type	Primary
Measure Title	Number of Participants Experiencing an Adverse Event (AE)
Measure Description	The number of participants experiencing AEs in each treatment group was monitored during the Vaniprevir/Placebo treatment (Day 1 to Day 28) and safety follow-up (Day 29 to Day 42) periods.
Time Frame	Up to Day 42
Safety Issue	Yes

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.
The Safety Population consists of all randomized participants who received at least 1 dose of study therapy.

Reporting Groups

	Description
Placebo + Peg-IFN/Ribavirin	Participants took double-blind Placebo + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by

	open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 800 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.

Measured Values

	Placebo + Peg-IFN/Ribavirin	Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
Number of Participants Analyzed [units: participants]	**19**	**18**	**20**	**18**	**19**
Number of Participants Experiencing an Adverse Event (AE) [units: Participants]	**18**	**15**	**18**	**16**	**18**

No statistical analysis provided for Number of Participants Experiencing an Adverse Event (AE)

3. Primary: Number of Participants Discontinuing From Study Therapy Due to AEs [Time Frame: Day 1 to Day 28]

Measure Type	Primary
Measure Title	Number of Participants Discontinuing From Study Therapy Due to AEs
Measure Description	An AE was defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of study therapy, whether or not considered related to the use of the product.
Time Frame	Day 1 to Day 28
Safety Issue	Yes

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.
The Safety Population consists of all randomized participants who received at least 1 dose of study therapy

Reporting Groups

	Description
Placebo + Peg-IFN/Ribavirin	Participants took double-blind Placebo + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.

Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 800 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.

Measured Values

	Placebo + Peg-IFN/Ribavirin	Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
Number of Participants Analyzed [units: participants]	**19**	**18**	**20**	**18**	**19**
Number of Participants Discontinuing From Study Therapy Due to AEs [units: Participants]	**0**	**0**	**0**	**0**	**0**

No statistical analysis provided for Number of Participants Discontinuing From Study Therapy Due to AEs

4. Secondary: Number of Participants With ≥2-log10 Decrease in HCV RNA [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Number of Participants With ≥2-log10 Decrease in HCV RNA
Measure Description	The number of participants with at least a 2-log10 decrease from baseline in HCV RNA following 4 weeks of treatment with Placebo or Vaniprevir.
Time Frame	Baseline and Week 4
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.
The Per Protocol population included all participants who did not have clinically important deviations from protocol-specified criteria. Only participants with an HCV RNA result at the Week 4 time point were included in the analysis.

Reporting Groups

	Description
Placebo + Peg-IFN/Ribavirin	Participants took double-blind Placebo + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 800 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week

	4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.

Measured Values

	Placebo + Peg-IFN/Ribavirin	Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
Number of Participants Analyzed [units: participants]	18	16	19	16	18
Number of Participants With ≥2-log10 Decrease in HCV RNA [units: Number of Participants]	16	16	19	16	17

Statistical Analysis 1 for Number of Participants With ≥2-log10 Decrease in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin
Adjusted difference [2]	11.2
95% Confidence Interval	-9.7 to 33.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Adjusted difference subtracts the percentage of placebo responders (88.9%) and stratifies by HCV genotype (1a vs. non-1a).

Statistical Analysis 2 for Number of Participants With ≥2-log10 Decrease in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin
Adjusted difference [2]	10.8
95% Confidence Interval	-7.6 to 33.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Adjusted difference subtracts the percentage of placebo responders (88.9%) and stratifies by HCV genotype (1a vs. non-1a).

Statistical Analysis 3 for Number of Participants With ≥2-log10 Decrease in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin
Adjusted difference [2]	11.2
95% Confidence Interval	-9.7 to 33.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Adjusted difference subtracts the percentage of placebo responders (88.9%) and stratifies by HCV genotype (1a vs. non-1a).

Statistical Analysis 4 for Number of Participants With ≥2-log10 Decrease in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
Adjusted difference [2]	5.4
95% Confidence Interval	-16.5 to 28.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Adjusted difference subtracts the percentage of placebo responders (88.9%) and stratifies by HCV genotype (1a vs. non-1a).

