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VX-950-TiDP24-C219: A Roll Over Trial for Patients in the Control Group of the C216 Study Who Received Telaprevir Placebo

This study has been completed.

Sponsor:
Janssen Infectious Diseases BVBA

Collaborator:
Vertex Pharmaceuticals Incorporated

Information provided by (Responsible Party):
Janssen Infectious Diseases BVBA

ClinicalTrials.gov Identifier:
NCT01054573

First received: January 21, 2010
Last updated: May 6, 2013
Last verified: May 2013
History of Changes

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Results First Received: March 8, 2013

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hepatitis C, Chronic
Interventions:	Drug: Telaprevir Drug: pegylated interferon (Peg-IFN) alfa-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
A total of 90 participants were enrolled and received treatment in the study: 9 participants from Phase 1 studies VX04-950-101 or Study VX05-950-103 and 81 participants from the Phase 3 study VX-950-TiDP24-C216 (NCT00703118) (referred to as the parent studies). The current study was conducted in 16 countries including the United States.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
This study provided participants with access to telaprevir who were randomized to the control group in a previous Phase 3 study and failed therapy with pegylated interferon (Peg-IFN) alfa-2a and ribavirin (RBV) or to participants who received telaprevir as monotherapy or in combination with Peg-IFN-alfa-2a in 2 previous Phase 1 studies.

Reporting Groups

	Description
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over

	from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior partial responders.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers.

Participant Flow: Overall Study

	Phase 1: T12 (Q8h)/PR	Phase 3: T12(Q8h)/PR - Prior Null Responder	Phase 3: T12(Q8h)/PR - Prior Partial Responder	Phase 3: T12(Q8h)/PR - Prior Relapser
STARTED	9	32	22	27
COMPLETED	8	28	19	25
NOT COMPLETED	1	4	3	2
Adverse Event	1	0	1	1
Lost to Follow-up	0	2	0	0
Withdrawal by Subject	0	2	2	1

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
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior partial responders.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers.
Total	Total of all reporting groups

Baseline Measures

	Phase 1: T12 (Q8h)/PR	Phase 3: T12(Q8h)/PR - Prior Null Responder	Phase 3: T12(Q8h)/PR - Prior Partial Responder	Phase 3: T12 (Q8h)/PR - Prior Relapser	Total
Number of Participants [units: participants]	9	32	22	27	90
Age [units: participants]					
<=18 years	0	0	0	0	0
	8	30	22	20	80

Between 18 and 65 years					
>=65 years	1	2	0	7	10
Age [units: years] Median (Inter-Quartile Range)	52 (49 to 61)	51.5 (42 to 59.5)	50.5 (47 to 58)	55 (46 to 66)	53 (45 to 60)
Gender [units: participants]					
Female	4	9	7	8	28
Male	5	23	15	19	62
Region of Enrollment [units: participants]					
Europe	9	18	10	14	51
North America	0	12	7	4	23
Other	0	2	5	9	16

Outcome Measures

Hide All Outcome Measures

1. Primary: The Percentage of Participants Achieving a Sustained Virologic Response (SVR) 24 Weeks After the Last Dose of Study Drug (SVR24 Actual) [Time Frame: End of trial (24 weeks after last dose, administerd at 48 weeks)]

Measure Type	Primary
Measure Title	The Percentage of Participants Achieving a Sustained Virologic Response (SVR) 24 Weeks After the Last Dose of Study Drug (SVR24 Actual)
Measure Description	The table below shows the percentage of participants acheiving a SVR 24 weeks after the last dose of study drug defined as having plasma hepatitis C virus (HCV) ribonucleic acid (RNA) levels < 25 IU/mL, target not detected at end of treatment (EOT) AND the participant did not relapse AND the participant completed the treatment; OR if the participant had plasma HCV RNA levels of < 25 IU/mL, target not detected at EOT AND the participant did not relapse AND the participant prematurely discontinued at least one study medication, but never for the reason virologic failure.
Time Frame	End of trial (24 weeks after last dose, administerd at 48 weeks)
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.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized participants who received at least one dose of study drug.

Reporting Groups

	Description
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior partial responders.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers.
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.

