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Trial record **1 of 1** for: TMC435-TIDP16-C206

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A Safety and Effectiveness Study of TMC435 in Chronic, Genotype 1, Hepatitis C Patients Who Failed to Previous Standard Treatment (ASPIRE)

This study has been completed.

Sponsor:
Tibotec Pharmaceuticals, Ireland

Information provided by (Responsible Party):
Tibotec Pharmaceuticals, Ireland

ClinicalTrials.gov Identifier:
NCT00980330

First received: September 10, 2009
Last updated: May 30, 2014
Last verified: May 2014
History of Changes

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Results First Received: December 18, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Hepatitis C
Interventions:	Drug: TMC435 Drug: Placebo Drug: Peg-IFN-alfa-2a (P) Drug: Ribavirin (R)

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
The study was conducted at 89 sites in 14 countries.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
A total of 618 participants were screened. Of these, 463 participants were randomized of whom 462 participants started treatment. One participant in the placebo group was 'randomized in error,' did not receive treatment, and was withdrawn from the study due to non-compliance (did not come for visit).

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.

TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Participant Flow: Overall Study

	TMC435 100mg 12 Wks + PR48	TMC435 100mg 24 Wks + PR48	TMC435 100mg 48 Wks + PR48	TMC435 150mg 12 Wks + PR48	TMC435 150mg 24 Wks + PR48	TMC435 150mg 48 Wks + PR48	Placebo 48Wks + PR48
STARTED	66	65	66	66	68	65	66
COMPLETED	61	60	58	61	63	61	59
NOT COMPLETED	5	5	8	5	5	4	7
Adverse Event	0	0	0	1	0	0	0
Lost to Follow-up	1	1	4	2	1	1	2
Withdrawal by Subject	2	4	4	1	3	2	5
(not specified)	2	0	0	1	1	1	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.
No text entered.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.

TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Total	Total of all reporting groups

Baseline Measures

	TMC435 100mg 12 Wks + PR48	TMC435 100mg 24 Wks + PR48	TMC435 100mg 48 Wks + PR48	TMC435 150mg 12 Wks + PR48	TMC435 150mg 24 Wks + PR48	TMC435 150mg 48 Wks + PR48	Placebo 48Wks + PR48	Total
Number of Participants [units: participants]	**66**	**65**	**66**	**66**	**68**	**65**	**66**	**462**
Age [units: years] Median (Full Range)	**51.5 (20 to 68)**	**50 (20 to 68)**	**50 (22 to 69)**	**48 (20 to 63)**	**51.5 (25 to 68)**	**50 (21 to 69)**	**50.5 (22 to 66)**	**50 (20 to 69)**
Gender [units: participants]								
Female	**22**	**21**	**21**	**21**	**25**	**17**	**24**	**151**
Male	**44**	**44**	**45**	**45**	**43**	**48**	**42**	**311**
Region of Enrollment [units: participants]								
Asia Pacific	**4**	**5**	**4**	**4**	**1**	**4**	**7**	**29**
Europe and Israel	**34**	**46**	**46**	**49**	**49**	**43**	**46**	**313**
North-America	**28**	**14**	**16**	**13**	**18**	**18**	**13**	**120**
Prior PR response [1] [units: participants]								
Null responder	**16**	**16**	**18**	**17**	**17**	**17**	**16**	**117**
Partial responder	**23**	**23**	**22**	**23**	**24**	**22**	**23**	**160**
Relapser	**27**	**26**	**26**	**26**	**27**	**26**	**27**	**185**
Metavir Score [2] [units: participants]								
Not reported	**1**	**2**	**0**	**0**	**1**	**1**	**2**	**7**
Score F0	**6**	**3**	**6**	**5**	**11**	**1**	**7**	**39**
Score F1	**17**	**14**	**23**	**19**	**11**	**27**	**18**	**129**
Score F2	**21**	**17**	**9**	**18**	**21**	**16**	**16**	**118**
Score F3	**14**	**16**	**14**	**11**	**11**	**7**	**13**	**86**
Score F4	**7**	**13**	**14**	**13**	**13**	**13**	**10**	**83**

[1] In the study, “Null Responders” were participants with less than 2 log10 IU/mL reduction in HCV RNA compared to baseline at Week 12 of the previous PegIFNα-2a/b and RBV treatment; “Partial Responders” were participants with a greater than or equal to 2 log10 IU/mL reduction in HCV RNA compared to baseline at Week 12, but not achieving an undetectable HCV RNA at the end of the previous PegIFNα-2a/b and RBV treatment; and “Relapsers” were participants with HCV RNA undetectable at end of the previous treatment with

PegIFNα-2a/b and RBV, but detectable HCV RNA within 24 weeks of follow-up.

[2] A Metavir score is used to interpret the degree of inflammation and fibrosis in a liver biopsy. Below are fibrosis scores graded on a 5-point scale from F0 (no fibrosis) to F4 (cirrhosis).

Outcome Measures

Hide All Outcome Measures

1. Primary: The Percentage of Participants Achieving a Sustained Virologic Response at the End of Treatment (EOT) and 24 Weeks After the EOT (SVR24) [Time Frame: Week 72]

Measure Type	Primary
Measure Title	The Percentage of Participants Achieving a Sustained Virologic Response at the End of Treatment (EOT) and 24 Weeks After the EOT (SVR24)
Measure Description	The table below shows the percentage of participants in the overall population with an SVR24, defined as having plasma levels of Hepatitis C Virus ribonucleic acid less than 25 IU/mL undetectable at the EOT and 24 weeks after the EOT.
Time Frame	Week 72
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: Participants who received at least 1 dose of study medication were included.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	**TMC435 100mg 24 Wks + PR48**	**TMC435 100mg 48 Wks + PR48**	**TMC435 150mg 12 Wks + PR48**	**TMC435 150mg 24 Wks + PR48**	**TMC435 150mg 48 Wks + PR48**	**Placebo 48Wks + PR48**
Number of Participants Analyzed [units: participants]	**66**	**65**	**66**	**66**	**68**	**65**	**66**
The Percentage of Participants Achieving a Sustained Virologic Response at the End of							

Treatment (EOT) and 24 Weeks After the EOT (SVR24) [units: Percentage of participants]	**69.7**	**66.2**	**60.6**	**66.7**	**72.1**	**80.0**	**22.7**

No statistical analysis provided for The Percentage of Participants Achieving a Sustained Virologic Response at the End of Treatment (EOT) and 24 Weeks After the EOT (SVR24)

2. Secondary: The Percentage of Participants With a Greater Than 2 log10 Drop in Plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels at Time Points During Treatment [Time Frame: Weeks, 2, 4, 8, and 12]