5. Secondary: Number of Participants With ≥3-log10 Decrease in HCV RNA [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Number of Participants With ≥3-log10 Decrease in HCV RNA
Measure Description	The number of participants with at least a 3-log10 decrease from baseline in HCV RNA following 4 weeks of treatment with Placebo or Vaniprevir.
Time Frame	Baseline and Week 4
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.
The Per Protocol population included all participants who did not have clinically important deviations from protocol-specified criteria. Only participants with an HCV RNA result at the Week 4 time point were included in the analysis.

Reporting Groups

	Description
Placebo + Peg-IFN/Ribavirin	Participants took double-blind Placebo + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 800 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.

Measured Values

	Placebo + Peg-IFN/Ribavirin	**Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin**	**Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin**	**Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin**	**Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin**

Number of Participants Analyzed [units: participants]	**18**	**16**	**19**	**16**	**18**
Number of Participants With ≥3-log10 Decrease in HCV RNA [units: Number of Participants]	**15**	**16**	**19**	**16**	**17**

Statistical Analysis 1 for Number of Participants With ≥3-log10 Decrease in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin
Adjusted difference [2]	16.9
95% Confidence Interval	-4.0 to 40.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Adjusted difference subtracts the percentage of placebo responders (83.3%) and stratifies by HCV genotype (1a vs. non-1a).

Statistical Analysis 2 for Number of Participants With ≥3-log10 Decrease in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin
Adjusted difference [2]	16.2
95% Confidence Interval	-2.2 to 39.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Adjusted difference subtracts the percentage of placebo responders (83.3%) and stratifies by HCV genotype (1a vs. non-1a).

Statistical Analysis 3 for Number of Participants With ≥3-log10 Decrease in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin
Adjusted difference [2]	16.9
95% Confidence Interval	-4.0 to 40.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Adjusted difference subtracts the percentage of placebo responders (83.3%) and stratifies by HCV genotype (1a vs. non-1a).

Statistical Analysis 4 for Number of Participants With ≥3-log10 Decrease in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
Adjusted difference [2]	10.7
95% Confidence Interval	-11.4 to 34.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Adjusted difference subtracts the percentage of placebo responders (83.3%) and stratifies by HCV genotype (1a vs. non-1a).

6. Secondary: Mean Log Change From Baseline in HCV RNA [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Mean Log Change From Baseline in HCV RNA
Measure Description	The mean changes from baseline in log10 HCV RNA in each vaniprevir group was compared against control treatment at Week 4.
Time Frame	Baseline and Week 4
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.
The Per Protocol population included all participants who did not have clinically important deviations from protocol-specified criteria. Only participants with an HCV RNA result at the Week 4 time point were included in the analysis.

Reporting Groups

	Description
Placebo + Peg-IFN/Ribavirin	Participants took double-blind Placebo + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 800 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.

Measured Values

	Placebo + Peg-IFN/Ribavirin	Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
Number of Participants Analyzed [units: participants]	**18**	**16**	**19**	**17**	**18**
Mean Log Change From Baseline in HCV RNA [units: Log10 IU/mL] Mean (Standard	**-3.6 (1.3)**	**-6.1 (1.1)**	**-6.3 (0.7)**	**-6.2 (0.6)**	**-6.3 (1.4)**

Deviation)					

Statistical Analysis 1 for Mean Log Change From Baseline in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin
Difference in Least Squares (LC) Means [2]	-2.5
95% Confidence Interval	-3.2 to -1.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	The difference in LS Means reflects the mean decrease from baseline in HCV RNA between vaniprevir and placebo at Week 4.

Statistical Analysis 2 for Mean Log Change From Baseline in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin
Difference in LS Means [2]	-2.7
95% Confidence Interval	-3.4 to -2.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	The difference in LS Means reflects the mean decrease from baseline in HCV RNA between vaniprevir and placebo at Week 4.

Statistical Analysis 3 for Mean Log Change From Baseline in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin
Difference in LS Means [2]	-2.7
95% Confidence Interval	-3.4 to -2.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	The difference in LS Means reflects the mean decrease from baseline in HCV RNA between vaniprevir and placebo at Week 4.

Statistical Analysis 4 for Mean Log Change From Baseline in HCV RNA

Groups [1]	Placebo + Peg-IFN/Ribavirin vs. Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
Difference in LS Means [2]	-2.7
95% Confidence Interval	-3.3 to -2.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:

	The difference in LS Means reflects the mean decrease from baseline in HCV RNA between vaniprevir and placebo at Week 4.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	AEs were monitored for 18 months in the study, including the Vaniprevir/Placebo + Peg-IFN Ribavirin treatment/follow-up period (Day 1 to Day 42) and subsequent Peg-IFN/Ribavirin treatment/follow-up period (Day 43 to Week 72).
Additional Description	The Safety Population consists of all randomized participants who received at least 1 dose of study therapy.

