An Efficacy, Safety, and Tolerability Study of TMC435 in Treatment-naive, Genotype 1 Hepatitis C-infected Participants (QUEST-2)

This study has been completed.

Sponsor:
Janssen R&D Ireland

Information provided by (Responsible Party):
Janssen R&D Ireland

ClinicalTrials.gov Identifier:
NCT01290679

First received: January 7, 2011
Last updated: June 10, 2014
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History of Changes

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Results First Received: February 3, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Condition:	Hepatitis **C**
Interventions:	Drug: Placebo Drug: **TMC435** Drug: Peginterferon alpha-2a or Peginterferon alpha-2b (PegIFNα-2a/b) Drug: Ribavirin (RBV)

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 from 18 January 2011 to 5 February 2013. The study was conducted at 76 sites in 14 countries.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
393 participants were randomly allocated to the 2 treatment arms. 391 participants received at least 1 dose of study medication and were included in the intent-to-treat analysis set.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Participant Flow: Overall Study

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
STARTED	257 [1]	134 [1]
COMPLETED	241	113
NOT COMPLETED	16	21
Adverse Event	2	0
Lost to Follow-up	8	10
Protocol Violation	0	1
Withdrawal by Subject	6	5
Subject Entered Another Trial	0	5

[1] Not including 1 participant was randomized to this group, but never received treatment.

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 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).
Total	Total of all reporting groups

Baseline Measures

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48	Total
Number of Participants [units: participants]	257	134	391
Age [units: years] Median (Full Range)	46 (18 to 73)	47 (18 to 73)	47 (18 to 73)
Gender [units: participants]			
Female	117	57	174
Male	140	77	217

Outcome Measures

Hide All Outcome Measures

1. Primary: The Percentage of Participants Achieving a Sustained Virologic Response 12 Weeks After the Planned End of Treatment (SVR12) [Time Frame: Week 36 or Week 60]

Measure Type	Primary

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 each treatment group who achieved a SVR12, defined as the percentage of participants with undetectable plasma Hepatitis C virus ribonucleic acid 12 weeks after planned end of treatment.
Time Frame	Week 36 or 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
The Percentage of Participants Achieving a Sustained Virologic Response 12 Weeks After the Planned End of Treatment (SVR12) [units: Percentage of participants]	**81.3**	**50.0**

Statistical Analysis 1 for The Percentage of Participants Achieving a Sustained Virologic Response 12 Weeks After the Planned End of Treatment (SVR12)

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
Difference in proportions of SVR12 [4]	32.2
95% Confidence Interval	(23.3 to 41.2)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis is there is no difference in proportions of SVR12 between the treatment groups.
[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:
	No text entered.

2. Secondary: The Percentage of Participants Achieving a Sustained Virologic Response at Week 72 (SVRW72) [Time Frame: Week 72]

Measure Type	Secondary
Measure Title	The Percentage of Participants Achieving a Sustained Virologic Response at Week 72 (SVRW72)
Measure Description	The table below shows the percentage of participants in each treatment group who achieved a SVRW72, defined as the percentage of participants with undetectable plasma Hepatitis C virus ribonucleic acid levels at end of treatment (EOT) and at Week 72.
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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
The Percentage of Participants Achieving a Sustained Virologic Response at Week 72 (SVRW72) [units: Percentage of participants]	**78.6**	**50.0**

Statistical Analysis 1 for The Percentage of Participants Achieving a Sustained Virologic Response at Week 72 (SVRW72)

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
Difference in proportions of SVRW72 [4]	29.3
95% Confidence Interval	(20.2 to 38.5)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis is there is no difference in proportions of SVRW72 between the treatment groups.
[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:
	No text entered.

3. Secondary: The Percentage of Participants Who Achieved a Sustained Virologic Response 24 Weeks After the Planned End of Treatment (SVR24) [Time Frame: Week 48 or Week 72]

Measure Type	Secondary
Measure Title	The Percentage of Participants Who Achieved a Sustained Virologic Response 24 Weeks After the Planned End of Treatment (SVR24)
Measure Description	The table below shows the percentage of participants in each treatment group who achieved a SVR24, defined as the percentage of participants with undetectable plasma Hepatitis C virus ribonucleic acid levels 24 weeks after planned end of treatment.
Time Frame	Week 48 or 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
The Percentage of Participants Who Achieved a Sustained Virologic Response 24 Weeks After the Planned End of Treatment (SVR24) [units: Percentage of participants]	**80.5**	**50.0**

Statistical Analysis 1 for The Percentage of Participants Who Achieved a Sustained Virologic Response 24 Weeks After the Planned End of Treatment (SVR24)

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
Difference in proportions of SVR24 [4]	31.5
95% Confidence Interval	(22.5 to 40.5)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis is there is no difference in proportions of SVR24 between the treatment groups.
[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:
	No text entered.

4. Secondary: The Percentage of Participants Who Achieved a Sustained Virologic Response 4 Weeks After the Planned End of Treatment (SVR4) [Time Frame: Week 28 or Week 52]

Measure Type	Secondary
Measure Title	The Percentage of Participants Who Achieved a Sustained Virologic Response 4 Weeks After the Planned End of Treatment (SVR4)
Measure Description	The table below shows the percentage of participants in each treatment group who achieved a SVR4, defined as the percentage of participants with undetectable plasma Hepatitis C virus ribonucleic acid levels 4 weeks after planned end of treatment.
Time Frame	Week 28 or Week 52
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 intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
The Percentage of Participants Who Achieved a Sustained Virologic Response 4 Weeks After the Planned End of Treatment (SVR4) [units: Percentage of participants]	**84.8**	**53.0**

Statistical Analysis 1 for The Percentage of Participants Who Achieved a Sustained Virologic Response 4 Weeks After the Planned End of Treatment (SVR4)

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
Difference in proportions of SVR4 [4]	32.3
95% Confidence Interval	(23.5 to 41.0)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The null hypothesis is there is no difference in proportions of SVR4 between the treatment groups.

[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:
	No text entered.