Measured Values

	Phase 3: T12 (Q8h)/PR - Prior Null Responder	Phase 3: T12 (Q8h)/PR - Prior Partial Responder	Phase 3: T12 (Q8h)/PR - Prior Relapser	Phase 1: T12 (Q8h)/PR
Number of Participants Analyzed [units: participants]	**32**	**22**	**27**	**9**
The Percentage of Participants Achieving a Sustained Virologic Response (SVR) 24 Weeks After the Last Dose of Study Drug (SVR24 Actual) [units: Percentage of participants with response]	**34.4**	**72.7**	**81.5**	**44.4**

No statistical analysis provided for The Percentage of Participants Achieving a Sustained Virologic Response (SVR) 24 Weeks After the Last Dose of Study Drug (SVR24 Actual)

2. Secondary: The Percentage of Participants Achieving Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values of Less Than 25 IU/ml, Target Not Detected at Different Time Points [Time Frame: Baseline, Weeks 4, 8, 12, 24, 36, and 48, and at the end of treatment (Week 48 or at time of early discontinuation)]

Measure Type	Secondary
Measure Title	The Percentage of Participants Achieving Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values of Less Than 25 IU/ml, Target Not Detected at Different Time Points
Measure Description	The table below shows the percentage of participants with undetectable hepatitis C virus (HCV) ribonucleic acid (RNA) levels of less than 25 IU/ml, target not detected at different time points during the study. Data was imputed for participants with missing values using the last observation carried forward (LOCF) method for missing values.
Time Frame	Baseline, Weeks 4, 8, 12, 24, 36, and 48, and at the end of treatment (Week 48 or at time of early discontinuation)
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.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized participants who received at least one dose of study drug.

Reporting Groups

	Description
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior partial responders.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers.
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.

Measured Values

	Phase 3: T12 (Q8h)/PR - Prior Null Responder	Phase 3: T12 (Q8h)/PR - Prior Partial Responder	Phase 3: T12 (Q8h)/PR - Prior Relapser	Phase 1: T12 (Q8h)/PR
Number of Participants Analyzed [units: participants]	**32**	**22**	**27**	**9**

The Percentage of Participants Achieving Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values of Less Than 25 IU/ml, Target Not Detected at Different Time Points [units: Percentage of participants with response]				
Basline	0	0	0	0
Week 4	37.5	77.3	85.2	33.3
Week 8	56.3	86.4	92.6	66.7
Week 12	59.4	90.9	92.6	66.7
Week 24	50.0	77.3	85.2	66.7
Week 36	43.8	81.8	85.2	77.8
Week 48	43.8	72.7	85.2	77.8
End of Treatment	43.8	86.4	92.6	77.8

No statistical analysis provided for The Percentage of Participants Achieving Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values of Less Than 25 IU/ml, Target Not Detected at Different Time Points

3. Secondary: Percentage of Participants Who Met a Virologic Stopping Rule That Required Them to Permanently Discontinue Telaprevir and Continue Pegylated Interferon (Peg-IFN) and Ribavirin (RBV) at Week 4 or Week 8 [Time Frame: Week 4, Week 8]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Met a Virologic Stopping Rule That Required Them to Permanently Discontinue Telaprevir and Continue Pegylated Interferon (Peg-IFN) and Ribavirin (RBV) at Week 4 or Week 8
Measure Description	The table below shows the percentage of participants at Week 4 or 8 who met a stopping rule defined as having a hepatitis C virus (HCV) ribonucleic acid (RNA) value >100 IU/mL.
Time Frame	Week 4, Week 8
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.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized participants who received at least one dose of study drug.

Reporting Groups

	Description
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior partial responders.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers.
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.