Measure Type	Secondary
Measure Title	The Percentage of Participants With a Greater Than 2 log10 Drop in Plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels at Time Points During Treatment
Measure Description	The table below shows the percentage of participants in each treatment group who achieved a greater than 2 log10 drop in plasma levels of HCV RNA at selected time points during treatment.
Time Frame	Weeks, 2, 4, 8, and 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: Participants who received at least 1 dose of study medication were included.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	**TMC435 100mg 24 Wks + PR48**	**TMC435 100mg 48 Wks + PR48**	**TMC435 150mg 12 Wks + PR48**	**TMC435 150mg 24 Wks + PR48**	**TMC435 150mg 48 Wks + PR48**	**Placebo 48Wks + PR48**
Number of Participants Analyzed [units: participants]	**66**	**65**	**66**	**66**	**68**	**65**	**66**
The Percentage of Participants With a Greater Than 2 log10 Drop in Plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels at Time Points During							

Treatment [units: Percentage of participants]							
Week 2	**97.0**	**93.8**	**97.0**	**100.0**	**95.6**	**96.9**	**24.2**
Week 4	**92.4**	**93.8**	**92.4**	**97.0**	**91.2**	**96.9**	**36.4**
Week 8	**92.4**	**89.2**	**89.4**	**93.9**	**91.2**	**95.4**	**57.6**
Week 12	**90.9**	**87.7**	**84.8**	**92.4**	**91.2**	**92.3**	**60.6**

No statistical analysis provided for The Percentage of Participants With a Greater Than 2 log10 Drop in Plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels at Time Points During Treatment

3. Secondary: The Percentage of Participants Achieving Plasma Levels of Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable During Treatment and Follow-up [Time Frame: Weeks, 2, 4, 8, 12, 24, 36, 48, 60, 72 and EOT (up to Week 48)]

Measure Type	Secondary
Measure Title	The Percentage of Participants Achieving Plasma Levels of Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable During Treatment and Follow-up
Measure Description	The table below shows the percentage of participants in each treatment who achieved plasma HCV RNA levels of <25 IU/mL undetectable at selected time points during treatment and follow-up and at the end of treatment (EOT).
Time Frame	Weeks, 2, 4, 8, 12, 24, 36, 48, 60, 72 and EOT (up to Week 48)
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: Participants who received at least 1 dose of study medication were included.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	**TMC435 100mg 24 Wks + PR48**	**TMC435 100mg 48 Wks + PR48**	**TMC435 150mg 12 Wks + PR48**	**TMC435 150mg 24 Wks + PR48**	**TMC435 150mg 48 Wks + PR48**	**Placebo 48Wks + PR48**

Number of Participants Analyzed [units: participants]	**66**	**65**	**66**	**66**	**68**	**65**	**66**
The Percentage of Participants Achieving Plasma Levels of Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable During Treatment and Follow-up [units: Percentage of participants]							
Week 2	**22.7**	**18.5**	**15.2**	**24.2**	**32.4**	**27.7**	**0.0**
Week 4	**66.7**	**58.5**	**53.0**	**62.1**	**67.6**	**66.2**	**1.5**
Week 8	**77.3**	**75.4**	**77.3**	**84.8**	**83.8**	**83.1**	**7.6**
Week 12	**81.8**	**73.8**	**72.7**	**80.3**	**85.3**	**83.1**	**19.7**
Week 24	**81.8**	**75.4**	**78.8**	**83.3**	**86.8**	**86.2**	**42.4**
Week 36	**78.8**	**73.8**	**78.8**	**80.3**	**83.8**	**81.5**	**39.4**
Week 48	**81.8**	**73.8**	**74.2**	**75.8**	**80.9**	**81.5**	**37.9**
Week 60	**69.7**	**67.7**	**59.1**	**66.7**	**72.1**	**76.9**	**22.7**
Week 72	**69.7**	**66.2**	**60.6**	**66.7**	**73.5**	**80.0**	**22.7**
EOT (up to Week 48)	**80.3**	**78.5**	**80.3**	**80.3**	**83.8**	**86.2**	**40.9**

No statistical analysis provided for The Percentage of Participants Achieving Plasma Levels of Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable During Treatment and Follow-up

4. Secondary: The Percentage of Participants Achieving Plasma Levels of Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Detectable or Undetectable During Treatment and Follow-up [Time Frame: Weeks, 2, 4, 8, 12, 24, 36, 48, 60, 72, and EOT (up to Week 48)]

Measure Type	Secondary
Measure Title	The Percentage of Participants Achieving Plasma Levels of Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Detectable or Undetectable During Treatment and Follow-up
Measure Description	The table below shows the percentage of participants in each treatment group who achieved plasma HCV RNA levels below the limit of quantification defined as less than 25 IU/mL (detectable or undetectable) at selected time points during treatment, follow-up, and at the end of treatment (EOT).
Time Frame	Weeks, 2, 4, 8, 12, 24, 36, 48, 60, 72, and EOT (up to Week 48)
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: Participants who received at least 1 dose of study medication were included.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R)

	twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	TMC435 100mg 24 Wks + PR48	TMC435 100mg 48 Wks + PR48	TMC435 150mg 12 Wks + PR48	TMC435 150mg 24 Wks + PR48	TMC435 150mg 48 Wks + PR48	Placebo 48Wks + PR48
Number of Participants Analyzed [units: participants]	**66**	**65**	**66**	**66**	**68**	**65**	**66**
The Percentage of Participants Achieving Plasma Levels of Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Detectable or Undetectable During Treatment and Follow-up [units: Percentage of Participants]							
Week 2	**60.6**	**55.4**	**54.5**	**63.6**	**60.3**	**66.2**	**3.0**
Week 4	**78.8**	**72.3**	**81.8**	**86.4**	**82.4**	**86.2**	**3.0**
Week 8	**87.9**	**81.5**	**84.8**	**87.9**	**89.7**	**87.7**	**12.1**
Week 12	**87.9**	**81.5**	**83.3**	**89.4**	**88.2**	**89.2**	**34.8**
Week 24	**84.8**	**78.5**	**80.3**	**86.4**	**86.8**	**89.2**	**50.0**
Week 36	**81.8**	**73.8**	**78.8**	**81.8**	**86.8**	**84.6**	**43.9**
Week 48	**83.3**	**73.8**	**74.2**	**78.8**	**82.4**	**81.5**	**40.9**
Week 60	**71.2**	**67.7**	**60.6**	**66.7**	**72.1**	**78.5**	**22.7**
Week 72	**69.7**	**66.2**	**60.6**	**66.7**	**73.5**	**80.0**	**22.7**
EOT (up to Week 48)	**86.4**	**81.5**	**81.8**	**89.4**	**89.7**	**89.2**	**47.0**

No statistical analysis provided for The Percentage of Participants Achieving Plasma Levels of Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Detectable or Undetectable During Treatment and Follow-up

