ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 03/04/2014

Grantor: CDER IND/IDE Number: 106,739 Serial Number: SN-0071

Phase 3 Study of Sofosbuvir and Ribavirin (FISSION)

This study has been completed.

Sponsor:	Gilead Sciences
Collaborators:	
Information provided by (Responsible Party):	Gilead Sciences
ClinicalTrials.gov Identifier:	NCT01497366

Purpose

This study was to assess the safety and efficacy of sofosbuvir (GS-7977; PSI-7977) in combination with ribavirin (RBV) administered for 12 weeks compared with pegylated interferon (PEG)/RBV administered for 24 weeks in treatment-naive patients with Hepatitis C (HCV) genotype 2 or 3. Efficacy was assessed by the rate of sustained viral response (SVR) 12 weeks after the discontinuation of therapy (SVR12). This was a non-inferiority study, and if non-inferiority was demonstrated, the study was then allowed to test for superiority.

Condition	Intervention	Phase
Hepatitis C	Drug: Sofosbuvir Drug: PEG Drug: RBV	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Open Label, Randomized, Safety/Efficacy Study
Official Title: A Phase 3, Multicenter, Randomized, Active-Controlled Study to Investigate the Safety and Efficacy of PSI-7977 and Ribavirin for 12 Weeks Compared to Pegylated Interferon and Ribavirin for 24 Weeks in Treatment-Naïve Patients With Chronic Genotype 2 or 3 HCV Infection

Further study details as provided by Gilead Sciences:
Primary Outcome Measure:

- Percentage of Participants With Sustained Virologic Response 12 Weeks After Stopping All Study Drugs (SVR12) [Time Frame: Post-treatment Week 12] [Designated as safety issue: No]
  SVR12 was defined as HCV RNA < the lower limit of quantitation (LLOQ; < 25 IU/mL) 12 weeks after study drug cessation.

Secondary Outcome Measures:

- Number of Participants Who Experienced Adverse Events (AEs) and Graded Laboratory Abnormalities [Time Frame: Up to 24 weeks plus 30 days following the last dose of study drug] [Designated as safety issue: No]
- Percentage of Participants With Sustained Virologic Response 24 Weeks After Stopping All Study Drugs (SVR24) [Time Frame: Post-treatment Week 24] [Designated as safety issue: No]
  SVR24 was defined as HCV RNA < LLOQ 24 weeks after study drug cessation.
- Percentage of Participants With HCV RNA < LLOQ on Treatment [Time Frame: Up to 12 Weeks] [Designated as safety issue: No]
- Change From Baseline in HCV RNA [Time Frame: Baseline to Week 12] [Designated as safety issue: No]
- Percentage of Participants With Virologic Failure During Treatment [Time Frame: Baseline up to Week 24] [Designated as safety issue: Yes]
  Virologic failure was defined as either • Viral breakthrough: HCV RNA ≥ 25 IU/mL after having previously had HCV RNA < 25 IU/mL while on treatment, confirmed with 2 consecutive values or last available measurement • Viral rebound: > 1 log10 IU/mL increase in HCV RNA from nadir while on treatment, confirmed with 2 consecutive values or last available measurement • Non-response: HCV RNA persistently ≥ 25 IU/ml while on treatment (through Week 12)
- Percentage of Participants With Viral Relapse Following Treatment [Time Frame: Up to Post-treatment Week 24] [Designated as safety issue: Yes]
  Viral relapse was defined as HCV RNA ≥ 25 IU/mL in post-treatment after having achieved < LLOQ at last on-treatment measurement, confirmed with 2 consecutive values or last available measurement.

