Appendix A: study list for ongoing clinical trials

Study 1:
NCT Number: NCT01768286
Title: Safety and Efficacy of Ledipasvir/Sofosbuvir Fixed-Dose Combination ± Ribavirin for the Treatment of HCV
Recruitment: Completed
Study Results: No Results Available
Conditions: Chronic Hepatitis C Virus
Interventions: Drug: Ledipasvir/sofosbuvir|Drug: RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 3
Enrollment: 441
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-0109
First Received: January 10, 2013
Start Date: January 2013
Completion Date: February 2014
Last Updated: April 23, 2014
Last Verified: April 2014
Acronym: ION-2
Results First Received: No Study Results Posted
Primary Completion Date: November 2013
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Incidence of adverse events leading to permanent discontinuation of study drug(s)|Proportion of participants with sustained virologic response at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)|Proportion of participants with HCV RNA < LLOQ on treatment|Change in HCV RNA from Baseline|Proportion of participants with virologic failure
URL: http://ClinicalTrials.gov/show/NCT01768286

Study 2:
NCT Number: NCT02125500
Title: Pilot Study to Assess Efficacy and Safety of Sofosbuvir/Ledipasvir Fixed-dose Combination in Treatment Experienced Subjects With Hepatitis C Virus (HCV) Genotype 1 - HIV Co-infection
Recruitment: Not yet recruiting
Study Results: No Results Available
Conditions: Viral Hepatitis C|HIV
Interventions: Drug: Sofosbuvir/Ledipasvir fixed dose
Sponsor/Collaborators: French National Institute for Health and Medical Research-French National Agency for Research on AIDS and Viral Hepatitis (Inserm-ANRS)
Gender: Both
Age Groups: Adult|Senior

Phases: Phase 2
Enrollment: 70
Funded Bys: Other
Study Types: Interventional
Study Designs: Endpoint Classification: Safety/Efficacy Study|Intervention Model: Single Group Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: ANRS HC31 SOFTRIH
First Received: April 24, 2014
Start Date: September 2014
Completion Date: November 2015
Last Updated: July 30, 2014
Last Verified: July 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: November 2015
Outcome Measures: Sustained virologic response 12 weeks after discontinuation of therapy (SVR12), i.e. at week 36.|Adverse clinical and biological events that occur during the treatment and up to 24 weeks after the end of the treatment|Number and causes of poor adherence and treatment interruptions|SVR rate 24 weeks (i.e. W48) after the end of treatment and according to the HCV sub-type|Number of patients with HCV resistance mutations to Sofosbuvir and/or Ledipasvir|HCV viral load|Plasma HIV RNA levels|Assess drug-drug interactions between HCV et HIV drugs|Patient's reported outcomes evaluation
URL: http://ClinicalTrials.gov/show/NCT02125500

Study 3:
NCT Number: NCT01193478
Title: A Multiple Ascending Dose Study of GS 5885 in Previously Untreated Subjects With Genotype 1 Chronic Hepatitis C
Recruitment: Completed
Study Results: No Results Available
Conditions: HCV Infection
Interventions: Drug: GS-5885|Drug: Placebo|Drug: GS-5885|Drug: Placebo|Drug: GS-5885|Drug: Placebo|Drug: GS-5885|Drug: Placebo|Drug: GS-5885|Drug: Placebo|Drug: GS-5885|Drug: Placebo
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult
Phases: Phase 1
Enrollment: 71
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Pharmacodynamics Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Double Blind (Subject, Investigator)
Other IDs: GS-US-256-0102
First Received: August 31, 2010
Start Date: August 2010
Completion Date: December 2011
Last Updated: January 18, 2013
Last Verified: January 2013

Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: January 2011
Outcome Measures: Number of subjects reporting an adverse event or experiencing a laboratory abnormality|Antiviral activity measures: measured by change in plasma HCV RNA levels form baseline|Measure of GS-5885 plasma concentration over time|Emergence of viral resistance
URL: http://ClinicalTrials.gov/show/NCT01193478