5. Secondary: The Percentage of Participants Achieving a Rapid Virologic Response (RVR) [Time Frame: Week 4]

Measure Type	Secondary
Measure Title	The Percentage of Participants Achieving a Rapid Virologic Response (RVR)
Measure Description	The table below shows the percentage of participants in each treatment group who achieved a RVR, defined as having an undetectable plasma Hepatitis C virus ribonucleic acid level after receiving 4 weeks of treatment.
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.
Intent-to-treat: Participants who received at least 1 dose of study medication were included.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	TMC435 100mg 24 Wks + PR48	TMC435 100mg 48 Wks + PR48	TMC435 150mg 12 Wks + PR48	TMC435 150mg 24 Wks + PR48	TMC435 150mg 48 Wks + PR48	Placebo 48Wks + PR48
Number of Participants Analyzed [units: participants]	**66**	**65**	**66**	**66**	**68**	**65**	**66**
The Percentage of Participants Achieving a Rapid Virologic Response (RVR) [units: Percentage of participants]	**66.7**	**58.5**	**53.0**	**62.1**	**67.6**	**66.2**	**1.5**

No statistical analysis provided for The Percentage of Participants Achieving a Rapid Virologic Response (RVR)

6. Secondary: The Percentage of Participants Achieving an Early Virologic Response (EVR) [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	The Percentage of Participants Achieving an Early Virologic Response (EVR)
Measure Description	The table below shows the percentage of participants who achieved an EVR, defined as having a greater than or equal to 2 log10 reduction in plasma Hepatitis C virus ribonucleic acid from baseline at Week 12.
Time Frame	Week 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: Participants who received at least 1 dose of study medication were included.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R)

	twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	TMC435 100mg 24 Wks + PR48	TMC435 100mg 48 Wks + PR48	TMC435 150mg 12 Wks + PR48	TMC435 150mg 24 Wks + PR48	TMC435 150mg 48 Wks + PR48	Placebo 48Wks + PR48
Number of Participants Analyzed [units: participants]	**66**	**65**	**66**	**66**	**68**	**65**	**66**
The Percentage of Participants Achieving an Early Virologic Response (EVR) [units: Percentage of participants]	**90.9**	**87.7**	**84.8**	**92.4**	**91.2**	**92.3**	**60.6**

No statistical analysis provided for The Percentage of Participants Achieving an Early Virologic Response (EVR)

7. Secondary: The Percentage of Participants Achieving a Complete Early Virologic Response (cEVR) [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	The Percentage of Participants Achieving a Complete Early Virologic Response (cEVR)
Measure Description	The table below shows the percentage of participants in each treatment group who had a cEVR, defined as having undetectable plasma levels of Hepatitis C virus ribonucleic acid at Week 12.
Time Frame	Week 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: Participants who received at least 1 dose of study medication were included.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R)

	twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	TMC435 100mg 24 Wks + PR48	TMC435 100mg 48 Wks + PR48	TMC435 150mg 12 Wks + PR48	TMC435 150mg 24 Wks + PR48	TMC435 150mg 48 Wks + PR48	Placebo 48Wks + PR48
Number of Participants Analyzed [units: participants]	**66**	**65**	**66**	**66**	**68**	**65**	**66**
The Percentage of Participants Achieving a Complete Early Virologic Response (cEVR) [units: Percentage of participants]	**81.8**	**73.8**	**72.7**	**80.3**	**85.3**	**83.1**	**19.7**

No statistical analysis provided for The Percentage of Participants Achieving a Complete Early Virologic Response (cEVR)

8. Secondary: The Percentage of Participants Achieving a Sustained Virologic Response 12 Weeks After the Planned End of Treatment (SVR12) [Time Frame: Week 60]

Measure Type	Secondary
Measure Title	The Percentage of Participants Achieving a Sustained Virologic Response 12 Weeks After the Planned End of Treatment (SVR12)
Measure Description	The table below shows the percentage of participants in the overall population who achieved undetectable plasma Hepatitis C virus ribonucleic acid levels at the end of treatment (EOT) and 12 Weeks after the planned EOT.
Time Frame	Week 60
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: Participants who received at least 1 dose of study medication were included.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.

TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	TMC435 100mg 24 Wks + PR48	TMC435 100mg 48 Wks + PR48	TMC435 150mg 12 Wks + PR48	TMC435 150mg 24 Wks + PR48	TMC435 150mg 48 Wks + PR48	Placebo 48Wks + PR48
Number of Participants Analyzed [units: participants]	**66**	**65**	**66**	**66**	**68**	**65**	**66**
The Percentage of Participants Achieving a Sustained Virologic Response 12 Weeks After the Planned End of Treatment (SVR12) [units: Percentage of participants]	**69.7**	**67.7**	**60.6**	**66.7**	**72.1**	**80.0**	**22.7**

No statistical analysis provided for The Percentage of Participants Achieving a Sustained Virologic Response 12 Weeks After the Planned End of Treatment (SVR12)

9. Secondary: The Percentage of Participants With Viral Breakthrough [Time Frame: EOT (up to Week 48)]

Measure Type	Secondary
Measure Title	The Percentage of Participants With Viral Breakthrough
Measure Description	The table below shows the percentage of participants in the overall population in each treatment group during the treatment period who experienced viral breakthrough, defined as a confirmed increase of greater than 1 log10 IU/mL in Hepatitis C virus (HCV) ribonucleic acid (RNA) from the lowest level reached or a confirmed HCV RNA of > 100 IU/mL in participants whose HCV RNA had previously been below the lower limit of quantification (i.e., less than 25 IU/mL detectable or undetectable).
Time Frame	EOT (up to Week 48)
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: Participants who received at least 1 dose of study medication were included.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R)

	twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	TMC435 100mg 24 Wks + PR48	TMC435 100mg 48 Wks + PR48	TMC435 150mg 12 Wks + PR48	TMC435 150mg 24 Wks + PR48	TMC435 150mg 48 Wks + PR48	Placebo 48Wks + PR48
Number of Participants Analyzed [units: participants]	**66**	**65**	**66**	**66**	**68**	**65**	**66**
The Percentage of Participants With Viral Breakthrough [units: Percentage of participants]	**10.6**	**13.8**	**13.6**	**9.1**	**10.3**	**7.7**	**1.5**

No statistical analysis provided for The Percentage of Participants With Viral Breakthrough