Enrollment: 527
Study Start Date: December 2011
Primary Completion Date: January 2013
Study Completion Date: April 2013

Arms	Assigned Interventions
Experimental: Sofosbuvir+RBV Participants were randomized to receive sofosbuvir+RBV for 12 weeks.	Drug: Sofosbuvir Sofosbuvir 400 mg (2 × 200 mg tablets) administered orally once daily Other Names: Sovaldi™ GS-7977 PSI-7977 Drug: RBV Ribavirin (RBV) administered as 200 mg tablets up to 1200 mg in a divided daily dose • Dose of sofosbuvir+RBV group based on baseline weight: < 75kg = 1000 mg and ≥ 75 kg = 1200 mg • Dose of PEG+RBV group: 800 mg
Active Comparator: PEG+RBV	Drug: PEG

Arms	Assigned Interventions
Participants were randomized to receive PEG+RBV for 24 weeks.	Pegylated interferon alfa-2a (PEG) 180 µg administered once weekly by subcutaneous injection Other Names: Pegasys® Drug: RBV Ribavirin (RBV) administered as 200 mg tablets up to 1200 mg in a divided daily dose • Dose of sofosbuvir+RBV group based on baseline weight: < 75kg = 1000 mg and ≥ 75 kg = 1200 mg • Dose of PEG+RBV group: 800 mg

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Chronic Genotype 2 or 3 HCV-infection
- Naive to all HCV antiviral treatment(s)

Exclusion Criteria:

- Positive test at Screening for HBsAg, anti-hepatitis B core immunoglobulin M antibody (anti-HBc IgM Ab), or anti-HIV Ab
- History of any other clinically significant chronic liver disease
- A history consistent with decompensated liver disease
- History or current evidence of psychiatric illness, immunologic disorder, hemoglobinopathy, pulmonary or cardiac disease, seizure disorder or anticonvulsant use, poorly controlled diabetes, cancer, or a history of malignancy, that makes the subject unsuitable for the study.
- Participation in a clinical study within 3 months prior to first dose

Contacts and Locations

Locations
United States, Alabama
University of Alabama at Birmingham
Birmingham, Alabama, United States, 35294
Alabama Liver & Digestive Specialist
Montgomery, Alabama, United States, 36116

United States, California
Franco Felizarta, MD
Bakersfield, California, United States, 93301
California Liver Institute
Beverly Hills, California, United States, 90210
Arrowhead Regional Medical Center
Colton, California, United States, 92324
SCTI Research Foundation
Coronado, California, United States, 92118
eStudy Site
La Mesa, California, United States, 91940
Peter J. Ruane, M.D. Inc.
Los Angeles, California, United States, 90036
eStudySite
Oceanside, California, United States, 92056
University of California, Davis - Health System
Sacramento, California, United States, 95817
Medical Associates Research Group, Inc.
San Diego, California, United States, 92123
University of California San Diego Medical Center
San Diego, California, United States, 92103
Research and Education, Inc.
San Diego, California, United States, 92105
Quest Clinical Research
San Francisco, California, United States, 94115
United States, Colorado
South Denver Gastroenterology, PC
Englewood, Colorado, United States, 80113
United States, Florida
Pointe West Infectious Diseases
Bradenton, Florida, United States, 34209
Midway Immunology & Research Center, LLC
Fort Pierce, Florida, United States, 34982
University of Florida College of Medicine
Gainesville, Florida, United States, 32610
Borland-Groover Clinic Baptist
Jacksonville, Florida, United States, 32256
University of Miami, School of Medicine
Miami, Florida, United States, 33136
Orlando Immunology Center
Orlando, Florida, United States, 32803
Internal Medicine Specialists
Orlando, Florida, United States, 32806
Advanced Research Institute
Trinity, Florida, United States, 34655

