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

This study has been completed.

Sponsor:
Janssen R&D Ireland

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

ClinicalTrials.gov Identifier:
NCT01289782

First received: January 7, 2011
Last updated: May 20, 2014
Last verified: May 2014
History of Changes

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Results First Received: January 27, 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 (PegIFN alpha-2a) 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 29 January 2013. The study was conducted at 71 sites in 13 countries.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
395 participants were randomly allocated to the 2 treatment arms. 394 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (P) and RBV (R) until Week 48 (PR 48).

Participant Flow: Overall Study

	TMC435 150mg 12Wks PR24/48	PBO 12Wks PR48
STARTED	264	130 [1]
COMPLETED	239	118
NOT COMPLETED	25	12
Lost to Follow-up	14	7
Protocol Violation	1	1
Withdrawal by Subject	8	2
Sponsor's Decision	1	0
Reason not specified	1	2

[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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	264	130	394
Age [units: years] Median (Full Range)	48 (19 to 68)	48 (20 to 66)	48 (19 to 68)
Gender [units: participants]			
Female	116	56	172
Male	148	74	222

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
The Percentage of Participants Achieving a Sustained Virologic Response 12 Weeks After the Planned End of Treatment (SVR12) [units: Percentage of participants]	**79.5**	**50**

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]	29.3
95% Confidence Interval	(20.1 to 38.6)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null hypothesis: 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
The Percentage of Participants Achieving a Sustained Virologic Response at Week 72 (SVRW72) [units: Percentage of participants]	**78.4**	**49.2**

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]	28.9

95% Confidence Interval	(19.6 to 38.2)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
The Percentage of Participants Who Achieved a Sustained Virologic Response 24 Weeks After the Planned End of Treatment (SVR24) [units: Percentage of participants]	**79.5**	**49.2**

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]	30.1
95% Confidence Interval	(20.8 to 39.3)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
The Percentage of Participants Who Achieved a Sustained Virologic Response 4 Weeks After the Planned End of Treatment (SVR4) [units: Percentage of participants]	**82.2**	**56.2**

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]	25.8
95% Confidence Interval	(16.8 to 34.8)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	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 the change from baseline in 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Change From Baseline in log10 Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) [units: log10 IU/mL] Mean ± Standard Error		
Day 3	**-3.52 ± 0.0459**	**-0.93 ± 0.0774**
Week 1	**-4.47 ± 0.0512**	**-1.08 ± 0.0835**
Week 4	**-5.22 ± 0.0552**	**-2.56 ± 0.1434**
Week 12	**-5.34 ± 0.0524**	**-4.18 ± 0.1510**
Week 24	**-5.32 ± 0.0604**	**-4.89 ± 0.1289**
Week 48	**-5.33 ± 0.2605**	**-5.23 ± 0.1670**

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Actual Values of log10 Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) [units: log10 IU/mL] Mean ± Standard Error		
Day 3	**2.914 ± 0.052**	**5.351 ± 0.104**
Week 1	**1.973 ± 0.052**	**5.202 ± 0.114**
Week 4	**1.223 ± 0.049**	**3.723 ± 0.159**
Week 12	**1.090 ± 0.041**	**2.111 ± 0.155**
Week 24	**1.113 ± 0.050**	**1.334 ± 0.110**
Week 48	**0.993 ± 0.039**	**0.961 ± 0.006**

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, < 25 IU/mL detectable or undetectable), the percentage of participants with plasma levels of HCV RNA <100 IU/mL, the percentage of 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**