10. Secondary: The Percentage of Participants With Viral Relapse [Time Frame: Up to Week 72]

Measure Type	Secondary
Measure Title	The Percentage of Participants With Viral Relapse
Measure Description	The table below shows the percentage of participants in the overall population who had viral relapse, defined as confirmed detectable Hepatitis C virus (HCV) ribonucleic acid (RNA) during the follow-up period in participants with HCV RNA less than 25 IU/mL undetectable at end of treatment.
Time Frame	Up to Week 72
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: Participants who received at least 1 dose of study medication were included.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily

	for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	TMC435 100mg 24 Wks + PR48	TMC435 100mg 48 Wks + PR48	TMC435 150mg 12 Wks + PR48	TMC435 150mg 24 Wks + PR48	TMC435 150mg 48 Wks + PR48	Placebo 48Wks + PR48
Number of Participants Analyzed [units: participants]	**66**	**65**	**66**	**66**	**68**	**65**	**66**
The Percentage of Participants With Viral Relapse [units: Percentage of participants]	**9.3**	**13.7**	**18.0**	**11.8**	**14.0**	**5.5**	**44.4**

No statistical analysis provided for The Percentage of Participants With Viral Relapse

11. Secondary: The Number of Participants Who Achieved Normalized Alanine Aminotransferase (ALT) Levels at the End of Treatment (EOT) [Time Frame: EOT (up to Week 48)]

Measure Type	Secondary
Measure Title	The Number of Participants Who Achieved Normalized Alanine Aminotransferase (ALT) Levels at the End of Treatment (EOT)
Measure Description	The table below shows the number of participants with abnormal ALT levels at Baseline who achieved the normal ALT levels at the EOT (up to Week 48).
Time Frame	EOT (up to Week 48)
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: Participants who received at least 1 dose of study medication were included.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
All TMC435	Participants in all 6 TMC435 treatment groups combined.

Measured Values

	TMC435	TMC435	TMC435	TMC435	TMC435	TMC435	

	100mg 12 Wks + PR48	100mg 24 Wks + PR48	100mg 48 Wks + PR48	150mg 12 Wks + PR48	150mg 24 Wks + PR48	150mg 48 Wks + PR48	All TMC435
Number of Participants Analyzed [units: participants]	**36**	**49**	**45**	**40**	**43**	**43**	**256**
The Number of Participants Who Achieved Normalized Alanine Aminotransferase (ALT) Levels at the End of Treatment (EOT) [units: Percentage of participants]	**26**	**37**	**31**	**23**	**31**	**33**	**181**

No statistical analysis provided for The Number of Participants Who Achieved Normalized Alanine Aminotransferase (ALT) Levels at the End of Treatment (EOT)

12. Secondary: Plasma Concentrations of TMC435 [Time Frame: 0 (predose, baseline) and 4, 8, 12, and 24 hours post-dose at Weeks 2, 4, 8, 12, 16, 24, and 48]

Measure Type	Secondary
Measure Title	Plasma Concentrations of TMC435
Measure Description	The table below shows median (range) predose plasma concentration (C0h) values and median (range) average steady-state plasma concentration (Css,av) values for TMC435 for participants in each of the 6 TMC435 treatment groups.
Time Frame	0 (predose, baseline) and 4, 8, 12, and 24 hours post-dose at Weeks 2, 4, 8, 12, 16, 24, and 48
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 received at least 1 dose of study medication with at least 1 post-baseline pharmacokinetic (PK) assessment were included in the PK analysis population.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	TMC435 100mg 24 Wks + PR48	TMC435 100mg 48 Wks + PR48	TMC435 150mg 12 Wks + PR48	TMC435 150mg 24 Wks + PR48	TMC435 150mg 48 Wks + PR48
Number of Participants						

Analyzed [units: participants]	**66**	**65**	**65**	**66**	**68**	**64**
Plasma Concentrations of TMC435 [units: ng/mL] Median (Full Range)						
C0h	**380.5 (34 to 3599)**	**411.3 (101 to 6943)**	**529.8 (62 to 4212)**	**1323.5 (37 to 12478)**	**1074.0 (110 to 14303)**	**886.1 (150 to 21825)**
Css,av	**691.1 (204 to 3960)**	**770.5 (344 to 7218)**	**892.0 (290 to 4580)**	**1960.9 (304 to 13047)**	**1792.3 (532 to 14892)**	**1606.9 (635 to 22417)**

No statistical analysis provided for Plasma Concentrations of TMC435

13. Secondary: Area Under the Plasma Concentration-time Curve From 0 to 24 Hours (AUC24h) for TMC435 [Time Frame: 0 (predose, baseline) and 4, 8, 12, and 24 hours post-dose at Weeks 2, 4, 8, 12, 16, 24, and 48]

Measure Type	Secondary
Measure Title	Area Under the Plasma Concentration-time Curve From 0 to 24 Hours (AUC24h) for TMC435
Measure Description	The table below shows the median (range) AUC24h values for TMC435 for participants in each TMC435 treatment group.
Time Frame	0 (predose, baseline) and 4, 8, 12, and 24 hours post-dose at Weeks 2, 4, 8, 12, 16, 24, and 48
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 received at least 1 dose of study medication with at least 1 post-baseline pharmacokinetic (PK) assessment were included in the PK analysis population.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Measured Values

	TMC435 100mg 12 Wks + PR48	**TMC435 100mg 24 Wks + PR48**	**TMC435 100mg 48 Wks + PR48**	**TMC435 150mg 12 Wks + PR48**	**TMC435 150mg 24 Wks + PR48**	**TMC435 150mg 48 Wks + PR48**

Number of Participants Analyzed [units: participants]	**66**	**65**	**65**	**66**	**68**	**64**
Area Under the Plasma Concentration-time Curve From 0 to 24 Hours (AUC24h) for TMC435 [units: ng.h/mL] Median (Full Range)	**16587.0 (4897 to 95030)**	**18492.5 (8252 to 173240)**	**21409.0 (6949 to 109920)**	**47061.8 (7301 to 313135)**	**43015.0 (12777 to 357415)**	**38564.5 (15233 to 538010)**

No statistical analysis provided for Area Under the Plasma Concentration-time Curve From 0 to 24 Hours (AUC24h) for TMC435

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Week 72
Additional Description	No text entered.