Measured Values

	Phase 3: T12 (Q8h)/PR - Prior Null Responder	Phase 3: T12 (Q8h)/PR - Prior Partial Responder	Phase 3: T12 (Q8h)/PR - Prior Relapser	Phase 1: T12 (Q8h)/PR

Number of Participants Analyzed [units: participants]	**32**	**22**	**27**	**9**
Percentage of Participants Who Met a Virologic Stopping Rule That Required Them to Permanently Discontinue Telaprevir and Continue Pegylated Interferon (Peg-IFN) and Ribavirin (RBV) at Week 4 or Week 8 [units: Percentage of participants]	**28.1**	**4.5**	**3.7**	**11.1**

No statistical analysis provided for Percentage of Participants Who Met a Virologic Stopping Rule That Required Them to Permanently Discontinue Telaprevir and Continue Pegylated Interferon (Peg-IFN) and Ribavirin (RBV) at Week 4 or Week 8

4. Secondary: Percentage of Participants Who Met a Virologic Stopping Rule That Required Them to Permanently Discontinue All Study Drugs at Week 12, 24, or 36 [Time Frame: Week 12 or Weeks 24 or 36]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Met a Virologic Stopping Rule That Required Them to Permanently Discontinue All Study Drugs at Week 12, 24, or 36
Measure Description	The table below shows the percentage of participants at Week 12, 24, and 36 who met a stopping rule. The stopping rule at Week 12 was having hepatitis C virus (HCV) ribonucleic acid (RNA) value of >100 IU/mL and the stopping rule at Weeks 24 or 36 was having a HCV RNA value of >=25 IU/mL.
Time Frame	Week 12 or Weeks 24 or 36
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.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized participants who received at least one dose of study drug.

Reporting Groups

	Description
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior partial responders.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers.
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.

Measured Values

	Phase 3: T12 (Q8h)/PR - Prior Null Responder	**Phase 3: T12 (Q8h)/PR - Prior Partial Responder**	**Phase 3: T12 (Q8h)/PR - Prior Relapser**	**Phase 1: T12 (Q8h)/PR**
Number of Participants Analyzed [units: participants]	**32**	**22**	**27**	**9**
Percentage of Participants Who Met a Virologic Stopping Rule That Required Them to Permanently Discontinue All Study Drugs at Week 12, 24, or 36 [units: Percentage of participants]				
Week 12	**31.2**	**4.5**	**0**	**11.1**
Week 24	**9.4**	**9.1**	**3.7**	**11.1**

Week 36	**9.4**	**0**	**0**	**0**

No statistical analysis provided for Percentage of Participants Who Met a Virologic Stopping Rule That Required Them to Permanently Discontinue All Study Drugs at Week 12, 24, or 36

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

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Rapid Virologic Response (RVR)
Measure Description	The table below shows the percentage of participants who had a rapid virologic response (RVR) (ie, those with undetectable hepatitis C virus [HCV] ribonucleic acid [RNA values of <25 IU/mL, target not detected at Week 4 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.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized participants who received at least one dose of study drug.

Reporting Groups

	Description
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior partial responders.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers.
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.

Measured Values

	Phase 3: T12(Q8h)/PR - Prior Null Responder	**Phase 3: T12(Q8h)/PR - Prior Partial Responder**	**Phase 3: T12 (Q8h)/PR - Prior Relapser**	**Phase 1: T12 (Q8h)/PR**
Number of Participants Analyzed [units: participants]	**32**	**22**	**27**	**9**
Percentage of Participants Achieving Rapid Virologic Response (RVR) [units: Percentage of participants]	**37.5**	**77.3**	**85.2**	**33.3**

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

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

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Extended Rapid Virologic Response (eRVR)
Measure Description	

	The table below shows the percentage of participants who had a Extended Rapid Virologic Response (eRVR) (ie, those with undetectable hepatitis C virus [HCV] ribonucleic acid [RNA values of <25 IU/mL, target not detected at at Weeks 4 and 12 of treatment).
Time Frame	Weeks 4 and 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized participants who received at least one dose of study drug.

Reporting Groups

	Description
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior partial responders.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers.
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.