5. Secondary: Change From Baseline in log10 Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) [Time Frame: Day 3, Week 1, Week 4, Week 12, Week 24, and Week 48]

Measure Type	Secondary
Measure Title	Change From Baseline in log10 Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA)
Measure Description	The table below shows changes from baseline in log10 HCV RNA.
Time Frame	Day 3, Week 1, Week 4, Week 12, Week 24, and 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
Change From Baseline in log10 Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) [units: log10 IU/mL] Mean ± Standard Error		
Day 3	**-3.60 ± 0.045**	**-1.22 ± 0.075**
Week 1	**-4.52 ± 0.043**	**-1.21 ± 0.094**
Week 4	**-5.28 ± 0.046**	**-2.72 ± 0.138**
Week 12	**-5.34 ± 0.053**	**-4.21 ± 0.129**
Week 24	**-5.27 ± 0.062**	**-4.93 ± 0.114**
Week 48	**-5.83 ± 0.074**	**-5.28 ± 0.084**

No statistical analysis provided for Change From Baseline in log10 Hepatitis C Virus (HCV) Ribonucleic Acid (RNA)

6. Secondary: Actual Values of log10 Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) [Time Frame: Day 3, Week 1, Week 4, Week 12, Week

24, and Week 48]

Measure Type	Secondary
Measure Title	Actual Values of log10 Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA)
Measure Description	The table below shows actual values of log10 HCV RNA levels.
Time Frame	Day 3, Week 1, Week 4, Week 12, Week 24, and 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
Actual Values of log10 Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) [units: log10 IU/mL] Mean ± Standard Error		
Day 3	**2.777 ± 0.050**	**5.165 ± 0.107**
Week 1	**1.852 ± 0.400**	**5.171 ± 0.129**
Week 4	**1.093 ± 0.027**	**3.657 ± 0.162**
Week 12	**1.027 ± 0.034**	**2.157 ± 0.141**
Week 24	**1.094 ± 0.049**	**1.388 ± 0.106**
Week 48	**1.015 ± 0.061**	**0.960 ± 0.005**

No statistical analysis provided for Actual Values of log10 Hepatitis C Virus (HCV) Ribonucleic Acid (RNA)

7. Secondary: Percentage of Participants With On-treatment Virologic Response at All Time Points [Time Frame: Day 3, Week 1, Week 2, Week 8, Week 16, Week 20, Week 28, Week 36, and Week 42]

Measure Type	Secondary
Measure Title	Percentage of Participants With On-treatment Virologic Response at All Time Points
Measure Description	The table below shows the percentage of participants with Hepatitis C Virus (HCV) ribonucleic acid (RNA) plasma levels below the limit of detection (ie, <25 IU/mL undetectable), the percentage of participants with a HCV RNA plasma level below the limit of quantification (ie, less than [<] 25 IU/mL detectable or undetectable), the percentage of participants with plasma levels of HCV RNA <100 IU/mL, the percentage of HCV-Infected participants with virologic responses of a greater than or equal to 2 log10 change from baseline in plasma levels of HCV RNA.
Time Frame	Day 3, Week 1, Week 2, Week 8, Week 16, Week 20, Week 28, Week 36, and Week 42
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 intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
Percentage of Participants With On-treatment Virologic Response at All Time Points [units: Percentage of participants]		
Day 3:<25 IU/mL undetectable	**0.4**	**0**
Week 1:<25 IU/mL undetectable	**6.3**	**1.5**
Week 2:<25 IU/mL undetectable	**31.7**	**3.8**
Week 8:<25 IU/mL undetectable	**93.7**	**31.3**
Week 16:<25 IU/mL undetectable	**96.3**	**65.5**
Week 20:<25 IU/mL undetectable	**95.9**	**68.2**
Week 28:<25 IU/mL undetectable	**66.7**	**88.0**
Week 36:<25 IU/mL undetectable	**100.0**	**95.3**
Week 42:<25 IU/mL undetectable	**100.0**	**95.0**
Day 3:<25 IU/mL detectable or undetectable	**4.7**	**0**
Week 1:<25 IU/mL detectable or undetectable	**37.0**	**2.3**
Week 2:<25 IU/mL detectable or undetectable	**80.7**	**12.0**
Week 8:<25 IU/mL detectable or undetectable	**98.0**	**45.0**
Week 16:<25 IU/mL detectable or undetectable	**98.0**	**73.5**
Week 20:<25 IU/mL detectable or undetectable	**97.1**	**79.1**
Week 28:<25 IU/mL detectable or undetectable	**77.8**	**97.8**
Week 36:<25 IU/mL detectable or undetectable	**100.0**	**98.8**
Week 42:<25 IU/mL detectable or undetectable	**100.0**	**100.0**
Day 3:<100 IU/mL	**15.3**	**1.5**
Week 1:<100 IU/mL	**65.7**	**6.0**
Week 2:<100 IU/mL	**92.0**	**14.3**
Week 8:<100 IU/mL	**98.8**	**50.4**
Week 16:<100 IU/mL	**98.8**	**77.0**
Week 20:<100 IU/mL	**98.0**	**83.6**
Week 28:<100 IU/mL	**77.8**	**97.8**
Week 36:<100 IU/mL	**100.0**	**98.8**
Week 42:<100 IU/mL	**100.0**	**100.0**

Day 3:> or = 2 log 10 change from baseline	**96.9**	**20.8**
Week 1:> or =2 log 10 change from baseline	**99.6**	**24.1**
Week 2:> or =2 log 10 change from baseline	**99.6**	**39.8**
Week 8:> or =2 log 10 change from baseline	**99.6**	**80.2**
Week 16:> or =2 log 10 change from baseline	**99.2**	**97.3**
Week 20:> or =2 log 10 change from baseline	**98.8**	**93.6**
Week 28:> or =2 log 10 change from baseline	**88.9**	**100.0**
Week 36:> or =2 log 10 change from baseline	**100.0**	**98.8**
Week 42:> or =2 log 10 change from baseline	**100.0**	**100.0**

No statistical analysis provided for Percentage of Participants With On-treatment Virologic Response at All Time Points

8. 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 undetectable plasma Hepatitis C virus ribonucleic acid levels 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
The Percentage of Participants Achieving a Rapid Virologic Response (RVR) [units: Percentage of participants]	**79.2**	**12.8**