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Serious Adverse Events

	TMC435 100mg 12 Wks + PR48	**TMC435 100mg 24 Wks + PR48**	**TMC435 100mg 48 Wks + PR48**	**TMC435 150mg 12 Wks + PR48**	**TMC435 150mg 24 Wks + PR48**	**TMC435 150mg 48 Wks + PR48**	**Placebo 48Wks + PR48**
Total, serious adverse events							
# participants affected / at risk	**3/66 (4.55%)**	**5/65 (7.69%)**	**3/66 (4.55%)**	**7/66 (10.61%)**	**5/68 (7.35%)**	**8/65 (12.31%)**	**4/66 (6.06%)**
Blood and lymphatic system disorders							
Anaemia † 1							
# participants affected / at risk	**1/66 (1.52%)**	**0/65 (0.00%)**	**0/66 (0.00%)**	**0/66 (0.00%)**	**0/68 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**
Haemorrhagic anaemia † 1							

# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	1/66 (1.52%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Neutropenia † [1]							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	1/66 (1.52%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Pancytopenia † [1]							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	1/65 (1.54%)	0/66 (0.00%)
Gastrointestinal disorders							
Vomiting † [1]							
# participants affected / at risk	0/66 (0.00%)	1/65 (1.54%)	0/66 (0.00%)	0/66 (0.00%)	1/68 (1.47%)	0/65 (0.00%)	1/66 (1.52%)
Abdominal pain † [1]							
# participants affected / at risk	0/66 (0.00%)	1/65 (1.54%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Diarrhoea † [1]							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	1/68 (1.47%)	0/65 (0.00%)	0/66 (0.00%)
Enteritis † [1]							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	1/68 (1.47%)	0/65 (0.00%)	0/66 (0.00%)
Gastrointestinal pain † [1]							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	1/65 (1.54%)	0/66 (0.00%)
Periodontal disease † [1]							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	1/66 (1.52%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Haemorrhoids † [1]							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	1/66 (1.52%)
Nausea † [1]							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	1/66 (1.52%)
General disorders							
Non-cardiac chest pain † [1]							
# participants affected / at risk	0/66 (0.00%)	1/65 (1.54%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Pyrexia † [1]							
# participants affected / at risk	0/66 (0.00%)	1/65 (1.54%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Hepatobiliary disorders							
Cholecystitis * [1]							
# participants affected / at risk	1/66 (1.52%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	1/65 (1.54%)	0/66 (0.00%)
Infections and infestations							
Urinary tract infection * [1]							
# participants affected / at risk	0/66 (0.00%)	2/65 (3.08%)	0/66 (0.00%)	1/66 (1.52%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Cellulitis * [1]							
# participants affected /							0/66 (0.00%)

at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	1/68 (1.47%)	1/65 (1.54%)	
Clostridium difficile colitis * 1							
# participants affected / at risk	0/66 (0.00%)	1/65 (1.54%)	1/66 (1.52%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Gingival infection * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	1/66 (1.52%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Lung infection * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	1/66 (1.52%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Meningitis bacterial * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	1/66 (1.52%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Pneumonia * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	1/68 (1.47%)	0/65 (0.00%)	0/66 (0.00%)
Pneumonia bordetella * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	1/68 (1.47%)	0/65 (0.00%)	0/66 (0.00%)
Salpingitis * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	1/66 (1.52%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Sinusitis * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	1/68 (1.47%)	0/65 (0.00%)	0/66 (0.00%)
Lower respiratory tract infection * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	1/66 (1.52%)
Tuberculosis * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	1/66 (1.52%)
Injury, poisoning and procedural complications							
Overdose * 1							
# participants affected / at risk	1/66 (1.52%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Thermal burn * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	1/66 (1.52%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Investigations							
Weight decreased * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	1/66 (1.52%)
Metabolism and nutrition disorders							
Dehydration * 1							
# participants affected / at risk	0/66 (0.00%)	1/65 (1.54%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	1/65 (1.54%)	0/66 (0.00%)

Diabetes mellitus * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	1/68 (1.47%)	0/65 (0.00%)	0/66 (0.00%)
Musculoskeletal and connective tissue disorders							
Intervertebral disc protrusion * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	1/65 (1.54%)	0/66 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Cervix carcinoma * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	1/65 (1.54%)	0/66 (0.00%)
Hepatic neoplasm malignant * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	1/65 (1.54%)	0/66 (0.00%)
Neurilemmoma benign * 1							
# participants affected / at risk	0/66 (0.00%)	1/65 (1.54%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Rectal cancer * 1							
# participants affected / at risk	1/66 (1.52%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Histiocytosis haematophagic * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	1/66 (1.52%)
Nervous system disorders							
Brain injury * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	1/66 (1.52%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Cerebral haemorrhage * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	1/66 (1.52%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Coma * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	1/66 (1.52%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Headache * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	1/65 (1.54%)	0/66 (0.00%)
Migraine * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	1/66 (1.52%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Viith nerve paralysis * 1							
# participants affected / at risk	0/66 (0.00%)	1/65 (1.54%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	0/66 (0.00%)
Sciatica * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	0/66 (0.00%)	0/66 (0.00%)	0/68 (0.00%)	0/65 (0.00%)	1/66 (1.52%)

Psychiatric disorders							
Alcohol abuse * 1							
# participants affected / at risk	**0/66 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**	**0/66 (0.00%)**	**0/68 (0.00%)**	**1/65 (1.54%)**	**0/66 (0.00%)**
Suicide attempt * 1							
# participants affected / at risk	**1/66 (1.52%)**	**0/65 (0.00%)**	**0/66 (0.00%)**	**0/66 (0.00%)**	**0/68 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**
Renal and urinary disorders							
Nephrolithiasis * 1							
# participants affected / at risk	**0/66 (0.00%)**	**1/65 (1.54%)**	**0/66 (0.00%)**	**0/66 (0.00%)**	**0/68 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**
Reproductive system and breast disorders							
Metrorrhagia * 1							
# participants affected / at risk	**0/66 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**	**1/66 (1.52%)**	**0/68 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**
Pelvic adhesions * 1							
# participants affected / at risk	**0/66 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**	**1/66 (1.52%)**	**0/68 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**
Respiratory, thoracic and mediastinal disorders							
Epistaxis * 1							
# participants affected / at risk	**0/66 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**	**0/66 (0.00%)**	**0/68 (0.00%)**	**1/65 (1.54%)**	**0/66 (0.00%)**
Pulmonary embolism * 1							
# participants affected / at risk	**0/66 (0.00%)**	**0/65 (0.00%)**	**1/66 (1.52%)**	**0/66 (0.00%)**	**0/68 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**
Skin and subcutaneous tissue disorders							
Drug eruption * 1							
# participants affected / at risk	**0/66 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**	**0/66 (0.00%)**	**1/68 (1.47%)**	**0/65 (0.00%)**	**0/66 (0.00%)**
Vascular disorders							
Hypertension * 1							
# participants affected / at risk	**0/66 (0.00%)**	**0/65 (0.00%)**	**0/66 (0.00%)**	**0/66 (0.00%)**	**0/68 (0.00%)**	**1/65 (1.54%)**	**0/66 (0.00%)**

† Events were collected by systematic assessment
* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 14.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Week 72
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
TMC435 100mg 12 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo with PR for 36 weeks.
TMC435 100mg 24 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed by Placebo with PR for 24 weeks.
TMC435 100mg 48 Wks + PR48	Participants received TMC435 100 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
TMC435 150mg 12 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 12 weeks followed by Placebo and PR for 36 weeks.
TMC435 150mg 24 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 24 weeks followed Placebo and PR for 24 weeks.
TMC435 150mg 48 Wks + PR48	Participants received TMC435 150 mg once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.
Placebo 48Wks + PR48	Participants received Placebo once daily with Peg-IFN-alfa-2a (P) once weekly and ribavirin (R) twice daily for 48 weeks.