Measured Values

	Phase 3: T12 (Q8h)/PR - Prior Null Responder	**Phase 3: T12(Q8h)/PR - Prior Partial Responder**	**Phase 3: T12 (Q8h)/PR - Prior Relapser**	**Phase 1: T12(Q8h)/PR**
Number of Participants Analyzed [units: participants]	**32**	**22**	**27**	**9**
Percentage of Participants Achieving Extended Rapid Virologic Response (eRVR) [units: Percentage of participants]	**34.4**	**72.7**	**85.2**	**33.3**

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

7. Secondary: Percentage of Participants With Viral Breakthrough [Time Frame: Week 48 (Period After Telaprevir Intake) and Week 12 (Telaprevir Treatment Phase)]

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 >1 log10 in hepatitis C virus (HCV) ribonucleic acid (RNA) level from the lowest level reached during the considered treatment phase up to the considered time point, if the lowest level reached is > 25 IU/mL, or a confirmed value of HCV RNA >100 IU/mL in participants whose HCV RNA had previously become <25 IU/mL (detected or target not detected) during the considered treatment phase.
Time Frame	Week 48 (Period After Telaprevir Intake) and Week 12 (Telaprevir Treatment Phase)
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.

All analyses were performed on the full analysis (FA) set, which was defined as all randomized participants who received at least one dose of study drug.

Reporting Groups

	Description
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior partial responders.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers.
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.

Measured Values

	Phase 3: T12(Q8h)/PR - Prior Null Responder	Phase 3: T12(Q8h)/PR - Prior Partial Responder	Phase 3: T12 (Q8h)/PR - Prior Relapser	Phase 1: T12 (Q8h)/PR
Number of Participants Analyzed [units: participants]	**32**	**22**	**27**	**9**
Percentage of Participants With Viral Breakthrough [units: Percentage of participants]				
Week 48 (Period After Telaprevir Intake)	**25.0**	**9.1**	**3.7**	**11.1**
Week 12 (Telaprevir Treatment Phase)	**15.6**	**4.5**	**0.0**	**11.1**

No statistical analysis provided for Percentage of Participants With Viral Breakthrough

8. Secondary: Percentage of Participants Who Relapsed During Follow-Up [Time Frame: During Follow-Up (24 weeks after the last dose of study drug, administerd at 48 weeks)]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Relapsed During Follow-Up
Measure Description	The table below shows the percentage of participants who relapsed (ie, those having confirmed detectable hepatitis C virus [HCV] ribonucleic acid [RNA] during the 24-week follow-up period after previous HCV RNA <25 IU/mL, target not detected, at end of treatment).
Time Frame	During Follow-Up (24 weeks after the last dose of study drug, administerd at 48 weeks)
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 analysis was performed on the full analysis (FA) set, which included all randomized participants who received at least one dose of study drug and had data at the follow-up visit performed 24 weeks after the last dose of study drug.

Reporting Groups

	Description
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over

	from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior partial responders.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers.
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.

Measured Values

	Phase 3: T12(Q8h)/PR - Prior Null Responder	Phase 3: T12(Q8h)/PR - Prior Partial Responder	Phase 3: T12 (Q8h)/PR - Prior Relapser	Phase 1: T12 (Q8h)/PR
Number of Participants Analyzed [units: participants]	**14**	**19**	**25**	**7**
Percentage of Participants Who Relapsed During Follow-Up [units: Percentage of participants]	**21.4**	**5.3**	**4.0**	**28.6**

No statistical analysis provided for Percentage of Participants Who Relapsed During Follow-Up

9. Secondary: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values Over Time [Time Frame: Baseline, Weeks 4, 8, 12, 24, 36, 48]

Measure Type	Secondary
Measure Title	Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values Over Time
Measure Description	The table below shows plasma Hepatitis C virus (HCV) ribonucleic acid (RNA) values measured over time.
Time Frame	Baseline, Weeks 4, 8, 12, 24, 36, 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.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized participants who received at least one dose of study drug.

Reporting Groups

	Description
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders. The number of participants analyzed at Baseline and Weeks 4, 8, 12, 24, 36, and 48 were: 32, 32, 32, 31, 23, 18, and 16, respectively.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior partial responders. The number of participants analyzed at Baseline and Weeks 4, 8, 12, 24, 36, and 48 were: 22, 22, 22, 22, 20, 19, and 16, respectively.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers. The number of participants analyzed at Baseline and Weeks 4, 8, 12, 24, 36, and 48 were: 27, 26, 26, 26, 24, 23, and 21, respectively.

Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103. The number of participants analyzed at Baseline and Weeks 4, 8, 12, 24, 36, and 48 were: 9, 9, 9, 9, 9, 8, 7, and 7, respectively.

Measured Values

	Phase 3: T12(Q8h)/PR - Prior Null Responder	Phase 3: T12(Q8h)/PR - Prior Partial Responder	Phase 3: T12 (Q8h)/PR - Prior Relapser	Phase 1: T12 (Q8h)/PR
Number of Participants Analyzed [units: participants]	**32**	**22**	**27**	**9**
Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values Over Time [units: Log 10 IU/mL] Median (Full Range)				
Baseline (n=32, 22, 27, and 9)	**6.63 (5.2 to 7.3)**	**6.72 (5.6 to 7.3)**	**6.48 (5.3 to 7.5)**	**6.76 (6.0 to 7.2)**
Week 4 (n=32, 22, 26, and 9)	**1.24 (0.7 to 6.7)**	**0.70 (0.7 to 1.2)**	**0.70 (0.7 to 2.3)**	**1.24 (0.7 to 1.5)**
Week 8 (n=32, 22, 26, and 9)	**0.70 (0.7 to 6.9)**	**0.70 (0.7 to 2.7)**	**0.70 (0.7 to 1.6)**	**0.70 (0.7 to 2.9)**
Week 12 (n=31, 22, 26, and 9)	**0.70 (0.7 to 7.1)**	**0.70 (0.7 to 4.3)**	**0.70 (0.7 to 1.2)**	**0.70 (0.7 to 5.5)**
Week 24 (n=23, 20, 26, and 8)	**0.70 (0.7 to 6.6)**	**0.70 (0.7 to 4.8)**	**0.70 (0.7 to 2.1)**	**0.70 (0.7 to 6.2)**
Week 36 (n=18, 19, 23, and 7)	**0.70 (0.7 to 4.8)**	**0.70 (0.7 to 4.8)**	**0.70 (0.7 to 0.7)**	**0.70 (0.7 to 0.7)**
Week 48 (n=16, 16, 21, and 7)	**0.70 (0.7 to 2.3)**	**0.70 (0.7 to 0.7)**	**0.70 (0.7 to 0.7)**	**0.70 (0.7 to 0.7)**

No statistical analysis provided for Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Values Over Time

10. Secondary: Change From Baseline in Log 10 Plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Level [Time Frame: Baseline, Weeks 4, 8, 12, 24, 36, and 48]

Measure Type	Secondary
Measure Title	Change From Baseline in Log 10 Plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Level
Measure Description	The table below shows change from baseline in log 10 plasma HCV RNA values measured over time.
Time Frame	Baseline, Weeks 4, 8, 12, 24, 36, and 48
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All analyses were performed on the full analysis (FA) set, which was defined as all randomized participants who received at least one dose of study drug.

Reporting Groups

	Description
Phase 3: T12(Q8h)/PR - Prior Null Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy due to virologic reasons and were categorized as prior null responders. The number of participants analyzed at Weeks 4, 8, 12, 24, 36, and 48 were: 32, 32, 31, 23, 18, and 15, respectively.
Phase 3: T12(Q8h)/PR - Prior Partial Responder	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior

	therapy for virologic reasons and were categorized as prior partial responders. The number of participants analyzed at Weeks 4, 8, 12, 24, 36, and 48 were: 22, 22, 22, 20, 19, and 16, respectively.
Phase 3: T12(Q8h)/PR - Prior Relapser	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216(NCT00703118) control group who failed prior therapy for virologic reasons and were categorized as prior relapsers. The number of participants analyzed at Weeks 4, 8, 12, 24, 36, and 48 were: 26, 26, 26, 24, 23, and 21, respectively.
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103. The number of participants analyzed at Weeks 4, 8, 12, 24, 36, and 48 were: 9, 9, 9, 8, 7, and 7, respectively.