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

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

Measure Type	Secondary
Measure Title	The Percentage of Participants Achieving a Early Virologic Response (EVR)
Measure Description	The table below shows the percentage of participants who achieved an EVR, defined as having a change from

	baseline in plasma Hepatitis C virus ribonucleic acid of 2 log10 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
The Percentage of Participants Achieving a Early Virologic Response (EVR) [units: Percentage of participants]	**98.8**	**89.8**

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

10. 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 Hepatitis C Virus ribonucleic acid levels 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
The Percentage of Participants Achieving a Complete Early Virologic Response (cEVR) [units: Percentage of participants]	**96.8**	**44.9**

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

11. Secondary: The Percentage of Participants Achieving a Extended Rapid Virologic Response (eRVR) [Time Frame: Weeks 4 and 12]

Measure Type	Secondary
Measure Title	The Percentage of Participants Achieving a Extended Rapid Virologic Response (eRVR)
Measure Description	The table below shows the percentage of participants in each treatment group who had a eRVR, defined as having undetectable plasma Hepatitis C Virus ribonucleic acid levels at Week 4 and 12.
Time Frame	Weeks 4 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
The Percentage of Participants Achieving a Extended Rapid Virologic Response (eRVR) [units: Percentage of participants]	**78.3**	**13.4**

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

12. Secondary: The Percentage of Participants With <1 log10 Decrease in Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) From Baseline at Week 4 [Time Frame: Week 4]

Measure Type	Secondary
Measure Title	The Percentage of Participants With <1 log10 Decrease in Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) From Baseline at Week 4
Measure Description	The table below shows the percentage of participants in each treatment group with <1 log10 HCV RNA decrease 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 intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
The Percentage of Participants With <1 log10 Decrease in Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) From Baseline at Week 4 [units: Percentage of participants]	**0.4**	**17.3**

No statistical analysis provided for The Percentage of Participants With <1 log10 Decrease in Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) From Baseline at Week 4

13. Secondary: Percentage of Participants With in Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) Levels >1000 IU/mL at Week 4 [Time Frame: Week 4]

Measure Type	Secondary
Measure Title	Percentage of Participants With in Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) Levels >1000 IU/mL at Week 4
Measure Description	The table below shows the percentage of participants in each treatment group with HCV RNA levels >1000 IU/mL 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 intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and

	ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
Percentage of Participants With in Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels >1000 IU/mL at Week 4 [units: Percentage of participants]	**1.2**	**61.2**

No statistical analysis provided for Percentage of Participants With in Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels >1000 IU/mL at Week 4

14. Secondary: Percentage of Participants With Null Response [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Percentage of Participants With Null Response
Measure Description	The table below shows the percentage of participants with null response, defined as <2 log10 reduction in Hepatitis C virus ribonucleic acid at Week 12 compared to baseline.
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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
Percentage of Participants With Null Response [units: Percentage of participants]	**1.2**	**10.2**

No statistical analysis provided for Percentage of Participants With Null Response

15. Secondary: Percentage of Participants With Partial Response [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Percentage of Participants With Partial Response
Measure Description	The table below shows the percentage of participants with partial response, defined as =>2 log10 reduction in Hepatitis C virus (HCV) ribonucleic acid (RNA) at Week 12 compared to baseline, but not achieving undetectable HCV

	RNA while on treatment.
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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
Percentage of Participants With Partial Response [units: Percentage of participants]	**0.4**	**17.3**

No statistical analysis provided for Percentage of Participants With Partial Response

16. Secondary: Percentage of Participants With Viral Breakthrough [Time Frame: Up to Week 48]

Measure Type	Secondary
Measure Title	Percentage of Participants With Viral Breakthrough
Measure Description	The table below shows the percentage of participants with viral breakthrough, defined as a confirmed increase of greater than 1 log10 IU/mL in plasma Hepatitis C virus (HCV) ribonucleic acid (RNA) level from the lowest level reached (ie, lowest value measured in between baseline and current value), or a confirmed plasma HCV RNA level of greater than 100 IU/mL in participants whose plasma HCV RNA had previously been below the limit of quantification (25 IU/mL detectable) or undetectable (<25 IU/mL undetectable).
Time Frame	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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
Percentage of Participants With Viral Breakthrough [units: Percentage of participants]	**4.7**	**10.4**

No statistical analysis provided for Percentage of Participants With Viral Breakthrough

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

Measure Type	Secondary
Measure Title	Percentage of Participants With Viral Relapse
Measure Description	The table below shows the percentage of participants with viral relapse, defined as having confirmed detectable plasma level of Hepatitis C virus (HCV) ribonucleic acid (RNA) during the follow-up period in participants with undetectable plasma HCV RNA (<25 IU/mL undetectable) at the 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
Percentage of Participants With Viral Relapse [units: Percentage of participants]	**12.3**	**23.9**

No statistical analysis provided for Percentage of Participants With Viral Relapse

18. Secondary: Percentage of Participants Who Completed All Study Treatment at Week 24 Because of the Treatment Duration Rule [Time Frame: Week 24]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Completed All Study Treatment at Week 24 Because of the Treatment Duration Rule
Measure Description	The table below shows the percentage of participants in the TMC435 treatment group who met the treatment duration rule (ie, having hepatitis C virus [HCV] ribonucleic acid [RNA] levels <25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA levels at Week 12) and completed treatment with PegIFNα-2a and RBV for 24 weeks. Participants in the TMC435 treatment group not meeting RGT criteria and participants in the placebo group were

	treated with PegIFNα-2a and RBV treatment for 48 weeks.
Time Frame	Week 24
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 intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
Percentage of Participants Who Completed All Study Treatment at Week 24 Because of the Treatment Duration Rule [units: Percentage of participants]	**89.5**	**NA** [1]

[1] RGT criteria did not apply to PBO arm

No statistical analysis provided for Percentage of Participants Who Completed All Study Treatment at Week 24 Because of the Treatment Duration Rule

19. Secondary: Percentage of Participants With On-treatment Failure [Time Frame: Week 48]

Measure Type	Secondary
Measure Title	Percentage of Participants With On-treatment Failure
Measure Description	The table below shows percentage of participants with on-treatment failure defined as confirmed detectable Hepatitis C virus ribonucleic acid levels at actual end of treatment.
Time Frame	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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).

PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
Percentage of Participants With On-treatment Failure [units: Percentage of participants]	**7.0**	**32.1**

No statistical analysis provided for Percentage of Participants With On-treatment Failure

20. Secondary: Time to Reach Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable or Detectable [Time Frame: Up to Week 48]

Measure Type	Secondary
Measure Title	Time to Reach Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable or Detectable
Measure Description	The table below shows the median time in days to reach HCV RNA levels <25 IU/mL undetectable or detectable.
Time Frame	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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
Time to Reach Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable or Detectable [units: Days] Median (95% Confidence Interval)	**14 (14 to 15)**	**85 (57 to 112)**

No statistical analysis provided for Time to Reach Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable or Detectable

21. Secondary: Time to Reach Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable [Time Frame: Up to Week 48]

Measure Type	Secondary
Measure Title	Time to Reach Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable
Measure Description	The table below shows the median time in days to reach HCV RNA levels <25 IU/mL undetectable.

Time Frame	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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
Time to Reach Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable [units: Days] Median (95% Confidence Interval)	**29 (28 to 29)**	**113 (85 to 141)**

No statistical analysis provided for Time to Reach Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable

22. Secondary: Time to Reach Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) <100 IU/mL [Time Frame: Up to Week 48]

Measure Type	Secondary
Measure Title	Time to Reach Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) <100 IU/mL
Measure Description	The table below shows the median time in days to reach HCV RNA levels <100 IU/mL.
Time Frame	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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
Time to Reach Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <100 IU/mL [units: Days] Median (95% Confidence Interval)	**8 (NA to NA) [1]**	**71 (57 to 86)**

[1] The 95% CI could not be calculated due to very low number of failures in the TMC435 group.

No statistical analysis provided for Time to Reach Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <100 IU/mL

23. Secondary: Time to Reach Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) <1000 IU/mL [Time Frame: Up to Week 48]

Measure Type	Secondary
Measure Title	Time to Reach Hepatitis **C** Virus (HCV) Ribonucleic Acid (RNA) <1000 IU/mL
Measure Description	The table below shows the median time in days to reach HCV RNA levels <1000 IU/mL.
Time Frame	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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
Time to Reach Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <1000 IU/mL [units: Days] Median (95% Confidence Interval)	**4 (3 to 4)**	**57 (56 to 58)**

No statistical analysis provided for Time to Reach Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <1000 IU/mL

24. Secondary: The Percentage of Participants With Viral Breakthrough at Different Time Points [Time Frame: Up to Week 48]

Measure Type	Secondary
Measure Title	The Percentage of Participants With Viral Breakthrough at Different Time Points
Measure Description	The table below shows the percentage of participants at different time points with viral breakthrough, defined as a confirmed increase of greater than 1 log10 IU/mL in plasma HCV ribonucleic acid (RNA) level from the lowest level reached (ie, lowest value measured in between baseline and current value), or a confirmed plasma HCV RNA level of greater than 100 IU/mL in participants whose plasma HCV RNA had previously been below the limit of quantification (25 IU/mL detectable) or undetectable (<25 IU/mL undetectable).
Time Frame	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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
The Percentage of Participants With Viral Breakthrough at Different Time Points [units: Percentage of participants]		
< 12 Weeks	**1.2**	**3.7**
Week 12 - Week 24	**3.3**	**6.4**
> Week 24	**12.5**	**2.1**

No statistical analysis provided for The Percentage of Participants With Viral Breakthrough at Different Time Points

25. Secondary: Time From End-of-treatment to Viral Relapse [Time Frame: Up to Week 72]

Measure Type	Secondary
Measure Title	Time From End-of-treatment to Viral Relapse
Measure Description	The table below shows the mean number of days to viral relapse, defined as participants having confirmed detectable plasma level of Hepatitis C Virus (HCV) ribonucleic acid (RNA) during the follow-up period in participants with undetectable plasma HCV RNA (<25 IU/mL undetectable) at the 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and

	ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**257**	**134**
Time From End-of-treatment to Viral Relapse [units: Days] Mean ± Standard Error	**229.77 ± 4.29**	**77.74 ± 2.34**

No statistical analysis provided for Time From End-of-treatment to Viral Relapse

26. Secondary: The Percentage of Participants With Normalization of Alanine Aminotransferase (ALT) [Time Frame: Up to Week 48]

Measure Type	Secondary
Measure Title	The Percentage of Participants With Normalization of Alanine Aminotransferase (ALT)
Measure Description	The percentage of participants analyzed were those with baseline ALT values out of the normal range (ie, 164 of 257 participants in the TMC435 treatment group and 79 of 134 participants in the Placebo group had ALT values at baseline that were out of the normal range.). Normalization of ALT values means that ALT values out of the normal range returned to within the normal range.
Time Frame	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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Number of Participants Analyzed [units: participants]	**169**	**79**
The Percentage of Participants With Normalization of Alanine Aminotransferase (ALT) [units: Percentage of participants]	**79.9**	**81.0**

No statistical analysis provided for The Percentage of Participants With Normalization of Alanine Aminotransferase (ALT)

27. Secondary: Median Time to Normalization of Alanine Aminotransferase (ALT) Levels [Time Frame: Up to Week 48]

Measure Type	Secondary
Measure Title	Median Time to Normalization of Alanine Aminotransferase (ALT) Levels

Measure Description	The table below shows the median time in weeks to normalization of ALT levels.
Time Frame	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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**257**	**134**
Median Time to Normalization of Alanine Aminotransferase (ALT) Levels [units: Weeks] Median (95% Confidence Interval)	**2.14 (1.29 to 2.14)**	**4.14 (4.14 to 12.00)**

No statistical analysis provided for Median Time to Normalization of Alanine Aminotransferase (ALT) Levels

28. Secondary: Plasma Concentration of **TMC435**: Area Under the Plasma Concentration-time Curve From the Time of Administration to 24 Hours After Dosing (AUC24h) [Time Frame: At protocol-specified time points from the time of administration up to 24 hours after dosing at Weeks 2, 4, 8, and 12]

Measure Type	Secondary
Measure Title	Plasma Concentration of **TMC435**: Area Under the Plasma Concentration-time Curve From the Time of Administration to 24 Hours After Dosing (AUC24h)
Measure Description	The table below shows the mean (standard deviation) values of the area under the plasma concentration-time curve from time of administration to 24 hours after dosing for TMC435.
Time Frame	At protocol-specified time points from the time of administration up to 24 hours after dosing at 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).