South Florida Center of Gastroenterology
Wellington, Florida, United States, 33414
United States, Georgia
AIDS Research Consortium of Atlanta, Inc.
Atlanta, Georgia, United States, 30308
Atlanta Gastroenterology Associates
Atlanta, Georgia, United States, 30308
Gastrointestinal Specialists of Georgia, PC
Marietta, Georgia, United States, 30060
United States, Illinois
University of Chicago
Chicago, Illinois, United States, 60637
United States, Indiana
Indianapolis Gastroenterology Research Foundation
Indianapolis, Indiana, United States, 46237
United States, Maryland
Digestive Disease Associates, P.A.
Baltimore, Maryland, United States, 21229
United States, Massachusetts
Beth Israel Deaconess Medical Center
Boston, Massachusetts, United States, 02115
The Research Institute
Springfield, Massachusetts, United States, 01105
University of Massachusetts, Worcester
Worcester, Massachusetts, United States, 01655
Partners in Internal Medicine, PC
Worcester, Massachusetts, United States, 01608-1320
University of Massachusetts, Worcester
Worcester, Massachusetts, United States, 01655
United States, Michigan
Henry Ford Health System
Detroit, Michigan, United States, 48202
United States, Mississippi
Digestive Health Specialists, PA
Tupelo, Mississippi, United States, 38801
United States, New Jersey
Veterans Affairs Medical Center
East Orange, New Jersey, United States, 07018
AGA Clinical Research Associates, LLC
Egg Harbor Township, New Jersey, United States, 08234
ID Care
Hillsborough, New Jersey, United States, 08844
Atlantic Research Affiliates, LLC
Morristown, New Jersey, United States, 07960
United States, New Mexico

Southwest C.A.R.E. Center
Santa Fe, New Mexico, United States, 87505
United States, New York
North Shore University Hospital
Manhasset, New York, United States, 11030
Mount Sinai School of Medicine
New York, New York, United States, 10029
Weill Cornell Medical College
New York, New York, United States, 10021
University of Rochester
Rochester, New York, United States, 14662
United States, North Carolina
Asheville Gastroenterology Associates, P.A.
Asheville, North Carolina, United States, 28801
Duke University Medical Center
Durham, North Carolina, United States, 27710
Carolinas Center for Liver Disease
Statesville, North Carolina, United States, 28677
Digestive Health Specialists, PA
Winston-Salem, North Carolina, United States, 27103
United States, Ohio
University of Cincinnati
Cincinnati, Ohio, United States, 45267
United States, Oklahoma
Gastroenterology United of Tulsa
Tulsa, Oklahoma, United States, 74135
United States, Oregon
Schleinitz Research and Gastroenterology LLC
Medford, Oregon, United States, 97504
Schleinitz Research and Gastroenterology LLC
Medford, Oregon, United States, 97504
United States, Pennsylvania
Regional Gastroenterology Associates of Lancaster, Ltd.
Lancaster, Pennsylvania, United States, 17604
UPMC Center For Liver Diseases
Pittsburgh, Pennsylvania, United States, 15213
United States, Rhode Island
University Gastroenterology
Warwick, Rhode Island, United States, 02886
United States, Tennessee
Gastro One
Germantown, Tennessee, United States, 38138
Nashville Gastrointestinal Specialists Inc.
Nashville, Tennessee, United States, 37211
United States, Texas

Texas Clinical Research Institute, LLC
Arlington, Texas, United States, 76012
Baylor University Medical Center
Dallas, Texas, United States, 75246
VAMC & Baylor College
Houston, Texas, United States, 77030
Kelsey-Seybold Clinic PA
Houston, Texas, United States, 77005
Research Specialists of Texas
Houston, Texas, United States, 77030
Alamo Medical Research
San Antonio, Texas, United States, 78215
United States, Virginia
Metropolitan Research
Fairfax, Virginia, United States, 22031
Digestive and Liver Disease Specialist, Ltd.
Norfolk, Virginia, United States, 23502
Digestive and Liver Disease Specialists
Norfolk, Virginia, United States, 23502
United States, Washington
Virginia Mason Medical Center
Seattle, Washington, United States, 98101
Australia, Australian Capital Territory
Canberra Hospital
Garran, Australian Capital Territory, Australia, 2605
Australia, New South Wales
Royal Prince Alfred Hospital
Camperdown, New South Wales, Australia, 2050
Concord Repatriation General Hospital
Concord, New South Wales, Australia, 2137
St. George Hospital
Kogarah, New South Wales, Australia, 2217
Australia, Queensland
Gallipoli MRF
Greenslopes, Queensland, Australia, 4120
Royal Brisbane Hospital Research Foundation
Herston, Queensland, Australia, 4029
Princess Alexandria
Woollongabba, Queensland, Australia, 4102
Australia, South Australia
Royal Adelaide Hospital
Adelaide, South Australia, Australia, 5000
Australia, Victoria
Monash Medical Centre
Clayton, Victoria, Australia, 3168