Reporting Groups

	Description
Placebo + Peg-IFN/Ribavirin	Participants took double-blind Placebo + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 800 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.

Serious Adverse Events

	Placebo + Peg-IFN/Ribavirin	Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
Total, serious adverse events					
# participants affected / at risk	**1/19 (5.26%)**	**3/18 (16.67%)**	**1/20 (5.00%)**	**2/18 (11.11%)**	**2/19 (10.53%)**
Hepatobiliary disorders					
Cholecystitis acute † 1					
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**0/20 (0.00%)**	**1/18 (5.56%)**	**0/19 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
Infections and infestations					
Appendicitis † 1					
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/20 (0.00%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**
Empyema † 1					
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**1/20 (5.00%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**

Gastroenteritis † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Lobar pneumonia † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Septic shock † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/20 (5.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	0	1	0	0
Investigations					
Haemoglobin decreased † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Musculoskeletal and connective tissue disorders					
Myopathy † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Colon cancer † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Psychiatric disorders					
Confusional state † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA version 13.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	AEs were monitored for 18 months in the study, including the Vaniprevir/Placebo + Peg-IFN Ribavirin treatment/follow-up period (Day 1 to Day 42) and subsequent Peg-IFN/Ribavirin treatment/follow-up period (Day 43 to Week 72).
Additional Description	The Safety Population consists of all randomized participants who received at least 1 dose of study therapy.

Frequency Threshold

Threshold above which other adverse events are	5%

reported	

Reporting Groups

	Description
Placebo + Peg-IFN/Ribavirin	Participants took double-blind Placebo + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 600 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.
Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin	Participants took double-blind Vaniprevir 800 mg q.d. + Peg-IFN/Ribavarin from Week 1 to Week 4, followed by open-label Peg-IFN/Ribavarin from Week 5 to Week 48.

Other Adverse Events

	Placebo + Peg-IFN/Ribavirin	Vaniprevir 300 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg b.i.d. + Peg-IFN/Ribavirin	Vaniprevir 600 mg q.d. + Peg-IFN/Ribavirin	Vaniprevir 800 mg q.d. + Peg-IFN/Ribavirin
Total, other (not including serious) adverse events					
# participants affected / at risk	**19/19 (100.00%)**	**16/18 (88.89%)**	**20/20 (100.00%)**	**17/18 (94.44%)**	**18/19 (94.74%)**
Blood and lymphatic system disorders					
Anaemia † 1					
# participants affected / at risk	**3/19 (15.79%)**	**2/18 (11.11%)**	**2/20 (10.00%)**	**1/18 (5.56%)**	**1/19 (5.26%)**
# events	**3**	**2**	**2**	**1**	**1**
Leukopenia † 1					
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**0/20 (0.00%)**	**0/18 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**0**	**0**	**0**	**1**
Neutropenia † 1					
# participants affected / at risk	**2/19 (10.53%)**	**1/18 (5.56%)**	**2/20 (10.00%)**	**1/18 (5.56%)**	**3/19 (15.79%)**
# events	**2**	**1**	**2**	**1**	**3**
Pancytopenia † 1					
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**0/20 (0.00%)**	**0/18 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**0**	**0**	**0**	**1**
Cardiac disorders					
Angina pectoris † 1					
# participants affected / at risk	**1/19 (5.26%)**	**0/18 (0.00%)**	**0/20 (0.00%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
# events	**2**	**0**	**0**	**0**	**0**
Palpitations † 1					

# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/20 (5.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	1	0	1
Tachycardia † 1					
# participants affected / at risk	2/19 (10.53%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	2	0	0	0	0
Ear and labyrinth disorders					
Ear pain † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	2	0	0	0
Hypoacusis † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Tinnitus † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	1/20 (5.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	2	2	0	0
Endocrine disorders					
Hyperthyroidism † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Hypothyroidism † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/20 (5.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	1	1	0
Eye disorders					
Vision blurred † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/20 (5.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	1	0	1
Vision acuity reduced † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	0	1	0
Visual brightness † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	2	0	0	0
Visual impairment † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	1/18 (5.56%)	1/19 (5.26%)
# events	0	1	0	1	1
Xerophthalmia † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	1/20 (5.00%)	0/18 (0.00%)	0/19 (0.00%)