Measured Values

	TMC435 150mg 12Wks PR24/48
Number of Participants Analyzed [units: participants]	**255**
Plasma Concentration of TMC435: Area Under the Plasma Concentration-time Curve From the Time of Administration to 24 Hours After Dosing (AUC24h) [units: ng*h/mL] Mean ± Standard Deviation	**56611 ± 66935.4**

No statistical analysis provided for Plasma Concentration of TMC435: Area Under the Plasma Concentration-time Curve From the Time of Administration to 24 Hours After Dosing (AUC24h)

29. Secondary: Plasma Concentration of **TMC435**: Predose Plasma Concentration (**C**0h) [Time Frame: Blood samples tested were taken before administration of TMC435 and at 2 random time points after dosing (taken atleast 2 hours apart from each other) at Week 2, 4, 8, and 12]

Measure Type	Secondary
Measure Title	Plasma Concentration of **TMC435**: Predose Plasma Concentration (**C**0h)
Measure Description	The table below shows the mean (standard deviation) of C0h values of TMC435. NOTE: the timing of collection of blood samples post-dose for analysis at Week 2, 4, 8, and 12 was not specifed; only the interval was between blood samples was specified (ie, 2 samples collected 2 hours apart at Week 2, 4, 8, and 12).
Time Frame	Blood samples tested were taken before administration of TMC435 and at 2 random time points after dosing (taken atleast 2 hours apart from each other) at Week 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).

Measured Values

	TMC435 150mg 12Wks PR24/48
Number of Participants Analyzed [units: participants]	**255**
Plasma Concentration of TMC435: Predose Plasma Concentration (C0h) [units: ng/mL] Mean ± Standard Deviation	**1902 ± 2781.1**

No statistical analysis provided for Plasma Concentration of TMC435: Predose Plasma Concentration (C0h)

30. Secondary: Plasma Concentration of **TMC435**: Systemic Clearance (CL) [Time Frame: At protocol-specified time points at Weeks 2, 4, 8, and 12]

Measure Type	Secondary
Measure Title	Plasma Concentration of **TMC435**: Systemic Clearance (CL)

Measure Description	The table below shows the mean (standard deviation) of CL values of TMC435. NOTE: the pre-dose CL values taken at Weeks, 2, 4, 8, and 12 were averaged and then the mean values from all participants were averaged to provide the final value reported below.
Time Frame	At protocol-specified time points at 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).

Measured Values

	TMC435 150mg 12Wks PR24/48
Number of Participants Analyzed [units: participants]	**255**
Plasma Concentration of TMC435: Systemic Clearance (CL) [units: L/h] Mean ± Standard Deviation	**5.23 ± 3.767**

No statistical analysis provided for Plasma Concentration of TMC435: Systemic Clearance (CL)

31. Secondary: Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for the Fatigue Severity Scale (FSS) Total Scores [Time Frame: Baseline to Week 60 and Week 72]

Measure Type	Secondary
Measure Title	Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for the Fatigue Severity Scale (FSS) Total Scores
Measure Description	Study participants completed FSS questionnaires during study visits before treatment and throughout follow-up to rate the severity and impact of fatigue experienced in the preceding 2 weeks. FSS total scores are the average of nine questions with a range from 1 [no fatigue] to 7 [worst fatigue]; the possible score range from baseline to Week 60 would be 60-420 and to Week 72 would be 72-504. The average FSS total score from baseline to Week 60 and to Week 72 was calculated for each participant and then the average of those values were calculated to show the average FSS total score for each treatment group. The null hypothesis was that there would be no difference between the treatment arms in the FSS total score. The Table below shows the lease squares (LS) mean estimates of the area under the curve (AUC) at Week 72 (as well as at Week 60) and the statistical comparison between treatment groups.
Time Frame	Baseline to Week 60 and 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24).

	Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**256**	**133**
Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for the Fatigue Severity Scale (FSS) Total Scores [units: Scores on a scale*weeks] Least Squares Mean (95% Confidence Interval)		
Week 60	**208.418 (199.4881 to 217.3476)**	**225.194 (213.8370 to 236.5513)**
Week 72	**240.695 (230.1386 to 251.2542)**	**259.532 (246.0810 to 272.9834)**

Statistical Analysis 1 for Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for the Fatigue Severity Scale (FSS) Total Scores

Groups [1]	All groups
Method [2]	Piecewise Linear Model
P Value [3]	0.008
Mean differences [4]	-16.776
Standard Error of the mean	± 6.3081
95% Confidence Interval	(-29.1502 to -4.4025)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Fatigue Severity Score AUC60
[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:
	No text entered.

Statistical Analysis 2 for Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for the Fatigue Severity Scale (FSS) Total Scores

Groups [1]	All groups
Method [2]	Piecewise Linear Model
P Value [3]	0.012
Mean differences [4]	-18.837
Standard Error of the mean	± 7.4715
95% Confidence Interval	(-33.4933 to -4.1801)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Fatigue Severity Score AUC72
[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:
	No text entered.