Austin Hospital
Heidelberg, Victoria, Australia, 3084
The Alfred
Melbourne, Victoria, Australia, 3004
Australia, Western Australia
Fremantle Hospital
Fremantle, Western Australia, Australia, 6160
Sir Charles Gairdner
Nedlands, Western Australia, Australia, 6009
Royal Perth Hospital
Perth, Western Australia, Australia, 6000
Canada, British Columbia
(G.I.R.I.) Gastrointestinal Research Institute
Vancouver, British Columbia, Canada, V6Z 2K5
Canada, Ontario
Mount Sinai Hospital
Toronto, Ontario, Canada, M5G 1X5
Toronto Liver Centre
Toronto, Ontario, Canada, M6H 3M1
University Health Network-Toronto Western Hospital
Toronto, Ontario, Canada, M5G 2N2
Toronto Digestive Disease Associates, Inc.
Vaughan, Ontario, Canada, L4L 4Y7
Italy
Casa Sollievo della Sofferenza Hospital
San Giovanni Rotondo, Italy, 71013
Netherlands
Academish Medisch Centrum
Amsterdam, Netherlands, 1105 AZ
New Zealand
Auckland City Hospital
Grafton, Auckland, New Zealand
Tauranga Hospital
Tauranga, BOP, New Zealand, 3143
Christchurch Hospital
Chrischurch, Canterbury, New Zealand, 8001
Mercy Hospital
Dunedin, OTA, New Zealand, 9010
Wellington Hospital
Newtown, WGN, New Zealand, 6021
Waikato Hospital (District Health Board)
Hamilton, Waikato, New Zealand, 3240
Puerto Rico
Fundacion de Investigacion de Diego
San Juan, Puerto Rico, Puerto Rico, 00927

Sweden
Sahlgrenska Universitetssjukhuset, Östra Sjukhus
Göteborg, Sweden, 41685
Karolinska Universitetssjukhuset, Solna
Stockholm, Sweden, 171 76

More Information

Responsible Party: Gilead Sciences
Study ID Numbers: P7977-1231
Health Authority: United States: Food and Drug Administration

Study Results

Participant Flow

Recruitment Details	Subjects were enrolled in a total of 90 study sites in the United States, Australia, New Zealand, Canada, Sweden, Italy, and the Netherlands. The first participant was screened on 19 December 2011. The last participant observation was on 08 April 2013.
Pre-Assignment Details	666 participants were screened and 527 were randomized; 499 participants received at least 1 dose of study drug, and comprise the Safety Analysis Set. The 496 participants with genotype 2 or 3 HCV infection who were randomized and received at least 1 dose of study drug comprise the Full Analysis Set.

Reporting Groups

	Description
Sofosbuvir+RBV	Participants were randomized to receive sofosbuvir+ribavirin (RBV) for 12 weeks.
PEG+RBV	Participants were randomized to receive PEG+RBV for 24 weeks.

Overall Study

	Sofosbuvir+RBV	PEG+RBV
Started	263	264
Randomized But Not Treated	7	21
Completed	224	176
Not Completed	39	88
Virologic failure	2	50

	Sofosbuvir+RBV	PEG+RBV
Lost to Follow-up	11	10
Withdrawal by Subject	6	6
Initiated Non-protocol HCV Treatment	7	0
Unknown	5	0
Death	1	1
Randomized but not treated	7	21

Baseline Characteristics

Analysis Population Description
Safety Analysis Set

Reporting Groups

	Description
Sofosbuvir+RBV	Participants were randomized to receive sofosbuvir+RBV for 12 weeks.
PEG+RBV	Participants were randomized to receive PEG+RBV for 24 weeks.