Percentage of Participants With On-treatment Virologic Response at All Time Points [units: Percentage of participants]		
Day 3:<25 IU/mL undetectable	0.4	0.8
Week 1:<25 IU/mL undetectable	6.6	0.8
Week 2:<25 IU/mL undetectable	35.8	2.3
Week 8:<25 IU/mL undetectable	90.0	26.2
Week 16:<25 IU/mL undetectable	93.8	69.2
Week 20:<25 IU/mL undetectable	93.4	78.2
Week 28:<25 IU/mL undetectable	90.9	96.3
Week 36:<25 IU/mL undetectable	90.9	100.0
Week 42:<25 IU/mL undetectable	90.9	98.7
Day 3:<25 IU/mL undetectable/detectable	2.4	0.8
Week 1:<25 IU/mL undetectable/detectable	36.8	2.3
Week 2:<25 IU/mL undetectable/detectable	76.7	6.3
Week 8:<25 IU/mL undetectable/detectable	94.0	40.5
Week 16:<25 IU/mL undetectable/detectable	95.4	82.7
Week 20:<25 IU/mL undetectable/detectable	95.0	84.2
Week 28:<25 IU/mL undetectable/detectable	100.0	98.8
Week 36:<25 IU/mL undetectable/detectable	100.0	100.0
Week 42:<25 IU/mL undetectable/detectable	100.0	100.0
Day 3:<100 IU/mL	11.4	1.6
Week 1:<100 IU/mL	62.8	3.1
Week 2:<100 IU/mL	85.2	7.8
Week 8:<100 IU/mL	94.8	46.0
Week 16:<100 IU/mL	96.7	84.6
Week 20:<100 IU/mL	96.7	86.1
Week 28:<100 IU/mL	100.0	98.8
Week 36:<100 IU/mL	100.0	100.0
Week 42:<100 IU/mL	100.0	100.0
Day 3:> or = 2 log10 change from baseline	95.3	13.3
Week 1:> or = 2 log10 change from baseline	98.1	20.2
Week 2:> or = 2 log10 change from baseline	98.8	35.2
Week 8:> or = 2 log10 change from baseline	98.4	80.2
Week 16:> or = 2 log10 change from baseline	100.0	99.0
Week 20:> or = 2 log10 change from baseline	98.3	97.0
Week 28:> or = 2 log10 change from baseline	100.0	97.5
Week 36:> or = 2 log10 change from baseline	100.0	98.7
Week 42:> or = 2 log10 change from baseline	100.0	98.7

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
The Percentage of Participants Achieving a Rapid Virologic Response (RVR) [units: Percentage of participants]	**79.5**	**11.8**

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 greater than or equal to 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
The Percentage of Participants Achieving a Early Virologic Response (EVR) [units: Percentage of participants]	**99.2**	**85.2**

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
The Percentage of Participants Achieving a Complete Early Virologic Response (cEVR) [units: Percentage of participants]	**92.8**	**50.8**

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: Week 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	Week 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
The Percentage of Participants Achieving a Extended Rapid Virologic Response (eRVR) [units: Percentage of participants]	**78.9**	**11.7**

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
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**	**15.7**

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Percentage of Participants With in Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Levels >1000 IU/mL at Week 4 [units: Percentage of participants]	**4.5**	**63.8**

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Percentage of Participants With Null Response [units: Percentage of participants]	**0.8**	**14.8**

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 greater than or equal to 2 log10 reduction in Hepatitis C virus ribonucleic acid 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Percentage of Participants With Partial Response [units: Percentage of participants]	**3.2**	**13.1**

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Percentage of Participants With Viral Breakthrough [units: Percentage of participants]	**4.9**	**7.7**

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 (less than 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Percentage of Participants With Viral Relapse [units: Percentage of participants]	**9.0**	**22.6**

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Percentage of Participants Who Completed All Study Treatment at Week 24 Because of the Treatment Duration Rule [units: Percentage of participants]	**83**	**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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Percentage of Participants With On-treatment Failure [units: Percentage of participants]	**9.1**	**33.8**

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 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
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 (84 to 110)**

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 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Time to Reach Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <25 IU/mL Undetectable	**28 (NA to NA) [1]**	**111 (85 to 139)**

[units: Days] Median (95% Confidence Interval)		

[1] Majority of the participants had HCV RNA undetectable for the first time at Day 28. So they all are concentrated in that time point and there is no a range around Day 28 to be drawn.