32. Secondary: Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Overall Work Productivity Due to Hepatitis **C** Virus (HCV) Infection and Its Treatment [Time Frame: Baseline to Week 60 and Week 72]

Measure Type	Secondary
Measure Title	Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Overall Work Productivity Due to Hepatitis **C** Virus (HCV) Infection and Its Treatment
Measure Description	Impairment in overall work productivity was measured using the Work Productivity and Activity Impairment (WPAI): Hepatitis C questionnaire completed by participants throughout the study. WPAI Overall Productivity Scores ranged from 0% to 100% (higher WPAI scores indicated greater impairment in productivity). The average WPAI score from baseline to Week 72 was calculated for each participant and then the average of those values were calculated to show the average WPAI score for each treatment group. The null hypothesis was there is no statistically significant difference between the treatment groups in the AUC for the change from baseline to Week 72 (AUC72) in WPAI Productivity Scores. The Table below shows WPAI Productivity Scores at Week 72 (as well as at Week 60) from the model used to calculate the AUC and the statistical comparison between treatment groups.
Time Frame	Baseline to Week 60 and 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**256**	**133**
Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Overall Work Productivity Due to Hepatitis C Virus (HCV) Infection and Its Treatment [units: Scores on a scale*weeks] Least Squares Mean (95% Confidence Interval)		
	1628.075	**1910.235**

Week 60	**(1492.3021 to 1763.8485)**	**(1730.5026 to 2089.9681)**
Week 72	**1781.768** **(1622.4802 to 1941.0560)**	**2106.131** **(1894.8814 to 2317.3811)**

Statistical Analysis 1 for Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Overall Work Productivity Due to Hepatitis C Virus (HCV) Infection and Its Treatment

Groups [1]	All groups
Method [2]	Piecewise Linear Model
P Value [3]	0.008
Mean differences [4]	-282.160
Standard Error of the mean	± 105.4927
95% Confidence Interval	(-489.1252 to -75.1949)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Impairment in Work Productivity AUC60
[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:
	No text entered.

Statistical Analysis 2 for Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Overall Work Productivity Due to Hepatitis C Virus (HCV) Infection and Its Treatment

Groups [1]	All groups
Method [2]	Piecewise Linear Model
P Value [3]	0.009
Mean differences [4]	-324.363
Standard Error of the mean	± 124.0260
95% Confidence Interval	(-567.7080 to -81.0182)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Impairment in Work Productivity AUC72
[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:
	No text entered.

33. Secondary: Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Daily Activities Due to Hepatitis **C** Virus (HCV) Infection and Its Treatment [Time Frame: Baseline to Week 60 and Week 72]

Measure Type	Secondary
Measure Title	Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Daily Activities Due to Hepatitis **C** Virus (HCV) Infection and Its Treatment
Measure Description	Impairment in daily activity was measured using the Work Productivity and Activity Impairment (WPAI): Hepatitis C questionnaire, Question 6. The possible impairment in WPAI daily activity score range from baseline to Week 60 was 0-6000 and to Week 72 was 0-7200, with the higher scores indicating more impairment in daily activities. The average WPAI impairment in daily activity score from baseline to Week 72 was calculated for each participant and then the average of those values were calculated to show the average WPAI impairment in daily activity score for each treatment group. The null hypothesis was there is no statistically significant difference between the treatment arms in the AUC for the change from baseline to Week 72 (AUC72) in WPAI impairment in daily activity scores. The Table below shows the WPAI Impairment in daily activity scores at Week 72 (as well as at Week 60) and the statistical analysis between treatment groups.
Time Frame	Baseline to Week 60 and 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**256**	**133**
Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Daily Activities Due to Hepatitis C Virus (HCV) Infection and Its Treatment [units: Scores on a scale*weeks] Least Squares Mean (95% Confidence Interval)		
Week 60	**1580.635 (1445.8307 to 1715.4397)**	**1863.071 (1684.4355 to 2041.7065)**
Week 72	**1727.079 (1568.9831 to 1885.1745)**	**2056.283 (1846.3791 to 2266.1868)**

Statistical Analysis 1 for Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Daily Activities Due to Hepatitis C Virus (HCV) Infection and Its Treatment

Groups [1]	All groups
Method [2]	Piecewise linear model
P Value [3]	0.007
	-282.436

Mean Differences [4]	
Standard Error of the mean	± 104.9894
95% Confidence Interval	(-488.4150 to -76.4566)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Impairment in Daily Activities AUC60
[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:
	No text entered.

Statistical Analysis 2 for Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Daily Activities Due to Hepatitis C Virus (HCV) Infection and Its Treatment

Groups [1]	All groups
Method [2]	Piecewise Linear Model
P Value [3]	0.008
Mean differences [4]	-329.204
Standard Error of the mean	± 123.4080
95% Confidence Interval	(-571.3389 to -87.0695)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Impairment in Daily Activities AUC72
[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:
	No text entered.

34. Secondary: Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Time Missed From Work Due to Hepatitis**C** Virus (HCV) Infection and Its Treatment [Time Frame: Baseline to Week 60 and Week 72]

Measure Type	Secondary
Measure Title	Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Time Missed From Work Due to Hepatitis **C** Virus (HCV) Infection and Its Treatment
Measure Description	Hours missed from work because of HCV infection or its treatment was assessed by measuring the change from baseline in the Work Productivity and Activity Impairment (WPAI): Hepatitis C questionnaire Absenteeism score (time missed from work). The possible WPAI WPAI absenteeism score range from baseline to Week 60 was 0-6000 and to Week 72 was 0-7200, with the higher scores indicating more impairment in WPAI absenteeism. The average WPAI absenteeism score from baseline to Week 60/72 was calculated for each participant and then the average of those values calculated for each treatment group. The area under the curve (AUC60/AUC72) over time from baseline to Week 60/72 was derived from a piecewise-linear model allowing the slopes to change at Week 4, 12, 24, 36, 48 and 60. The null hypothesis was there is no statistically significant difference between the treatment arms in the area under the curve (AUC) from baseline to Week 72 (AUC72) in WPAI absenteeism score.
Time Frame	Baseline to Week 60 and 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.
The intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication) was used for all analyses.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Measured Values

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Number of Participants Analyzed [units: participants]	**182**	**89**
Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Time Missed From Work Due to Hepatitis C Virus (HCV) Infection and Its Treatment [units: Scores on a scale*weeks] Least Squares Mean (95% Confidence Interval)		
Week 60	**653.642 (511.4925 to 795.7918)**	**840.495 (637.5293 to 1043.4599)**
Week 72	**698.223 (533.6236 to 862.8224)**	**886.425 (650.2224 to 1122.6266)**

Statistical Analysis 1 for Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Time Missed From Work Due to Hepatitis C Virus (HCV) Infection and Its Treatment

Groups [1]	All groups
Method [2]	Piecewise linear model
P Value [3]	0.125
Mean differences [4]	-186.852
Standard Error of the mean	± 121.4741
95% Confidence Interval	(-425.4109 to 51.7059)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Time Missed from Work AUC60
[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:
	No text entered.