Baseline Measures

	Sofosbuvir+RBV	PEG+RBV	Total
Number of Participants	256	243	499
Age, Continuous [units: years] Mean (Standard Deviation)	48 (10.8)	48 (11.4)	48 (11.0)
Gender, Male/Female [units: participants]			
Female	85	87	172
Male	171	156	327
Ethnicity (NIH/OMB) [units: participants]			
Hispanic or Latino	41	31	72
Not Hispanic or Latino	215	212	427
Unknown or Not Reported	0	0	0

	Sofosbuvir+RBV	PEG+RBV	Total
Race/Ethnicity, Customized [units: participants]			
Black or African American	12	5	17
White	223	212	435
Asian	14	15	29
American Indian/Alaska Native/ First Nations	4	4	8
Hawaiian or Pacific Islander	2	6	8
Black and White	1	0	1
South American	0	1	1
Region of Enrollment [units: participants]			
United States	165	151	316
Canada	15	24	39
Australia	32	29	61
Netherlands	3	1	4
Italy	8	4	12
New Zealand	29	30	59
Sweden	4	4	8
Hepatitis C Virus (HCV) genotype [units: participants]			
Genotype 1	3	0	3
Genotype 2	70	67	137
Genotype 3	183	176	359
Baseline HCV RNA [units: log10 IU/mL] Mean (Standard Deviation)	6.0 (0.82)	6.0 (0.78)	6.0 (0.80)
Baseline HCV RNA Category [units: participants]			
< 6 log10 IU/mL	108	106	214

	Sofosbuvir+RBV	PEG+RBV	Total
≥ 6 log10 IU/mL	148	137	285
IL28b genotype [units: participants]			
CC	108	106	214
CT	121	98	219
TT	25	38	63
Missing	2	1	3
Cirrhosis [units: participants]			
No	205	189	394
Yes	50	50	100
Missing	1	4	5

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Sustained Virologic Response 12 Weeks After Stopping All Study Drugs (SVR12)
Measure Description	SVR12 was defined as HCV RNA < the lower limit of quantitation (LLOQ; < 25 IU/mL) 12 weeks after study drug cessation.
Time Frame	Post-treatment Week 12
Safety Issue?	No

Analysis Population Description
Full Analysis Set

Reporting Groups

	Description
Sofosbuvir+RBV	Participants were randomized to receive sofosbuvir+RBV for 12 weeks.
PEG+RBV	Participants were randomized to receive PEG+RBV for 24 weeks.

Measured Values

	Sofosbuvir+RBV	PEG+RBV
Number of Participants Analyzed	253	243
Percentage of Participants With Sustained Virologic Response 12 Weeks After Stopping All Study Drugs (SVR12) [units: percentage of participants]	67	67

Statistical Analysis 1 for Percentage of Participants With Sustained Virologic Response 12 Weeks After Stopping All Study Drugs (SVR12)

Statistical Analysis Overview	Comparison Groups	Sofosbuvir+RBV, PEG+RBV
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	Non-inferiority would be demonstrated if the lower bound of the 2-sided 95% confidence interval (CI) for the difference in SVR12 rates was greater than -15%.

Method of Estimation	Estimation Parameter	Other [Difference in percentages]
	Estimated Value	0.3
	Confidence Interval	(2-Sided) 95% -7.5 to 8.0
	Estimation Comments	The difference in percentages between treatment groups and the 95% CI calculated were based on stratum adjusted Mantel-Haenszel proportions.