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 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Time to Reach Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <100 IU/mL [units: Days] Median (95% Confidence Interval)	**28 (NA to NA) [1]**	**84 (57 to 85)**

[1] Majority of the participants had HCV RNA undetectable for the first time at Day 28. So they all are concentrated in that time point and there is no a range around Day 28 to be drawn.

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 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Time to Reach Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) <1000 IU/mL [units: Days] Median (95% Confidence Interval)	**4 (3 to 4)**	**56.5 (56 to 57)**

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
The Percentage of Participants With Viral Breakthrough at Different Time Points [units: Percentage of participants]		
< 12 Weeks	**2.7**	**1.5**
Week 12 - Week 24	**2.5**	**6.8**
> Week 24	**0**	**1.2**

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**264**	**130**
Time From End-of-treatment to Viral Relapse [units: Days] Mean ± Standard Error	**100.96 ± 1.21**	**146.04 ± 5.22**

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, 158 of 264 participants in the TMC435 treatment group and 89 of 130 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.
Participants with baseline ALT values out of normal range were used for this analysis from intent-to-treat population (defined as all participants who were randomized and received at least one dose of study medication).

Reporting Groups

	Description
TMC435 150mg 12Wks PR24/48	Participants were given TMC435 150 mg once daily plus peginterferon alpha-2a (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**158**	**89**
The Percentage of Participants With Normalization of Alanine Aminotransferase (ALT) [units: Percentage of participants]	**81.0**	**77.5**

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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**158**	**89**
Median Time to Normalization of Alanine Aminotransferase (ALT) Levels [units: Weeks] Median (95% Confidence Interval)	**2.14 (1.86 to 4.00)**	**8.14 (4.14 to 16.29)**

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: Fom 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 mean (standard deviation) values of the area under the plasma concentration-time curve from time of administration to 24 hours after dosing for TMC435 for all participants. To calculate the mean AUC 24 for the study, AUC 24 hr values were derived for each participant at each visit and then a median AUC value calcuated across all visits for each participant. The median AUC value across all visits for each participant was used to calculate the mean AUC 24 hr all participants in the study.
Time Frame	Fom 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**259**
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	**54795 ± 55627.3**

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 (C0h) [Time Frame: Before administration of TMC435 at Weeks 2, 4, 8, and 12]

Measure Type	Secondary
Measure Title	Plasma Concentration of TMC435: Predose Plasma Concentration (C0h)
Measure Description	The table below shows the mean (standard deviation) values for the C0h of TMC435.To calculate the mean C0h for the study, C0h values were derived for each participant at each visit and then a median C0H value calculated across visits for each participant. The median COh value for each participant across all visits was used to calculate the mean C0h for the study.
Time Frame	Before administration of TMC435 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**259**
Plasma Concentration of TMC435: Predose Plasma Concentration (C0h) [units: ng/mL] Mean ± Standard Deviation	**1825 ± 2306.1**

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

30. Secondary: Plasma Concentration of TMC435: Systemic Clearance (CL) [Time Frame: Across 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) values for the CL of TMC435.To calculate the mean CL for all participants in the study, CL values were first derived for each participant at each visit and then a median CL value calculated across visits for each participant. The median CL value for each participant was used to calculate the mean CL for all participants in the study.
Time Frame	Across 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**259**
Plasma Concentration of TMC435: Systemic Clearance (CL) [units: L/h] Mean ± Standard Deviation	**5.05 ± 3.319**