Other Adverse Events

	TMC435 100mg 12 Wks + PR48	TMC435 100mg 24 Wks + PR48	TMC435 100mg 48 Wks + PR48	TMC435 150mg 12 Wks + PR48	TMC435 150mg 24 Wks + PR48	TMC435 150mg 48 Wks + PR48	Placebo 48Wks + PR48
Total, other (not including serious) adverse events							
# participants affected / at risk	**63/66 (95.45%)**	**61/65 (93.85%)**	**65/66 (98.48%)**	**63/66 (95.45%)**	**65/68 (95.59%)**	**63/65 (96.92%)**	**63/66 (95.45%)**
Blood and lymphatic system disorders							
Neutropenia * 1							
# participants affected / at risk	**16/66 (24.24%)**	**15/65 (23.08%)**	**15/66 (22.73%)**	**17/66 (25.76%)**	**18/68 (26.47%)**	**20/65 (30.77%)**	**11/66 (16.67%)**
Anaemia * 1							
# participants affected / at risk	**14/66 (21.21%)**	**11/65 (16.92%)**	**12/66 (18.18%)**	**10/66 (15.15%)**	**16/68 (23.53%)**	**13/65 (20.00%)**	**13/66 (19.70%)**
Thrombocytopenia * 1							
# participants affected / at risk	**2/66 (3.03%)**	**2/65 (3.08%)**	**1/66 (1.52%)**	**7/66 (10.61%)**	**6/68 (8.82%)**	**5/65 (7.69%)**	**3/66 (4.55%)**
Leukopenia * 1							
# participants affected / at risk	**0/66 (0.00%)**	**1/65 (1.54%)**	**1/66 (1.52%)**	**4/66 (6.06%)**	**3/68 (4.41%)**	**4/65 (6.15%)**	**2/66 (3.03%)**
Ear and labyrinth disorders							
Vertigo * 1							
# participants affected / at risk	**2/66 (3.03%)**	**4/65 (6.15%)**	**4/66 (6.06%)**	**0/66 (0.00%)**	**3/68 (4.41%)**	**1/65 (1.54%)**	**4/66 (6.06%)**

Endocrine disorders							
Hypothyroidism * 1							
# participants affected / at risk	**1/66 (1.52%)**	**1/65 (1.54%)**	**2/66 (3.03%)**	**0/66 (0.00%)**	**4/68 (5.88%)**	**1/65 (1.54%)**	**1/66 (1.52%)**
Eye disorders							
Dry eye * 1							
# participants affected / at risk	**1/66 (1.52%)**	**4/65 (6.15%)**	**4/66 (6.06%)**	**0/66 (0.00%)**	**3/68 (4.41%)**	**2/65 (3.08%)**	**1/66 (1.52%)**
Gastrointestinal disorders							
Nausea * 1							
# participants affected / at risk	**17/66 (25.76%)**	**10/65 (15.38%)**	**20/66 (30.30%)**	**20/66 (30.30%)**	**11/68 (16.18%)**	**17/65 (26.15%)**	**14/66 (21.21%)**
Diarrhoea * 1							
# participants affected / at risk	**9/66 (13.64%)**	**11/65 (16.92%)**	**13/66 (19.70%)**	**9/66 (13.64%)**	**8/68 (11.76%)**	**9/65 (13.85%)**	**13/66 (19.70%)**
Dry mouth * 1							
# participants affected / at risk	**6/66 (9.09%)**	**4/65 (6.15%)**	**4/66 (6.06%)**	**3/66 (4.55%)**	**4/68 (5.88%)**	**2/65 (3.08%)**	**2/66 (3.03%)**
Abdominal pain * 1							
# participants affected / at risk	**3/66 (4.55%)**	**4/65 (6.15%)**	**1/66 (1.52%)**	**2/66 (3.03%)**	**6/68 (8.82%)**	**5/65 (7.69%)**	**3/66 (4.55%)**
Vomiting * 1							
# participants affected / at risk	**3/66 (4.55%)**	**2/65 (3.08%)**	**5/66 (7.58%)**	**6/66 (9.09%)**	**3/68 (4.41%)**	**2/65 (3.08%)**	**5/66 (7.58%)**
Abdominal pain upper * 1							
# participants affected / at risk	**2/66 (3.03%)**	**2/65 (3.08%)**	**4/66 (6.06%)**	**5/66 (7.58%)**	**4/68 (5.88%)**	**0/65 (0.00%)**	**2/66 (3.03%)**
Dyspepsia * 1							
# participants affected / at risk	**1/66 (1.52%)**	**3/65 (4.62%)**	**3/66 (4.55%)**	**1/66 (1.52%)**	**4/68 (5.88%)**	**3/65 (4.62%)**	**1/66 (1.52%)**
Gastrooesophageal reflux disease * 1							
# participants affected / at risk	**2/66 (3.03%)**	**1/65 (1.54%)**	**2/66 (3.03%)**	**1/66 (1.52%)**	**3/68 (4.41%)**	**4/65 (6.15%)**	**0/66 (0.00%)**
Toothache * 1							
# participants affected / at risk	**1/66 (1.52%)**	**4/65 (6.15%)**	**2/66 (3.03%)**	**2/66 (3.03%)**	**2/68 (2.94%)**	**2/65 (3.08%)**	**2/66 (3.03%)**
Constipation * 1							
# participants affected / at risk	**2/66 (3.03%)**	**4/65 (6.15%)**	**2/66 (3.03%)**	**0/66 (0.00%)**	**0/68 (0.00%)**	**2/65 (3.08%)**	**0/66 (0.00%)**