2. Secondary Outcome Measure:

Measure Title	Number of Participants Who Experienced Adverse Events (AEs) and Graded Laboratory Abnormalities
Measure Description	
Time Frame	Up to 24 weeks plus 30 days following the last dose of study drug
Safety Issue?	No

Analysis Population Description

Safety Analysis Set

Reporting Groups

	Description
Sofosbuvir+RBV	Participants were randomized to receive sofosbuvir+RBV for 12 weeks.
PEG+RBV	Participants were randomized to receive PEG+RBV for 24 weeks.

Measured Values

	Sofosbuvir+RBV	PEG+RBV
Number of Participants Analyzed	256	243
Number of Participants Who Experienced Adverse Events (AEs) and Graded Laboratory Abnormalities [units: participants]		
AEs leading to discontinuation of any study drug	3	29
Serious AEs	7	3
Grade 3 laboratory abnormalities	33	80
Grade 4 laboratory abnormalities	3	21
Deaths	1	0

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Sustained Virologic Response 24 Weeks After Stopping All Study Drugs (SVR24)
Measure Description	SVR24 was defined as HCV RNA < LLOQ 24 weeks after study drug cessation.
Time Frame	Post-treatment Week 24
Safety Issue?	No

Analysis Population Description
Full Analysis Set

Reporting Groups

	Description
Sofosbuvir+RBV	Participants were randomized to receive sofosbuvir+RBV for 12 weeks.
PEG+RBV	Participants were randomized to receive PEG+RBV for 24 weeks.

Measured Values

	Sofosbuvir+RBV	PEG+RBV
Number of Participants Analyzed	253	243
Percentage of Participants With Sustained Virologic Response 24 Weeks After Stopping All Study Drugs (SVR24) [units: percentage of participants]	66.8	65.4

4. Secondary Outcome Measure:

Measure Title	Percentage of Participants With HCV RNA < LLOQ on Treatment
Measure Description	
Time Frame	Up to 12 Weeks
Safety Issue?	No

Analysis Population Description

Participants in the Full Analysis Set with available data were analyzed.

Reporting Groups

	Description
Sofosbuvir+RBV	Participants were randomized to receive sofosbuvir (SOF)+RBV for 12 weeks.
PEG+RBV	Participants were randomized to receive PEG+RBV for 24 weeks.

Measured Values

	Sofosbuvir+RBV	PEG+RBV
Number of Participants Analyzed	253	243
Percentage of Participants With HCV RNA < LLOQ on Treatment [units: percentage of participants]		
Week 1 (SOF+RBV, n = 252; PEG+RBV, n = 243)	43.7	6.6
Week 2 (SOF+RBV, n = 251; PEG+RBV, n = 241)	92.0	31.5
Week 4 (SOF+RBV, n = 250; PEG+RBV, n = 236)	99.6	66.9
Week 8 (SOF+RBV, n = 248; PEG+RBV, n = 231)	99.6	85.7

	Sofosbuvir+RBV	PEG+RBV
Week 12 (SOF+RBV, n = 244; PEG+RBV, n = 224)	99.2	92.4

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in HCV RNA
Measure Description	
Time Frame	Baseline to Week 12
Safety Issue?	No

Analysis Population Description

Participants in the Full Analysis Set with available data were analyzed.

Reporting Groups

	Description
Sofosbuvir+RBV	Participants were randomized to receive sofosbuvir (SOF)+RBV for 12 weeks.
PEG+RBV	Participants were randomized to receive PEG+RBV for 24 weeks.