Statistical Analysis 2 for Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Time Missed From Work Due to Hepatitis C Virus (HCV) Infection and Its Treatment

Groups [1]	All groups
Method [2]	Piecewise linear model
P Value [3]	0.183
Mean differences [4]	-188.202
Standard Error of the mean	± 141.1702
95% Confidence Interval	(-465.5070 to 89.1040)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Time Missed from Work AUC72
[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:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	72 weeks
Additional Description	No text entered.

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Serious Adverse Events

	TMC435 150mg 12Wks PR24/48	**PBO 12Wks PR48**
Total, serious adverse events		
# participants affected / at risk	**16/257 (6.23%)**	**10/134 (7.46%)**
Blood and lymphatic system disorders		
Anaemia * 1		
# participants affected / at risk	**2/257 (0.78%)**	**1/134 (0.75%)**
Pancytopenia * 1		
# participants affected / at risk	**0/257 (0.00%)**	**1/134 (0.75%)**
Cardiac disorders		
Angina unstable * 1		
# participants affected / at risk	**0/257 (0.00%)**	**1/134 (0.75%)**
Ear and labyrinth disorders		

Mixed deafness [*1]		
# participants affected / at risk	**1/257 (0.39%)**	**0/134 (0.00%)**
Endocrine disorders		
Hyperthyroidism [*1]		
# participants affected / at risk	**1/257 (0.39%)**	**0/134 (0.00%)**
Eye disorders		
Hyphaema [*1]		
# participants affected / at risk	**1/257 (0.39%)**	**0/134 (0.00%)**
Visual impairment [*1]		
# participants affected / at risk	**1/257 (0.39%)**	**0/134 (0.00%)**
Retinal ischaemia [*1]		
# participants affected / at risk	**0/257 (0.00%)**	**1/134 (0.75%)**
Gastrointestinal disorders		
Enterocutaneous fistula [*1]		
# participants affected / at risk	**1/257 (0.39%)**	**0/134 (0.00%)**
Pancreatitis acute [*1]		
# participants affected / at risk	**0/257 (0.00%)**	**1/134 (0.75%)**
Vomiting [*1]		
# participants affected / at risk	**0/257 (0.00%)**	**1/134 (0.75%)**
General disorders		
Death [*1]		
# participants affected / at risk	**1/257 (0.39%)**	**0/134 (0.00%)**
Hepatobiliary disorders		
Autoimmune hepatitis [*1]		
# participants affected / at risk	**1/257 (0.39%)**	**0/134 (0.00%)**
Cholecystitis acute [*1]		
# participants affected / at risk	**0/257 (0.00%)**	**1/134 (0.75%)**
Infections and infestations		
Anal abscess [*1]		
# participants affected / at risk	**1/257 (0.39%)**	**0/134 (0.00%)**
Lymphadenitis bacterial [*1]		
# participants affected / at risk	**1/257 (0.39%)**	**0/134 (0.00%)**
Urinary tract infection [*1]		
# participants affected / at risk	**1/257 (0.39%)**	**0/134 (0.00%)**
Respiratory tract infection viral [*1]		
# participants affected / at risk	**0/257 (0.00%)**	**1/134 (0.75%)**
Viral infection [*1]		
# participants affected / at risk	**0/257 (0.00%)**	**1/134 (0.75%)**
Injury, poisoning and procedural complications		
Meniscus lesion [*1]		
# participants affected / at risk	**0/257 (0.00%)**	**1/134 (0.75%)**
Metabolism and nutrition disorders		
Fluid overload [*1]		
# participants affected / at risk	**1/257 (0.39%)**	**0/134 (0.00%)**
Dehydration [*1]		
# participants affected / at risk	**0/257 (0.00%)**	**1/134 (0.75%)**
Musculoskeletal and connective tissue disorders		
Back pain [*1]		

# participants affected / at risk	1/257 (0.39%)	0/134 (0.00%)
Muscle spasms * 1		
# participants affected / at risk	1/257 (0.39%)	0/134 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Colon cancer * 1		
# participants affected / at risk	1/257 (0.39%)	0/134 (0.00%)
Nervous system disorders		
Epilepsy * 1		
# participants affected / at risk	1/257 (0.39%)	0/134 (0.00%)
Memory impairment * 1		
# participants affected / at risk	1/257 (0.39%)	0/134 (0.00%)
Syncope * 1		
# participants affected / at risk	1/257 (0.39%)	0/134 (0.00%)
Loss of consciousness * 1		
# participants affected / at risk	0/257 (0.00%)	1/134 (0.75%)
Neuropathy peripheral * 1		
# participants affected / at risk	0/257 (0.00%)	1/134 (0.75%)
Thoracic outlet syndrome * 1		
# participants affected / at risk	0/257 (0.00%)	1/134 (0.75%)
Psychiatric disorders		
Aggression * 1		
# participants affected / at risk	1/257 (0.39%)	0/134 (0.00%)
Drug abuse * 1		
# participants affected / at risk	0/257 (0.00%)	1/134 (0.75%)
Respiratory, thoracic and mediastinal disorders		
Pulmonary embolism * 1		
# participants affected / at risk	0/257 (0.00%)	1/134 (0.75%)

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	72 weeks
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 24 (PR24). Treatment was to be stopped at Week 24 for participants who achieved HCV RNA < 25 IU/mL detectable or undetectable at Week 4 and undetectable HCV RNA at Week 12. Other participants continued PR until Week 48 (PR48).
PBO 12Wks PR48	Participants were given placebo (PBO) once daily plus peginterferon alpha-2a/b (PegIFN alpha-2a/b) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a/b (P) and RBV (R) until Week 48 (PR 48).