# events	0	1	1	0	0
Conjunctival haemorrhage † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	0	1	0
Conjunctivitis † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Dry eye † 1					
# participants affected / at risk	1/19 (5.26%)	1/18 (5.56%)	0/20 (0.00%)	1/18 (5.56%)	1/19 (5.26%)
# events	1	1	0	1	1
Eye irritation † 1					
# participants affected / at risk	1/19 (5.26%)	1/18 (5.56%)	1/20 (5.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	1	1	1	0	1
Eye pain † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	2	0	0	0	0
Eye pruritus † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Eye swelling † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Eyelid function disorder † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	0	1	0
Ocular icterus † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Photopsia † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Diplopia † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Gastrointestinal disorders					
Abdominal discomfort † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	1/20 (5.00%)	0/18 (0.00%)	0/19 (0.00%)

# events	0	1	2	0	0
Abdominal pain † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	1/20 (5.00%)	2/18 (11.11%)	1/19 (5.26%)
# events	0	1	3	2	2
Abdominal pain upper † 1					
# participants affected / at risk	3/19 (15.79%)	1/18 (5.56%)	3/20 (15.00%)	4/18 (22.22%)	2/19 (10.53%)
# events	5	1	3	4	2
Aphthous stomatitis † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	0	1	0
Constipation † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Diarrhoea † 1					
# participants affected / at risk	4/19 (21.05%)	1/18 (5.56%)	7/20 (35.00%)	2/18 (11.11%)	6/19 (31.58%)
# events	4	1	8	2	7
Dry mouth † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	2/20 (10.00%)	2/18 (11.11%)	1/19 (5.26%)
# events	0	1	2	2	1
Duodenitis † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Dyspepsia † 1					
# participants affected / at risk	4/19 (21.05%)	4/18 (22.22%)	0/20 (0.00%)	2/18 (11.11%)	4/19 (21.05%)
# events	4	4	0	2	4
Flatulence † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Gastritis † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	2/19 (10.53%)
# events	0	0	0	0	2
Gastrooesophogeal reflux disease † 1					
# participants affected / at risk	2/19 (10.53%)	2/18 (11.11%)	0/20 (0.00%)	4/18 (22.22%)	0/19 (0.00%)
# events	2	2	0	4	0
Gingival bleeding † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	2/20 (10.00%)	0/18 (0.00%)	0/19 (0.00%)

# events	0	0	2	0	0
Glossodynia † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	0	1	0
Ileus † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Lip dry † 1					
# participants affected / at risk	2/19 (10.53%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	2	0	0	0	1
Lip erosion † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Nausea † 1					
# participants affected / at risk	6/19 (31.58%)	5/18 (27.78%)	8/20 (40.00%)	7/18 (38.89%)	6/19 (31.58%)
# events	7	7	14	8	6
Oesophogeal pain † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Oral pain † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Stomatitis † 1					
# participants affected / at risk	1/19 (5.26%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	1	0	0	0
Vomiting † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	9/20 (45.00%)	4/18 (22.22%)	3/19 (15.79%)
# events	0	0	16	5	6
General disorders					
Asthenia † 1					
# participants affected / at risk	4/19 (21.05%)	2/18 (11.11%)	4/20 (20.00%)	4/18 (22.22%)	3/19 (15.79%)
# events	5	2	6	4	3
Chest pain † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	3/19 (15.79%)
# events	0	0	0	0	4
Chills † 1					
# participants affected / at risk	2/19 (10.53%)	1/18 (5.56%)	1/20 (5.00%)	0/18 (0.00%)	3/19 (15.79%)

# events	2	1	1	0	4
Discomfort † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	2
Fatigue † 1					
# participants affected / at risk	7/19 (36.84%)	3/18 (16.67%)	7/20 (35.00%)	4/18 (22.22%)	3/19 (15.79%)
# events	7	3	10	4	3
Feeling cold † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Influenza like illness † 1					
# participants affected / at risk	4/19 (21.05%)	4/18 (22.22%)	4/20 (20.00%)	4/18 (22.22%)	5/19 (26.32%)
# events	5	4	4	4	6
Injection site erythema † 1					
# participants affected / at risk	0/19 (0.00%)	2/18 (11.11%)	2/20 (10.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	2	2	1	0
Injection site irritation † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Injection site reaction † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	1/20 (5.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	1	0	0
Irritability † 1					
# participants affected / at risk	3/19 (15.79%)	2/18 (11.11%)	1/20 (5.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	4	3	1	0	1
Mucosal dryness † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Mucosal inflammation † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Oedema peripheral † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/20 (5.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	3	1	0
Pain † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	3/20 (15.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	0	3	0	0