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 began and throughout treatment and follow-up to rate the severity and impact of fatigue they experienced in the preceding 2 weeks on their daily lives. FSS total scores are the average of nine questions with a range from 1 [no fatigue] to 7 [worst possible fatigue]. An area under the curve (AUC) analysis compared the overall severity of fatigue in each treatment group from baseline to Week 72. The null hypothesis was that there would be no difference between the treatment arms in the amount of fatigue participants experienced throughout the study resulting in equal AUC from baseline to Week 72 (AUC72) for FSS total scores. The Table below shows the lease squares (LS) mean estimates of 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**260**	**130**
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	**214.907 (205.9021 to 223.9115)**	**235.586 (224.2016 to 246.9700)**
Week 72	**250.522 (239.8398 to 261.2051)**	**274.322 (260.8164 to 287.8279)**

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 Approach
P Value [3]	<0.001
Mean differences [4]	-20.679
Standard Error of the mean	± 6.0979
95% Confidence Interval	(-32.6399 to -8.7181)

[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]	<0.001
Mean differences [4]	-23.800
Standard Error of the mean	± 7.2358
95% Confidence Interval	(-37.9931 to -9.6064)

[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 Scores 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 Scores 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 during study visits throughout the study. WPAI Overall Productivity Scores ranged from 0% to 100% (higher WPAI scores indicated greater impairment in productivity). An area under the curve (AUC) analysis compared the overall WPAI Overall Work Productivity Scores in each treatment group from Baseline to Week 72. The null hypothesis was that there would be no difference between the treatment arms in the WPAI Overall Work Productivity Scores from Baseline to Week 72. The Table below shows the lease squares (LS) mean estimates of AUC at Week 72 (as well as at Week 60) in WPAI Work Productivity Scores 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**260**	**130**
Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Overall Work Productivity Scores Due to Hepatitis C Virus (HCV) Infection and Its Treatment [units: scores on a scale*weeks] Least Squares Mean (95% Confidence Interval)		
Week 60	**1555.204 (1419.4052 to 1691.0026)**	**1785.668 (1603.4340 to 1967.9027)**
Week 72	**1718.241 (1558.7326 to 1877.7493)**	**1966.449 (1752.2268 to 2180.6720)**

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

Groups [1]	All groups
Method [2]	Piecewise Linear Model
P Value [3]	0.030
Mean differences [4]	-230.464
Standard Error of the mean	± 105.9203
95% Confidence Interval	(-438.2662 to -22.6626)

[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 Scores Due to Hepatitis C Virus (HCV) Infection and Its Treatment

Groups [1]	All groups
Method [2]	Piecewise Linear Model
P Value [3]	0.047

Mean differences [4]	-248.208
Standard Error of the mean	± 124.6753
95% Confidence Interval	(-492.8253 to -3.5916)

[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 Activity Scores 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 Activity Scores 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. Scores ranged from 0 (no effect on activities) to 10 (completely prevented me from doing my daily activities). An area under the curve (AUC) analysis compared the impairment in daily activity scores in each treatment group from Baseline to Week 72. The null hypothesis was that there would be no difference between the treatment arms in impairment in daily activity scores from Baseline to Week 72. The Table below shows the lease squares (LS) mean estimates of AUC at Week 72 (as well as at Week 60) in the impairment in daily activity scores 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**260**	**130**
Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Daily Activity Scores Due to Hepatitis C Virus (HCV) Infection and Its Treatment [units: scores on a scale*weeks] Least Squares Mean (95% Confidence Interval)		
Week 60	**1514.400 (1379.7183 to 1649.0812)**	**1792.460 (1611.2749 to 1973.6441)**
Week 72	**1667.735 (1509.6180 to 1825.8526)**	**1975.457 (1762.6198 to 2188.2942)**

Statistical Analysis 1 for Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) for Impairment in Daily Activity Scores 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]	-278.060
Standard Error of the mean	± 105.6088
95% Confidence Interval	(-485.2529 to -70.8668)

[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 Activity Scores Due to Hepatitis C Virus (HCV) Infection and Its Treatment

Groups [1]	All groups
Method [2]	Piecewise Linear Model
P Value [3]	0.013
Mean differences [4]	-307.722
Standard Error of the mean	± 124.1956
95% Confidence Interval	(-551.4006 to -64.0429)