Measured Values

	Phase 3: T12(Q8h)/PR - Prior Null Responder	Phase 3: T12(Q8h)/PR - Prior Partial Responder	Phase 3: T12 (Q8h)/PR - Prior Relapser	Phase 1: T12 (Q8h)/PR
Number of Participants Analyzed [units: participants]	**32**	**22**	**27**	**9**
Change From Baseline in Log 10 Plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Level [units: log 10 IU/ml] Median (Full Range)				
Week 4 (n=32, 22, 26, and 9)	**-5.39 (-6.6 to -0.6)**	**-5.83 (-6.6 to -4.9)**	**-5.59 (-6.8 to -4.4)**	**-5.55 (-6.1 to -5.1)**
Week 8 (n=32, 22, 26, and 9)	**-5.51 (-6.6 to -0.4)**	**-5.88 (-6.6 to -4.6)**	**-5.62 (-6.8 to -4.6)**	**-5.96 (-6.3 to -3.4)**
Week 12 (n=31, 22, 26, 9)	**-5.40 (-6.6 to -0.2)**	**-5.88 (-6.6 to -3.0)**	**-5.62 (-6.8 to -4.6)**	**-5.96 (-6.3 to -0.9)**
Week 24 (n=23, 20, 24, and 8)	**-5.89 (-6.6 to 1.0)**	**-5.72 (-6.6 to -2.2)**	**-5.75 (-6.8 to -4.6)**	**-5.87 (-6.1 to -1.0)**
Week 36 (n=18, 19, 23, and 7)	**-5.95 (-6.6 to -0.6)**	**-5.86 (-6.6 to -2.3)**	**-5.78 (-6.8 to -4.6)**	**-6.07 (-6.3 to -5.3)**
Week 48 (n=15, 16, 21, and 7)	**-6.03 (-6.6 to -4.1)**	**-5.88 (-6.6 to -5.2)**	**-5.71 (-6.8 to -4.6)**	**-6.07 (-6.3 to -5.3)**

No statistical analysis provided for Change From Baseline in Log 10 Plasma Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Level

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From Baseline (Day 1) through Week 48 (or last dose of study drug received) + 24 week follow-up period.
Additional Description	No text entered.

Reporting Groups

	Description
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.
Phase 3: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy due to virologic reasons (ncludes all participants, ie, those categorized as prior null responders, prior partial responders, and prior relapsers).

Serious Adverse Events

	Phase 1: T12(Q8h)/PR	Phase 3: T12(Q8h)/PR
Total, serious adverse events		

# participants affected / at risk	0/9 (0.00%)	5/81 (6.17%)
Blood and lymphatic system disorders		
Anaemia *1		
# participants affected / at risk	0/9 (0.00%)	3/81 (3.70%)
Hepatobiliary disorders		
Biliary colic *1		
# participants affected / at risk	0/9 (0.00%)	1/81 (1.23%)
Infections and infestations		
Pyelonephritis *1		
# participants affected / at risk	0/9 (0.00%)	1/81 (1.23%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	From Baseline (Day 1) through Week 48 (or last dose of study drug received) + 24 week follow-up period.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Phase 1: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 1 Studies VX04-950-101 or VX05-950-103.
Phase 3: T12(Q8h)/PR	T12(Q8)/PR=Telaprevir every 8 hours for 12 weeks in combination with pegylated interferon (Peg-IFN) alfa-2a + ribavirin (RBV) administered for 48 weeks to participants who rolled-over from Phase 3 Study VX-950-TiDP24-C216 (NCT00703118) control group who failed prior therapy due to virologic reasons (ncludes all participants, ie, those categorized as prior null responders, prior partial responders, and prior relapsers).

Other Adverse Events

	Phase 1: T12(Q8h)/PR	Phase 3: T12(Q8h)/PR
Total, other (not including serious) adverse events		
# participants affected / at risk	9/9 (100.00%)	77/81 (95.06%)
Blood and lymphatic system disorders		
Anaemia *1		
# participants affected / at risk	1/9 (11.11%)	23/81 (28.40%)
Leukopenia *1		
# participants affected / at risk	0/9 (0.00%)	8/81 (9.88%)
Neutropenia *1		
# participants affected / at risk	1/9 (11.11%)	11/81 (13.58%)
Thrombocytopenia *1		
# participants affected / at risk	1/9 (11.11%)	7/81 (8.64%)
Ear and labyrinth disorders		
Vertigo *1		
# participants affected / at risk	1/9 (11.11%)	1/81 (1.23%)
Eye disorders		
Dry eye *1		
# participants affected / at risk	1/9 (11.11%)	1/81 (1.23%)