Other Adverse Events

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
Total, other (not including serious) adverse events		
# participants affected / at risk	243/257 (94.55%)	131/134 (97.76%)
Blood and lymphatic system disorders		
Neutropenia [*1]		
# participants affected / at risk	49/257 (19.07%)	29/134 (21.64%)
Anaemia [*1]		
# participants affected / at risk	46/257 (17.90%)	33/134 (24.63%)
Thrombocytopenia [*1]		
# participants affected / at risk	13/257 (5.06%)	9/134 (6.72%)
Leukopenia [*1]		
# participants affected / at risk	10/257 (3.89%)	7/134 (5.22%)
Gastrointestinal disorders		
Nausea [*1]		
# participants affected / at risk	63/257 (24.51%)	24/134 (17.91%)
Diarrhoea [*1]		
# participants affected / at risk	34/257 (13.23%)	12/134 (8.96%)
Vomiting [*1]		
# participants affected / at risk	17/257 (6.61%)	7/134 (5.22%)
Dry mouth [*1]		
# participants affected / at risk	13/257 (5.06%)	6/134 (4.48%)
Abdominal pain [*1]		
# participants affected / at risk	12/257 (4.67%)	7/134 (5.22%)
Abdominal pain upper [*1]		
# participants affected / at risk	11/257 (4.28%)	12/134 (8.96%)
Constipation [*1]		
# participants affected / at risk	8/257 (3.11%)	7/134 (5.22%)
General disorders		
Fatigue [*1]		
# participants affected / at risk	95/257 (36.96%)	56/134 (41.79%)
Pyrexia [*1]		
# participants affected / at risk	80/257 (31.13%)	53/134 (39.55%)
Influenza like illness [*1]		
# participants affected / at risk	66/257 (25.68%)	35/134 (26.12%)
Asthenia [*1]		
# participants affected / at risk	59/257 (22.96%)	38/134 (28.36%)
Chills [*1]		
# participants affected / at risk	21/257 (8.17%)	12/134 (8.96%)
Injection site erythema [*1]		
# participants affected / at risk	15/257 (5.84%)	9/134 (6.72%)
Infections and infestations		
Influenza [*1]		
# participants affected / at risk	5/257 (1.95%)	8/134 (5.97%)
Sinusitis [*1]		
# participants affected / at risk	5/257 (1.95%)	7/134 (5.22%)
Investigations		

Weight decreased [*1]		
# participants affected / at risk	**14/257 (5.45%)**	**6/134 (4.48%)**
Neutrophil count decreased [*1]		
# participants affected / at risk	**8/257 (3.11%)**	**7/134 (5.22%)**
Metabolism and nutrition disorders		
Decreased appetite [*1]		
# participants affected / at risk	**46/257 (17.90%)**	**21/134 (15.67%)**
Musculoskeletal and connective tissue disorders		
Myalgia [*1]		
# participants affected / at risk	**58/257 (22.57%)**	**28/134 (20.90%)**
Arthralgia [*1]		
# participants affected / at risk	**32/257 (12.45%)**	**14/134 (10.45%)**
Back pain [*1]		
# participants affected / at risk	**25/257 (9.73%)**	**13/134 (9.70%)**
Muscle spasms [*1]		
# participants affected / at risk	**8/257 (3.11%)**	**7/134 (5.22%)**
Nervous system disorders		
Headache [*1]		
# participants affected / at risk	**101/257 (39.30%)**	**49/134 (36.57%)**
Dizziness [*1]		
# participants affected / at risk	**21/257 (8.17%)**	**9/134 (6.72%)**
Disturbance in attention [*1]		
# participants affected / at risk	**13/257 (5.06%)**	**8/134 (5.97%)**
Dysgeusia [*1]		
# participants affected / at risk	**6/257 (2.33%)**	**7/134 (5.22%)**
Psychiatric disorders		
Insomnia [*1]		
# participants affected / at risk	**51/257 (19.84%)**	**21/134 (15.67%)**
Depression [*1]		
# participants affected / at risk	**29/257 (11.28%)**	**19/134 (14.18%)**
Mood altered [*1]		
# participants affected / at risk	**22/257 (8.56%)**	**15/134 (11.19%)**
Anxiety [*1]		
# participants affected / at risk	**17/257 (6.61%)**	**6/134 (4.48%)**
Sleep disorder [*1]		
# participants affected / at risk	**13/257 (5.06%)**	**5/134 (3.73%)**
Respiratory, thoracic and mediastinal disorders		
Cough [*1]		
# participants affected / at risk	**32/257 (12.45%)**	**22/134 (16.42%)**
Dyspnoea [*1]		
# participants affected / at risk	**23/257 (8.95%)**	**11/134 (8.21%)**
Skin and subcutaneous tissue disorders		
Pruritus [*1]		
# participants affected / at risk	**65/257 (25.29%)**	**34/134 (25.37%)**
Rash [*1]		
# participants affected / at risk	**46/257 (17.90%)**	**15/134 (11.19%)**
Alopecia [*1]		
# participants affected / at risk	**43/257 (16.73%)**	**27/134 (20.15%)**

Dry skin * 1		
# participants affected / at risk	**28/257 (10.89%)**	**18/134 (13.43%)**
Eczema * 1		
# participants affected / at risk	**4/257 (1.56%)**	**9/134 (6.72%)**

* 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.

Results Point of Contact:

Name/Title: Global Clinical Development Manager
Organization: Janssen-Cilag France
e-mail: ClinicalTrialDisclosure@its.jnj.com

No publications provided by Janssen R&D Ireland

Publications automatically indexed to this study:

Manns M, Marcellin P, Poordad F, de Araujo ES, Buti M, Horsmans Y, Janczewska E, Villamil F, Scott J, Peeters M, Lenz O, Ouwerkerk-Mahadevan S, De La Rosa G, Kalmeijer R, Sinha R, Beumont-Mauviel M. Simeprevir with pegylated interferon alfa 2a or 2b plus ribavirin in treatment-naive patients with chronic hepatitis C virus genotype 1 infection (QUEST-2): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet. 2014 Aug 2;384(9941):414-26. doi: 10.1016/S0140-6736(14)60538-9. Epub 2014 Jun 4.

Responsible Party:	Janssen R&D Ireland
ClinicalTrials.gov Identifier:	NCT01290679 History of Changes
Other Study ID Numbers:	CR017380, **TMC435-TiDP**16-**C216**, 2010-021174-11
Study First Received:	January 7, 2011
Results First Received:	February 3, 2014
Last Updated:	June 10, 2014
Health Authority:	United States: Food and Drug Administration Ireland: Irish Agriculture and Food Development Authority

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For Patients & Families | **For Researchers** | **For Study Record Managers**

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