[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) in Work Productivity and Activity (WPAI) Absenteeism Scores 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) in Work Productivity and Activity (WPAI) Absenteeism Scores Due to Hepatitis C Virus (HCV) Infection and Its Treatment
Measure Description	Time missed from work in hours 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, question #2). The number of hours missed from work because of HCV was divided by the total number of hours supposed to work, and expressed as a percentage. An area under the curve (AUC) analysis compared the WPAI absenteeism scores in each treatment group from Baseline to Week 72. The null hypothesis was that there would be no difference between the treatment arms WPAI absenteeism scores from Baseline to Week 72. The Table below shows the lease squares (LS) mean estimates of AUC at Week 72 (as well as at Week 60) in WPAI absenteeism scores 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.
Analysis Population Description: 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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]	**167**	**80**
Area Under the Curve From Baseline to Week 60 (AUC60) and Week 72 (AUC72) in Work Productivity and Activity (WPAI) Absenteeism Scores Due to Hepatitis C Virus (HCV) Infection and Its Treatment [units: scores on a scale*weeks] Least Squares Mean (95% Confidence Interval)		

Week 60	**447.170 (329.8666 to 564.4736)**	**400.771 (235.0986 to 566.4429)**
Week 72	**487.449 (352.1468 to 622.7508)**	**430.285 (239.3346 to 621.2359)**

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

Groups [1]	All groups
Method [2]	Piecewise linear model
P Value [3]	0.642
Mean differences [4]	46.399
Standard Error of the mean	± 99.7966
95% Confidence Interval	(-149.6374 to 242.4360)

[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) in Work Productivity and Activity (WPAI) Absenteeism Scores Due to Hepatitis C Virus (HCV) Infection and Its Treatment

Groups [1]	All groups
Method [2]	Piecewise Linear Model
P Value [3]	0.620
Mean differences [4]	57.164
Standard Error of the mean	± 115.1548
95% Confidence Interval	(-169.1143 to 283.4414)

[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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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	**10/264 (3.79%)**	**8/130 (6.15%)**
Blood and lymphatic system disorders		
Anaemia [*1]		
# participants affected / at risk	**0/264 (0.00%)**	**1/130 (0.77%)**
Cardiac disorders		
Palpitations [*1]		
# participants affected / at risk	**1/264 (0.38%)**	**0/130 (0.00%)**
Acute myocardial infarction [*1]		
# participants affected / at risk	**0/264 (0.00%)**	**1/130 (0.77%)**
Myocardial infarction [*1]		
# participants affected / at risk	**0/264 (0.00%)**	**1/130 (0.77%)**
Endocrine disorders		
Goitre [*1]		
# participants affected / at risk	**0/264 (0.00%)**	**1/130 (0.77%)**
Gastrointestinal disorders		
Vomiting [*1]		
# participants affected / at risk	**1/264 (0.38%)**	**0/130 (0.00%)**
Hepatobiliary disorders		
Bile duct obstruction [*1]		
# participants affected / at risk	**1/264 (0.38%)**	**0/130 (0.00%)**
Hepatic lesion [*1]		
# participants affected / at risk	**1/264 (0.38%)**	**0/130 (0.00%)**
Infections and infestations		
Abscess limb [*1]		

# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Cellulitis *1		
# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Lower respiratory tract infection *1		
# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Pneumonia *1		
# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Staphylococcal infection *1		
# participants affected / at risk	0/264 (0.00%)	1/130 (0.77%)
Injury, poisoning and procedural complications		
Overdose *1		
# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Rib fracture *1		
# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Metabolism and nutrition disorders		
Hyponatraemia *1		
# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Nervous system disorders		
Syncope *1		
# participants affected / at risk	3/264 (1.14%)	0/130 (0.00%)
Migraine *1		
# participants affected / at risk	0/264 (0.00%)	1/130 (0.77%)
Psychiatric disorders		
Depression *1		
# participants affected / at risk	2/264 (0.76%)	0/130 (0.00%)
Major depression *1		
# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Suicidal ideation *1		
# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Anxiety *1		
# participants affected / at risk	0/264 (0.00%)	1/130 (0.77%)
Renal and urinary disorders		
Acute prerenal failure *1		
# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Epistaxis *1		
# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Vascular disorders		
Hypotension *1		
# participants affected / at risk	1/264 (0.38%)	0/130 (0.00%)
Aortic stenosis *1		
# participants affected / at risk	0/264 (0.00%)	1/130 (0.77%)
Arterial stenosis limb *1		
# participants affected / at risk	0/264 (0.00%)	1/130 (0.77%)

* 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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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 (PegIFN alpha-2a) and ribavirin (RBV) for 12 Weeks (Wks) followed by PegIFN alpha-2a (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	**252/264 (95.45%)**	**124/130 (95.38%)**
Blood and lymphatic system disorders		
Neutropenia *1		
# participants affected / at risk	**54/264 (20.45%)**	**15/130 (11.54%)**
Anaemia *1		
# participants affected / at risk	**44/264 (16.67%)**	**24/130 (18.46%)**
Thrombocytopenia *1		
# participants affected / at risk	**18/264 (6.82%)**	**5/130 (3.85%)**
Gastrointestinal disorders		
Nausea *1		
# participants affected / at risk	**65/264 (24.62%)**	**32/130 (24.62%)**
Diarrhoea *1		
# participants affected / at risk	**35/264 (13.26%)**	**19/130 (14.62%)**
Vomiting *1		
# participants affected / at risk	**23/264 (8.71%)**	**9/130 (6.92%)**
Abdominal pain upper *1		
# participants affected / at risk	**17/264 (6.44%)**	**9/130 (6.92%)**
Constipation *1		
# participants affected / at risk	**16/264 (6.06%)**	**4/130 (3.08%)**
Dyspepsia *1		
# participants affected / at risk	**14/264 (5.30%)**	**5/130 (3.85%)**
General disorders		

Fatigue [*1]		
# participants affected / at risk	111/264 (42.05%)	53/130 (40.77%)
Influenza like illness [*1]		
# participants affected / at risk	62/264 (23.48%)	26/130 (20.00%)
Pyrexia [*1]		
# participants affected / at risk	51/264 (19.32%)	28/130 (21.54%)
Chills [*1]		
# participants affected / at risk	33/264 (12.50%)	18/130 (13.85%)
Asthenia [*1]		
# participants affected / at risk	25/264 (9.47%)	21/130 (16.15%)
Pain [*1]		
# participants affected / at risk	12/264 (4.55%)	9/130 (6.92%)
Hepatobiliary disorders		
Hyperbilirubinaemia [*1]		
# participants affected / at risk	14/264 (5.30%)	4/130 (3.08%)
Infections and infestations		
Upper respiratory tract infection [*1]		
# participants affected / at risk	8/264 (3.03%)	7/130 (5.38%)
Investigations		
Neutrophil count decreased [*1]		
# participants affected / at risk	10/264 (3.79%)	8/130 (6.15%)
Alanine aminotransferase increased [*1]		
# participants affected / at risk	3/264 (1.14%)	9/130 (6.92%)
Aspartate aminotransferase increased [*1]		
# participants affected / at risk	3/264 (1.14%)	7/130 (5.38%)
Blood thyroid stimulating hormone increased [*1]		
# participants affected / at risk	1/264 (0.38%)	7/130 (5.38%)
Metabolism and nutrition disorders		
Decreased appetite [*1]		
# participants affected / at risk	47/264 (17.80%)	19/130 (14.62%)
Musculoskeletal and connective tissue disorders		
Myalgia [*1]		
# participants affected / at risk	39/264 (14.77%)	18/130 (13.85%)
Arthralgia [*1]		
# participants affected / at risk	34/264 (12.88%)	21/130 (16.15%)
Back pain [*1]		
# participants affected / at risk	21/264 (7.95%)	10/130 (7.69%)
Nervous system disorders		
Headache [*1]		
# participants affected / at risk	88/264 (33.33%)	51/130 (39.23%)
Dizziness [*1]		
# participants affected / at risk	23/264 (8.71%)	9/130 (6.92%)
Dysgeusia [*1]		
# participants affected / at risk	16/264 (6.06%)	4/130 (3.08%)