Measured Values

	Sofosbuvir+RBV	PEG+RBV
Number of Participants Analyzed	253	243
Change From Baseline in HCV RNA [units: log10 IU/mL] Mean (Standard Deviation)		
Week 1 (SOF+RBV, n = 239; PEG+RBV, n = 236)	-4.26 (0.689)	-2.19 (1.287)
Week 2 (SOF+RBV, n = 246; PEG+RBV, n = 233)	-4.60 (0.820)	-3.19 (1.572)
Week 4 (SOF+RBV, n = 250; PEG+RBV, n = 235)	-4.64 (0.816)	-4.04 (1.389)
Week 8 (SOF+RBV, n = 248; PEG+RBV, n = 228)	-4.63 (0.850)	-4.42 (1.163)
Week 12 (SOF+RBV, n = 243; PEG+RBV, n = 222)	-4.65 (0.820)	-4.45 (1.226)

6. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Virologic Failure During Treatment
Measure Description	Virologic failure was defined as either • Viral breakthrough: HCV RNA ≥ 25 IU/mL after having previously had HCV RNA < 25 IU/mL while on treatment, confirmed with 2 consecutive values or last available measurement • Viral rebound: > 1 log10 IU/mL increase in HCV RNA from nadir while on treatment, confirmed with 2 consecutive values or last available measurement • Non-response: HCV RNA persistently ≥ 25 IU/ml while on treatment (through Week 12)
Time Frame	Baseline up to Week 24
Safety Issue?	Yes

Analysis Population Description
Full Analysis Set

Reporting Groups

	Description
Sofosbuvir+RBV	Participants were randomized to receive sofosbuvir+RBV for 12 weeks.
PEG+RBV	Participants were randomized to receive PEG+RBV for 24 weeks.

Measured Values

	Sofosbuvir+RBV	PEG+RBV
Number of Participants Analyzed	253	243
Percentage of Participants With Virologic Failure During Treatment [units: percentage of participants]	0.4	7.4

7. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Viral Relapse Following Treatment
Measure Description	Viral relapse was defined as HCV RNA ≥ 25 IU/mL in post-treatment after having achieved < LLOQ at last on-treatment measurement, confirmed with 2 consecutive values or last available measurement.
Time Frame	Up to Post-treatment Week 24
Safety Issue?	Yes

Analysis Population Description

Participants in the Full Analysis Set with available data were analyzed.

Reporting Groups

	Description
Sofosbuvir+RBV	Participants were randomized to receive sofosbuvir+RBV for 12 weeks.
PEG+RBV	Participants were randomized to receive PEG+RBV for 24 weeks.

Measured Values

	Sofosbuvir+RBV	PEG+RBV
Number of Participants Analyzed	249	217
Percentage of Participants With Viral Relapse Following Treatment [units: percentage of participants]	30.5	22.6

Reported Adverse Events

Time Frame	Up to 24 weeks plus 30 days following the last dose of study drug
Additional Description	[Not specified]

Reporting Groups

	Description
Sofosbuvir+RBV	Participants were randomized to receive sofosbuvir+RBV for 12 weeks.
PEG+RBV	Participants were randomized to receive PEG+RBV for 24 weeks.

Serious Adverse Events

	Sofosbuvir+RBV	PEG+RBV
	Affected/At Risk (%)	Affected/At Risk (%)
Total	7/256 (2.73%)	3/243 (1.23%)
Blood and lymphatic system disorders		
Anaemia [A] †	1/256 (0.39%)	0/243 (0%)