Pyrexia † [1]					
# participants affected / at risk	2/19 (10.53%)	0/18 (0.00%)	2/20 (10.00%)	2/18 (11.11%)	4/19 (21.05%)
# events	3	0	2	2	4
Immune system disorders					
Seasonal allergy † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Infections and infestations					
Bronchitis † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	1/20 (5.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	1	0	1	1	0
Ear infection † [1]					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Gastroenteritis † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Herpes virus infection † [1]					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Hordeolum † [1]					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Laryngitis † [1]					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Nasopharyngitis † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	1/20 (5.00%)	0/18 (0.00%)	3/19 (15.79%)
# events	1	0	1	0	4
Oesophageal candidiasis † [1]					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Oral herpes † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	1	0	0	1	0
Sinusitis † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	1/20 (5.00%)	1/18 (5.56%)	0/19 (0.00%)

# events	1	0	1	1	0
Tinea infection † [1]					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	0	1	0
Tinea pedis † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Tinea versicolour † [1]					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Tracheobronchitis † [1]					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Upper respiratory tract infection † [1]					
# participants affected / at risk	1/19 (5.26%)	1/18 (5.56%)	0/20 (0.00%)	2/18 (11.11%)	0/19 (0.00%)
# events	1	1	0	2	0
Urinary tract infection † [1]					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	2/20 (10.00%)	2/18 (11.11%)	1/19 (5.26%)
# events	0	0	2	2	5
Viral infection † [1]					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	1	0	0	1
Vulvovaginal mycotic infection † [1]					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	0	2	0
Injury, poisoning and procedural complications					
Joint injury † [1]					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Post-traumatic pain † [1]					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Skin laceration † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0

Thermal burn † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/20 (5.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	1	1	0
Investigations					
Blood glucose increased † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Body temperature decreased † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Body temperature increased † 1					
# participants affected / at risk	1/19 (5.26%)	1/18 (5.56%)	0/20 (0.00%)	1/18 (5.56%)	1/19 (5.26%)
# events	1	2	0	1	1
Glucose urine present † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Haemoglobin decreased † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	2/20 (10.00%)	1/18 (5.56%)	1/19 (5.26%)
# events	0	0	2	1	1
Neutrophil count decreased † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	1/20 (5.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	1	0	0
Platelet count decreased † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/20 (5.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	1	1	0
Weight decreased † 1					
# participants affected / at risk	2/19 (10.53%)	0/18 (0.00%)	2/20 (10.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	2	0	2	0	0
White blood cell count decreased † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	1	0	0	1
Metabolism and nutrition disorders					
Appetite disorder † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)

# events	1	0	0	0	0
Decreased appetite † [1]					
# participants affected / at risk	2/19 (10.53%)	4/18 (22.22%)	6/20 (30.00%)	2/18 (11.11%)	1/19 (5.26%)
# events	3	4	6	2	1
Fluid retention † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Musculoskeletal and connective tissue disorders					
Arthralgia † [1]					
# participants affected / at risk	2/19 (10.53%)	3/18 (16.67%)	2/20 (10.00%)	3/18 (16.67%)	0/19 (0.00%)
# events	2	4	4	3	0
Arthritis † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Back pain † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	3/20 (15.00%)	0/18 (0.00%)	3/19 (15.79%)
# events	1	0	5	0	3
Flank pain † [1]					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Muscle spasms † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Muscular weakness † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Musculoskeletal chest pain † [1]					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Musculoskeletal pain † [1]					
# participants affected / at risk	0/19 (0.00%)	2/18 (11.11%)	1/20 (5.00%)	2/18 (11.11%)	1/19 (5.26%)
# events	0	2	1	2	1
Myalgia † [1]					
# participants affected / at risk	3/19 (15.79%)	1/18 (5.56%)	1/20 (5.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	3	1	1	1	0
Myosclerosis † [1]					

# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Neck pain † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/20 (5.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	1	1	0
Pain in extremity † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/20 (5.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	4	0	1
Rotator cuff syndrome † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Melanocytic naevus † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Nervous system disorders					
Cervicobrachial syndrome † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Coordination abnormal † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Disturbance in attention † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Dizziness † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	1/20 (5.00%)	1/18 (5.56%)	2/19 (10.53%)
# events	0	1	1	1	3
Dysgeusia † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	1/19 (5.26%)
# events	0	0	0	1	1
Head discomfort † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Headache † 1					
# participants affected / at					

risk	7/19 (36.84%)	4/18 (22.22%)	9/20 (45.00%)	8/18 (44.44%)	5/19 (26.32%)
# events	10	4	12	9	6
Hyperaesthesia † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Intercostal neuralgia † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Memory impairment † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Paraesthesia † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/20 (5.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	1	0	1
Poor quality sleep † 1					
# participants affected / at risk	1/19 (5.26%)	1/18 (5.56%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	1	1	0	1	0
Restless legs syndrome † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	1/20 (5.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	1	0	1	0	1
Somnolence † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	2/18 (11.11%)	1/19 (5.26%)
# events	0	0	0	2	1
Psychiatric disorders					
Abnormal dreams † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Agitation † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Anxiety † 1					
# participants affected / at risk	1/19 (5.26%)	2/18 (11.11%)	1/20 (5.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	1	2	1	0	1
Depressed mood † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	3/20 (15.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	3	0	0
Depression † 1					

# participants affected / at risk	3/19 (15.79%)	3/18 (16.67%)	2/20 (10.00%)	3/18 (16.67%)	0/19 (0.00%)
# events	3	3	2	3	0
Disorientation † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Dysthymic disorder † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Initial insomnia † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Insomnia † 1					
# participants affected / at risk	2/19 (10.53%)	4/18 (22.22%)	4/20 (20.00%)	5/18 (27.78%)	2/19 (10.53%)
# events	2	4	4	5	2
Libido decreased † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Mood swings † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	1	0	0	1	0
Nervousness † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Restlessness † 1					
# participants affected / at risk	2/19 (10.53%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	2	0	0	0	0
Sleep disorder † 1					
# participants affected / at risk	2/19 (10.53%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	2	0	0	0	0
Renal and urinary disorders					
Pollakiuria † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Urine odour abnormal † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Reproductive system and breast					

disorders					
Erectile dysfunction † 1					
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/20 (0.00%)**	**0/18 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**	**0**	**0**	**1**
Respiratory, thoracic and mediastinal disorders					
Asthma † 1					
# participants affected / at risk	**0/19 (0.00%)**	**2/18 (11.11%)**	**0/20 (0.00%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
# events	**0**	**3**	**0**	**0**	**0**
Cough † 1					
# participants affected / at risk	**3/19 (15.79%)**	**3/18 (16.67%)**	**2/20 (10.00%)**	**2/18 (11.11%)**	**1/19 (5.26%)**
# events	**3**	**4**	**3**	**2**	**1**
Dry throat † 1					
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**0/20 (0.00%)**	**1/18 (5.56%)**	**0/19 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
Dyspnoea † 1					
# participants affected / at risk	**5/19 (26.32%)**	**3/18 (16.67%)**	**1/20 (5.00%)**	**1/18 (5.56%)**	**2/19 (10.53%)**
# events	**5**	**3**	**1**	**1**	**2**
Dyspnoea exertional † 1					
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**1/20 (5.00%)**	**1/18 (5.56%)**	**0/19 (0.00%)**
# events	**0**	**0**	**1**	**1**	**0**
Epistaxis † 1					
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**0/20 (0.00%)**	**0/18 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**0**	**0**	**0**	**1**
Nasal congestion † 1					
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**2/20 (10.00%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
# events	**0**	**1**	**2**	**0**	**0**
Nasal ulcer † 1					
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**0/20 (0.00%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**
Oropharyngeal pain † 1					
# participants affected / at risk	**0/19 (0.00%)**	**1/18 (5.56%)**	**1/20 (5.00%)**	**0/18 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**	**2**	**0**	**1**
Productive cough † 1					
# participants affected / at risk	**0/19 (0.00%)**	**0/18 (0.00%)**	**2/20 (10.00%)**	**0/18 (0.00%)**	**0/19 (0.00%)**
# events	**0**	**0**	**2**	**0**	**0**
Sinus congestion † 1					
# participants affected / at					