Psychiatric disorders		
Insomnia *1		
# participants affected / at risk	**56/264 (21.21%)**	**31/130 (23.85%)**
Mood altered *1		
# participants affected / at risk	**39/264 (14.77%)**	**19/130 (14.62%)**
Depression *1		
# participants affected / at risk	**23/264 (8.71%)**	**16/130 (12.31%)**
Anxiety *1		
# participants affected / at risk	**16/264 (6.06%)**	**10/130 (7.69%)**
Depressed mood *1		
# participants affected / at risk	**13/264 (4.92%)**	**11/130 (8.46%)**
Sleep disorder *1		
# participants affected / at risk	**10/264 (3.79%)**	**7/130 (5.38%)**
Respiratory, thoracic and mediastinal disorders		
Cough *1		
# participants affected / at risk	**25/264 (9.47%)**	**20/130 (15.38%)**
Dyspnoea *1		
# participants affected / at risk	**23/264 (8.71%)**	**9/130 (6.92%)**
Dyspnoea exertional *1		
# participants affected / at risk	**17/264 (6.44%)**	**1/130 (0.77%)**
Oropharyngeal pain *1		
# participants affected / at risk	**16/264 (6.06%)**	**5/130 (3.85%)**
Rhinorrhoea *1		
# participants affected / at risk	**2/264 (0.76%)**	**7/130 (5.38%)**
Skin and subcutaneous tissue disorders		
Pruritus *1		
# participants affected / at risk	**68/264 (25.76%)**	**20/130 (15.38%)**
Rash *1		
# participants affected / at risk	**60/264 (22.73%)**	**30/130 (23.08%)**
Dry skin *1		
# participants affected / at risk	**33/264 (12.50%)**	**11/130 (8.46%)**
Alopecia *1		
# participants affected / at risk	**30/264 (11.36%)**	**16/130 (12.31%)**
Erythema *1		
# participants affected / at risk	**15/264 (5.68%)**	**3/130 (2.31%)**

* 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: Jan-Cil France
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No publications provided by Janssen R&D Ireland

Publications automatically indexed to this study:

Jacobson IM, Dore GJ, Foster GR, Fried MW, Radu M, Rafalsky VV, Moroz L, Craxi A, Peeters M, Lenz O, Ouwerkerk-Mahadevan S, De La Rosa G, Kalmeijer R, Scott J, Sinha R, Beumont-Mauviel M. Simeprevir with pegylated interferon alfa 2a plus ribavirin in treatment-naive patients with chronic hepatitis C virus genotype 1 infection (QUEST-1): a phase 3, randomised, double-blind, placebo-controlled trial. Lancet. 2014 Aug 2;384 (9941):403-13. doi: 10.1016/S0140-6736(14)60494-3. Epub 2014 Jun 4.

Responsible Party:	Janssen R&D Ireland
ClinicalTrials.gov Identifier:	NCT01289782 History of Changes
Other Study ID Numbers:	**CR017386**, TMC435-TiDP16-C208
Study First Received:	January 7, 2011
Results First Received:	January 27, 2014
Last Updated:	May 20, 2014
Health Authority:	United States: Food and Drug Administration Ireland: Irish Agriculture and Food Development Authority Australia: Department of Health and Ageing Therapeutic Goods Administration Canada: Health Canada Germany: Ethics Commission Great Britain: Medicines and Healthcare Products Regulatory Agency Ukraine: State Pharmacological Center - Ministry of Health