Gastrointestinal disorders		
Anal pruritus [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**6/81 (7.41%)**
Anorectal discomfort [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**6/81 (7.41%)**
Aphthous stomatitis [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**1/81 (1.23%)**
Constipation [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**1/81 (1.23%)**
Diarrhoea [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**12/81 (14.81%)**
Dry mouth [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**5/81 (6.17%)**
Dyspepsia [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**5/81 (6.17%)**
Gastritis [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**0/81 (0.00%)**
Haemorrhoids [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**9/81 (11.11%)**
Nausea [*1]		
# participants affected / at risk	**5/9 (55.56%)**	**18/81 (22.22%)**
Vomiting [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**5/81 (6.17%)**
General disorders		
Asthenia [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**15/81 (18.52%)**
Fatigue [*1]		
# participants affected / at risk	**7/9 (77.78%)**	**33/81 (40.74%)**
Influenza like illness [*1]		
# participants affected / at risk	**3/9 (33.33%)**	**8/81 (9.88%)**
Irritability [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**10/81 (12.35%)**
Mucosal inflammation [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**0/81 (0.00%)**
Pyrexia [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**11/81 (13.58%)**
Infections and infestations		
Bronchitis [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**0/81 (0.00%)**
Cystitis [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**1/81 (1.23%)**
Fungal infection [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**0/81 (0.00%)**
Nasopharyngitis [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**2/81 (2.47%)**
Upper respiratory tract infection [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**2/81 (2.47%)**
Investigations		
Weight decreased [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**5/81 (6.17%)**

Metabolism and nutrition disorders		
Anorexia [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**5/81 (6.17%)**
Decreased appetite [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**12/81 (14.81%)**
Hyperuricaemia [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**5/81 (6.17%)**
Musculoskeletal and connective tissue disorders		
Back pain [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**0/81 (0.00%)**
Myalgia [*1]		
# participants affected / at risk	**2/9 (22.22%)**	**7/81 (8.64%)**
Nervous system disorders		
Disturbance in attention [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**2/81 (2.47%)**
Dizziness [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**9/81 (11.11%)**
Headache [*1]		
# participants affected / at risk	**3/9 (33.33%)**	**17/81 (20.99%)**
Psychiatric disorders		
Depression [*1]		
# participants affected / at risk	**3/9 (33.33%)**	**6/81 (7.41%)**
Insomnia [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**12/81 (14.81%)**
Reproductive system and breast disorders		
Genital rash [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**0/81 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Cough [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**9/81 (11.11%)**
Dyspnoea [*1]		
# participants affected / at risk	**3/9 (33.33%)**	**9/81 (11.11%)**
Skin and subcutaneous tissue disorders		
Alopecia [*1]		
# participants affected / at risk	**0/9 (0.00%)**	**5/81 (6.17%)**
Dermatitis bullous [*1]		
# participants affected / at risk	**2/9 (22.22%)**	**0/81 (0.00%)**
Dry skin [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**9/81 (11.11%)**
Prurigo [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**0/81 (0.00%)**
Pruritus [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**33/81 (40.74%)**
Rash [*1]		
# participants affected / at risk	**3/9 (33.33%)**	**17/81 (20.99%)**
Skin exfoliation [*1]		
# participants affected / at risk	**1/9 (11.11%)**	**1/81 (1.23%)**
Vascular disorders		
Hypertension [*1]		

# participants affected / at risk	1/9 (11.11%)	1/81 (1.23%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

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.

☑ **Restriction Description:** It is the policy of the sponsor not to allow the investigators to publish their results or findings prior to the sponsor's publication of the overall trial results. The investigator agrees that before he/she publishes any results of this trial, he/she shall allow at least 45 days for the sponsor to review the prepublication manuscript prior to submission of the manuscript to the publisher as specified in the Clinical Trial Agreement between institution/investigator and sponsor.

Results Point of Contact:

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phone: 1 609 730-3174

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