Aphthous stomatitis * 1							
# participants affected / at risk	**0/66 (0.00%)**	**1/65 (1.54%)**	**4/66 (6.06%)**	**0/66 (0.00%)**	**2/68 (2.94%)**	**0/65 (0.00%)**	**0/66 (0.00%)**
Abdominal distension * 1							
# participants affected / at risk	**0/66 (0.00%)**	**1/65 (1.54%)**	**4/66 (6.06%)**	**1/66 (1.52%)**	**0/68 (0.00%)**	**0/65 (0.00%)**	**1/66 (1.52%)**
General disorders							
Fatigue * 1							
# participants affected / at risk	**30/66 (45.45%)**	**28/65 (43.08%)**	**34/66 (51.52%)**	**26/66 (39.39%)**	**28/68 (41.18%)**	**28/65 (43.08%)**	**29/66 (43.94%)**
Influenza like illness * 1							
# participants affected / at risk	**23/66 (34.85%)**	**24/65 (36.92%)**	**21/66 (31.82%)**	**16/66 (24.24%)**	**18/68 (26.47%)**	**14/65 (21.54%)**	**13/66 (19.70%)**
Asthenia * 1							
# participants affected / at risk	**6/66 (9.09%)**	**16/65 (24.62%)**	**11/66 (16.67%)**	**16/66 (24.24%)**	**16/68 (23.53%)**	**19/65 (29.23%)**	**7/66 (10.61%)**
Pyrexia * 1							
# participants affected / at risk	**6/66 (9.09%)**	**10/65 (15.38%)**	**13/66 (19.70%)**	**14/66 (21.21%)**	**17/68 (25.00%)**	**9/65 (13.85%)**	**9/66 (13.64%)**
Irritability * 1							
# participants affected / at risk	**9/66 (13.64%)**	**8/65 (12.31%)**	**10/66 (15.15%)**	**8/66 (12.12%)**	**10/68 (14.71%)**	**8/65 (12.31%)**	**7/66 (10.61%)**
Chills * 1							
# participants affected / at risk	**7/66 (10.61%)**	**4/65 (6.15%)**	**4/66 (6.06%)**	**6/66 (9.09%)**	**6/68 (8.82%)**	**7/65 (10.77%)**	**6/66 (9.09%)**
Injection site erythema * 1							
# participants affected / at risk	**3/66 (4.55%)**	**4/65 (6.15%)**	**1/66 (1.52%)**	**3/66 (4.55%)**	**3/68 (4.41%)**	**7/65 (10.77%)**	**2/66 (3.03%)**
Injection site reaction * 1							
# participants affected / at risk	**3/66 (4.55%)**	**2/65 (3.08%)**	**4/66 (6.06%)**	**2/66 (3.03%)**	**3/68 (4.41%)**	**1/65 (1.54%)**	**0/66 (0.00%)**
Pain * 1							
# participants affected / at risk	**1/66 (1.52%)**	**2/65 (3.08%)**	**1/66 (1.52%)**	**4/66 (6.06%)**	**2/68 (2.94%)**	**3/65 (4.62%)**	**4/66 (6.06%)**
Hepatobiliary disorders							
Hyperbilirubinaemia * 1							
# participants							

affected / at risk	3/66 (4.55%)	1/65 (1.54%)	2/66 (3.03%)	2/66 (3.03%)	7/68 (10.29%)	3/65 (4.62%)	1/66 (1.52%)
Infections and infestations							
Nasopharyngitis * 1							
# participants affected / at risk	1/66 (1.52%)	7/65 (10.77%)	1/66 (1.52%)	2/66 (3.03%)	4/68 (5.88%)	3/65 (4.62%)	0/66 (0.00%)
Urinary tract infection * 1							
# participants affected / at risk	1/66 (1.52%)	3/65 (4.62%)	3/66 (4.55%)	3/66 (4.55%)	4/68 (5.88%)	1/65 (1.54%)	5/66 (7.58%)
Sinusitis * 1							
# participants affected / at risk	7/66 (10.61%)	0/65 (0.00%)	3/66 (4.55%)	1/66 (1.52%)	3/68 (4.41%)	0/65 (0.00%)	3/66 (4.55%)
Upper respiratory tract infection * 1							
# participants affected / at risk	4/66 (6.06%)	1/65 (1.54%)	0/66 (0.00%)	2/66 (3.03%)	0/68 (0.00%)	3/65 (4.62%)	2/66 (3.03%)
Injury, poisoning and procedural complications							
Sunburn * 1							
# participants affected / at risk	1/66 (1.52%)	0/65 (0.00%)	2/66 (3.03%)	2/66 (3.03%)	0/68 (0.00%)	5/65 (7.69%)	0/66 (0.00%)
Investigations							
Weight decreased * 1							
# participants affected / at risk	4/66 (6.06%)	3/65 (4.62%)	3/66 (4.55%)	5/66 (7.58%)	3/68 (4.41%)	7/65 (10.77%)	3/66 (4.55%)
Neutrophil count decreased * 1							
# participants affected / at risk	2/66 (3.03%)	5/65 (7.69%)	0/66 (0.00%)	2/66 (3.03%)	1/68 (1.47%)	2/65 (3.08%)	2/66 (3.03%)
Alanine aminotransferase increased * 1							
# participants affected / at risk	2/66 (3.03%)	2/65 (3.08%)	1/66 (1.52%)	1/66 (1.52%)	0/68 (0.00%)	4/65 (6.15%)	1/66 (1.52%)
Gamma-glutamyltransferase increased * 1							
# participants affected / at risk	0/66 (0.00%)	1/65 (1.54%)	0/66 (0.00%)	3/66 (4.55%)	4/68 (5.88%)	0/65 (0.00%)	1/66 (1.52%)
Metabolism and nutrition disorders							
Decreased appetite *							

[1]							
# participants affected / at risk	11/66 (16.67%)	11/65 (16.92%)	11/66 (16.67%)	13/66 (19.70%)	13/68 (19.12%)	10/65 (15.38%)	9/66 (13.64%)
Musculoskeletal and connective tissue disorders							
Myalgia [*1]							
# participants affected / at risk	16/66 (24.24%)	4/65 (6.15%)	6/66 (9.09%)	11/66 (16.67%)	11/68 (16.18%)	16/65 (24.62%)	12/66 (18.18%)
Arthralgia [*1]							
# participants affected / at risk	7/66 (10.61%)	5/65 (7.69%)	9/66 (13.64%)	15/66 (22.73%)	7/68 (10.29%)	7/65 (10.77%)	9/66 (13.64%)
Back pain [*1]							
# participants affected / at risk	2/66 (3.03%)	2/65 (3.08%)	2/66 (3.03%)	3/66 (4.55%)	9/68 (13.24%)	2/65 (3.08%)	8/66 (12.12%)
Muscle spasms [*1]							
# participants affected / at risk	4/66 (6.06%)	3/65 (4.62%)	1/66 (1.52%)	3/66 (4.55%)	4/68 (5.88%)	1/65 (1.54%)	4/66 (6.06%)
Nervous system disorders							
Headache [*1]							
# participants affected / at risk	18/66 (27.27%)	19/65 (29.23%)	23/66 (34.85%)	29/66 (43.94%)	26/68 (38.24%)	23/65 (35.38%)	24/66 (36.36%)
Dizziness [*1]							
# participants affected / at risk	1/66 (1.52%)	4/65 (6.15%)	7/66 (10.61%)	6/66 (9.09%)	4/68 (5.88%)	7/65 (10.77%)	6/66 (9.09%)
Disturbance in attention [*1]							
# participants affected / at risk	3/66 (4.55%)	8/65 (12.31%)	5/66 (7.58%)	1/66 (1.52%)	3/68 (4.41%)	5/65 (7.69%)	3/66 (4.55%)
Dysgeusia [*1]							
# participants affected / at risk	5/66 (7.58%)	2/65 (3.08%)	6/66 (9.09%)	6/66 (9.09%)	1/68 (1.47%)	2/65 (3.08%)	3/66 (4.55%)
Psychiatric disorders							
Insomnia [*1]							
# participants affected / at risk	11/66 (16.67%)	11/65 (16.92%)	16/66 (24.24%)	11/66 (16.67%)	20/68 (29.41%)	10/65 (15.38%)	9/66 (13.64%)
Depression [*1]							
# participants affected / at risk	7/66 (10.61%)	8/65 (12.31%)	8/66 (12.12%)	10/66 (15.15%)	6/68 (8.82%)	6/65 (9.23%)	6/66 (9.09%)
Sleep disorder [*1]							
# participants				7/66 (10.61%)			