	Sofosbuvir+RBV	PEG+RBV
	Affected/At Risk (%)	Affected/At Risk (%)
Cardiac disorders		
Atrioventriclar shock [A] †	0/256 (0%)	1/243 (0.41%)
General disorders		
Chest pain [A] †	1/256 (0.39%)	0/243 (0%)
Immune system disorders		
Allergy to arthropod sting [A] †	1/256 (0.39%)	0/243 (0%)
Infections and infestations		
Cellulitis [A] †	1/256 (0.39%)	0/243 (0%)
Infection [A] †	0/256 (0%)	1/243 (0.41%)
Osteomyelitis chronic [A] †	1/256 (0.39%)	0/243 (0%)
Urinary tract infection [A] †	1/256 (0.39%)	0/243 (0%)
Injury, poisoning and procedural complications		
Clavicle fracture [A] †	0/256 (0%)	1/243 (0.41%)
Rib fracture [A] †	0/256 (0%)	1/243 (0.41%)
Toxicity to various agents [A] †	1/256 (0.39%)	0/243 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer in situ [A] †	0/256 (0%)	1/243 (0.41%)
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease [A] †	1/256 (0.39%)	0/243 (0%)
Pneumothorax [A] †	0/256 (0%)	1/243 (0.41%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA Version 15.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Sofosbuvir+RBV	PEG+RBV
	Affected/At Risk (%)	Affected/At Risk (%)
Total	219/256 (85.55%)	233/243 (95.88%)
Blood and lymphatic system disorders		
Anaemia [A] †	20/256 (7.81%)	28/243 (11.52%)
Neutropenia [A] †	0/256 (0%)	30/243 (12.35%)
Thrombocytopenia [A] †	0/256 (0%)	23/243 (9.47%)
Gastrointestinal disorders		
Diarrhoea [A] †	23/256 (8.98%)	42/243 (17.28%)
Dry mouth [A] †	10/256 (3.91%)	15/243 (6.17%)
Nausea [A] †	46/256 (17.97%)	70/243 (28.81%)
Vomiting [A] †	17/256 (6.64%)	23/243 (9.47%)
General disorders		
Chills [A] †	7/256 (2.73%)	44/243 (18.11%)
Fatigue [A] †	92/256 (35.94%)	134/243 (55.14%)
Influenza like illness [A] †	7/256 (2.73%)	44/243 (18.11%)
Injection site erythema [A] †	0/256 (0%)	14/243 (5.76%)
Injection site reaction [A] †	0/256 (0%)	17/243 (7%)
Irritability [A] †	25/256 (9.77%)	40/243 (16.46%)
Pain [A] †	5/256 (1.95%)	30/243 (12.35%)
Pyrexia [A] †	6/256 (2.34%)	33/243 (13.58%)
Infections and infestations		
Nasopharyngitis [A] †	13/256 (5.08%)	5/243 (2.06%)
Metabolism and nutrition disorders		

	Sofosbuvir+RBV	PEG+RBV
	Affected/At Risk (%)	Affected/At Risk (%)
Decreased appetite [A] †	17/256 (6.64%)	44/243 (18.11%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] †	15/256 (5.86%)	35/243 (14.4%)
Back pain [A] †	9/256 (3.52%)	20/243 (8.23%)
Myalgia [A] †	21/256 (8.2%)	40/243 (16.46%)
Nervous system disorders		
Dizziness [A] †	27/256 (10.55%)	33/243 (13.58%)
Headache [A] †	64/256 (25%)	108/243 (44.44%)
Psychiatric disorders		
Anxiety [A] †	11/256 (4.3%)	16/243 (6.58%)
Depression [A] †	14/256 (5.47%)	35/243 (14.4%)
Insomnia [A] †	31/256 (12.11%)	71/243 (29.22%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] †	19/256 (7.42%)	21/243 (8.64%)
Dyspnoea [A] †	18/256 (7.03%)	20/243 (8.23%)
Oropharyngeal pain [A] †	14/256 (5.47%)	10/243 (4.12%)
Skin and subcutaneous tissue disorders		
Alopecia [A] †	12/256 (4.69%)	24/243 (9.88%)
Dry skin [A] †	11/256 (4.3%)	23/243 (9.47%)
Pruritus [A] †	19/256 (7.42%)	42/243 (17.28%)
Rash [A] †	23/256 (8.98%)	43/243 (17.7%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA Version 15.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

After conclusion of the study and without prior written approval from Gilead, investigators in this study may communicate, orally present, or publish in scientific journals or other media only after the following conditions have been met:

- The results of the study in their entirety have been publicly disclosed by or with the consent of Gilead in an abstract, manuscript, or presentation form; or
- The study has been completed at all study sites for at least 2 years

Results Point of Contact:

Name/Official Title: Clinical Trial Disclosures
Organization: Gilead Sciences, Inc.
Phone:
Email: ClinicalTrialDisclosures@gilead.com