risk	2/19 (10.53%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	2	0	0	0	0
Throat irritation † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	0	1	0
Skin and subcutaneous tissue disorders					
Alopecia † 1					
# participants affected / at risk	3/19 (15.79%)	0/18 (0.00%)	1/20 (5.00%)	3/18 (16.67%)	2/19 (10.53%)
# events	3	0	1	3	2
Dermatitis † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	1/20 (5.00%)	3/18 (16.67%)	0/19 (0.00%)
# events	0	0	1	3	0
Dry skin † 1					
# participants affected / at risk	6/19 (31.58%)	1/18 (5.56%)	3/20 (15.00%)	1/18 (5.56%)	1/19 (5.26%)
# events	6	1	3	1	1
Eczema † 1					
# participants affected / at risk	0/19 (0.00%)	2/18 (11.11%)	3/20 (15.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	2	4	0	2
Eczema nummular † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Erythema † 1					
# participants affected / at risk	2/19 (10.53%)	1/18 (5.56%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	2	1	0	1	0
Hyperhidrosis † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	3/20 (15.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	0	4	0	0
Hypotrichosis † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Night sweats † 1					
# participants affected / at risk	1/19 (5.26%)	1/18 (5.56%)	1/20 (5.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	1	1	0	0
Pain of skin † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	2	0	0	0
Pruritus † 1					

# participants affected / at risk	4/19 (21.05%)	4/18 (22.22%)	0/20 (0.00%)	1/18 (5.56%)	4/19 (21.05%)
# events	8	4	0	1	4
Rash † 1					
# participants affected / at risk	4/19 (21.05%)	3/18 (16.67%)	2/20 (10.00%)	3/18 (16.67%)	2/19 (10.53%)
# events	5	6	2	3	3
Rash erythematous † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	1/20 (5.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	2	0	0
Rash papular † 1					
# participants affected / at risk	1/19 (5.26%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	1	1	0	0	1
Rash pruritic † 1					
# participants affected / at risk	0/19 (0.00%)	2/18 (11.11%)	1/20 (5.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	2	2	0	0
Skin reaction † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	1	0	0	0	0
Skin ulcer † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	0	0	0	1	0
Xeroderma † 1					
# participants affected / at risk	0/19 (0.00%)	1/18 (5.56%)	0/20 (0.00%)	0/18 (0.00%)	0/19 (0.00%)
# events	0	1	0	0	0
Vascular disorders					
Hot flush † 1					
# participants affected / at risk	1/19 (5.26%)	0/18 (0.00%)	0/20 (0.00%)	1/18 (5.56%)	0/19 (0.00%)
# events	1	0	0	2	0
Hyperaemia † 1					
# participants affected / at risk	0/19 (0.00%)	0/18 (0.00%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	0	0	0	1
Hypertension † 1					
# participants affected / at risk	0/19 (0.00%)	2/18 (11.11%)	0/20 (0.00%)	0/18 (0.00%)	1/19 (5.26%)
# events	0	2	0	0	1

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA version 13.0

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

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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.

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Publications of Results:

Manns MP, Gane E, Rodriguez-Torres M, Stoehr A, Yeh CT, Marcellin P, Wiedmann RT, Hwang PM, Caro L, Barnard RJ, Lee AW; MK-7009 Protocol 007 Study Group. Vaniprevir with pegylated interferon alpha-2a and ribavirin in treatment-naïve patients with chronic hepatitis C: a randomized phase II study. Hepatology. 2012 Sep;56(3):884-93. doi: 10.1002/hep.25743. Epub 2012 Jul 17.

Publications automatically indexed to this study:

Lawitz E, Sulkowski M, Jacobson I, Kraft WK, Maliakkal B, Al-Ibrahim M, Gordon SC, Kwo P, Rockstroh JK, Panorchan P, Miller M, Caro L, Barnard R, Hwang PM, Gress J, Quirk E, Mobashery N. Characterization of vaniprevir, a hepatitis C virus NS3/4A protease inhibitor, in patients with HCV genotype 1 infection: safety, antiviral activity, resistance, and pharmacokinetics. Antiviral Res. 2013 Sep;99(3):214-20. doi: 10.1016/j.antiviral.2013.05.015. Epub 2013 Jun 7.

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