affected / at risk	5/66 (7.58%)	2/65 (3.08%)	5/66 (7.58%)		2/68 (2.94%)	5/65 (7.69%)	2/66 (3.03%)
Anxiety * 1							
# participants affected / at risk	5/66 (7.58%)	2/65 (3.08%)	3/66 (4.55%)	2/66 (3.03%)	2/68 (2.94%)	3/65 (4.62%)	3/66 (4.55%)
Depressed mood * 1							
# participants affected / at risk	2/66 (3.03%)	2/65 (3.08%)	3/66 (4.55%)	0/66 (0.00%)	2/68 (2.94%)	5/65 (7.69%)	3/66 (4.55%)
Mood altered * 1							
# participants affected / at risk	2/66 (3.03%)	0/65 (0.00%)	3/66 (4.55%)	4/66 (6.06%)	0/68 (0.00%)	1/65 (1.54%)	2/66 (3.03%)
Respiratory, thoracic and mediastinal disorders							
Cough * 1							
# participants affected / at risk	10/66 (15.15%)	18/65 (27.69%)	13/66 (19.70%)	11/66 (16.67%)	8/68 (11.76%)	16/65 (24.62%)	8/66 (12.12%)
Dyspnoea * 1							
# participants affected / at risk	10/66 (15.15%)	9/65 (13.85%)	8/66 (12.12%)	4/66 (6.06%)	8/68 (11.76%)	10/65 (15.38%)	4/66 (6.06%)
Dyspnoea exertional * 1							
# participants affected / at risk	4/66 (6.06%)	4/65 (6.15%)	4/66 (6.06%)	2/66 (3.03%)	3/68 (4.41%)	3/65 (4.62%)	3/66 (4.55%)
Epistaxis * 1							
# participants affected / at risk	1/66 (1.52%)	3/65 (4.62%)	3/66 (4.55%)	4/66 (6.06%)	2/68 (2.94%)	1/65 (1.54%)	4/66 (6.06%)
Nasal dryness * 1							
# participants affected / at risk	0/66 (0.00%)	0/65 (0.00%)	4/66 (6.06%)	1/66 (1.52%)	1/68 (1.47%)	2/65 (3.08%)	1/66 (1.52%)
Oropharyngeal pain * 1							
# participants affected / at risk	2/66 (3.03%)	1/65 (1.54%)	0/66 (0.00%)	0/66 (0.00%)	3/68 (4.41%)	1/65 (1.54%)	5/66 (7.58%)
Skin and subcutaneous tissue disorders							
Pruritus * 1							
# participants affected / at risk	19/66 (28.79%)	26/65 (40.00%)	21/66 (31.82%)	20/66 (30.30%)	25/68 (36.76%)	24/65 (36.92%)	11/66 (16.67%)
Dry skin * 1							
# participants affected / at risk	9/66 (13.64%)	15/65 (23.08%)	12/66 (18.18%)	14/66 (21.21%)	10/68 (14.71%)	12/65 (18.46%)	10/66 (15.15%)
Rash * 1							

# participants affected / at risk	**8/66 (12.12%)**	**8/65 (12.31%)**	**6/66 (9.09%)**	**10/66 (15.15%)**	**13/68 (19.12%)**	**16/65 (24.62%)**	**9/66 (13.64%)**
Alopecia * 1							
# participants affected / at risk	**5/66 (7.58%)**	**3/65 (4.62%)**	**7/66 (10.61%)**	**7/66 (10.61%)**	**6/68 (8.82%)**	**7/65 (10.77%)**	**5/66 (7.58%)**
Erythema * 1							
# participants affected / at risk	**4/66 (6.06%)**	**5/65 (7.69%)**	**7/66 (10.61%)**	**3/66 (4.55%)**	**5/68 (7.35%)**	**2/65 (3.08%)**	**2/66 (3.03%)**
Eczema * 1							
# participants affected / at risk	**3/66 (4.55%)**	**3/65 (4.62%)**	**5/66 (7.58%)**	**3/66 (4.55%)**	**0/68 (0.00%)**	**1/65 (1.54%)**	**2/66 (3.03%)**
Photosensitivity reaction * 1							
# participants affected / at risk	**0/66 (0.00%)**	**1/65 (1.54%)**	**2/66 (3.03%)**	**1/66 (1.52%)**	**3/68 (4.41%)**	**7/65 (10.77%)**	**1/66 (1.52%)**
Night sweats * 1							
# participants affected / at risk	**1/66 (1.52%)**	**1/65 (1.54%)**	**5/66 (7.58%)**	**1/66 (1.52%)**	**1/68 (1.47%)**	**1/65 (1.54%)**	**3/66 (4.55%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 14.0

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

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.

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Lenz O, Verbinnen T, Fevery B, Tambuyzer L, Vijgen L, Peeters M, Buelens A, Ceulemans H, Beumont M, Picchio G, De Meyer S. Virology analyses of HCV isolates from genotype 1-infected patients treated with simeprevir plus peginterferon/ribavirin in Phase IIb/III studies. J Hepatol. 2015 May;62(5):1008-14. doi: 10.1016/j.jhep.2014.11.032. Epub 2014 Nov 28.

Zeuzem S, Berg T, Gane E, Ferenci P, Foster GR, Fried MW, Hezode C, Hirschfield GM, Jacobson I, Nikitin I, Pockros PJ, Poordad F, Scott J, Lenz O, Peeters M, Sekar V, De Smedt G, Sinha R, Beumont-Mauviel M. Simeprevir increases rate of sustained virologic response among treatment-experienced patients with HCV genotype-1 infection: a phase IIb trial. Gastroenterology. 2014 Feb;146(2):430-41.e6. doi: 10.1053/j.gastro.2013.10.058. Epub 2013 Nov 1.

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