Study 4:
NCT Number: NCT01353248
Title: GS 5885 Administered Concomitantly With GS-9451, Tegobuvir and Ribavirin (RBV) in Chronic Genotype 1 Hepatitis C Virus (HCV) Infection
Recruitment: Completed
Study Results: No Results Available
Conditions: Hepatitis C, Chronic
Interventions: Drug: GS-5885|Drug: Tegobuvir|Drug: GS-9451|Drug: ribavirin tablet|Drug: GS-5885
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 141
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-248-0120
First Received: April 22, 2011
Start Date: May 2011
Completion Date: March 2013
Last Updated: November 26, 2013
Last Verified: November 2013
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: October 2012
Outcome Measures: Sustained virologic response (SVR)|Safety and tolerability|HCV RNA < Lower Limit Of Quantification|Rescue Therapy Substudy SVR|Emergence of viral resistance|Viral dynamics of GS-5885, GS-9451 and Tegobuvir when administered in combination with RBV|Pharmacokinetics of GS-5885, GS-9451 and Tegobuvir when administered in combination with RBV
URL: http://ClinicalTrials.gov/show/NCT01353248

Study 5:
NCT Number: NCT01356160
Title: GS-5885 Alone or in Combination With GS-9451 With Peginterferon Alfa 2a and Ribavirin in Treatment Chronic Genotype 1 Hepatitis C Virus
Recruitment: Completed
Study Results: No Results Available
Conditions: Hepatitis C, Chronic

Interventions: Drug: GS-5885|Drug: GS-9451|Biological: peginterferon alfa-2a|Drug: ribavirin tablet|Drug: GS-9451 Placebo
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 351
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Double Blind (Subject, Investigator)
Other IDs: GS-US-256-0148
First Received: May 2, 2011
Start Date: July 2011
Completion Date: June 2013
Last Updated: January 2, 2014
Last Verified: January 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: June 2013
Outcome Measures: To evaluate the antiviral efficacy of response guided therapy.|To evaluate the safety and tolerability of each regimen.|To characterize viral dynamics of GS-5885 and GS-9451 when administered with PEG and RBV.|To characterize the viral resistance to GS-5885 and GS-9451 when administered in combination with PEG and RBV.|To characterize steady state pharmacokinetics of GS-5885 and GS-9451 when administered with PEG and RBV.
URL: http://ClinicalTrials.gov/show/NCT01356160

Study 6:
NCT Number: NCT01435226
Title: GS-5885, GS-9451, Tegobuvir and Ribovirin in Treatment-Experienced Subjects With Chronic Genotype 1a Or 1b Hepatitis C Virus (HCV) Infection
Recruitment: Completed
Study Results: No Results Available
Conditions: Hepatitis C, Chronic
Interventions: Drug: GS-5885|Drug: GS-9451|Drug: tegobuvir|Drug: placebo to match tegobuvir|Drug: placebo to match RBV|Drug: Ribavirin
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 170
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Other IDs: GS-US-248-0131
First Received: September 13, 2011
Start Date: September 2011

Completion Date: July 2013
Last Updated: November 22, 2013
Last Verified: November 2013
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: January 2013
Outcome Measures: Safety and Tolerability|Antiviral Activity|Viral Dynamics|Composite (or Profile) of Pharmacokinetics Composite (or Profile) of Pharmacokinetics|Antiviral Efficacy
URL: http://ClinicalTrials.gov/show/NCT01435226

Study 7:
NCT Number: NCT01371578
Title: Oral Antivirals (GS-5885, Tegobuvir, and/or GS-9451) With Peginterferon Alfa 2a and Ribavirin in Treatment Experienced Subjects With Chronic Genotype 1 Hepatitis C Virus Infection
Recruitment: Completed
Study Results: No Results Available
Conditions: Hepatitis C, Chronic
Interventions: Drug: GS-5885 tablet|Drug: GS-9451 tablet|Biological: peginterferon alfa-2a|Drug: ribavirin tablet
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 163
Funded Bys: Industry
Study Types: Interventional
Study Designs: Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-256-0124
First Received: June 9, 2011
Start Date: July 2011
Completion Date: March 2013
Last Updated: January 14, 2014
Last Verified: January 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: March 2013
Outcome Measures: Sustained Virologic Response (SVR)|Sustained Virologic Response(SVR) of each regimen administered for 24 to 48 weeks|Safety and Tolerability|Characterize the viral dynamics of GS-5885, GS-9451 when administered in combination with PEG and RBV|Characterize the pharmacokinetics of GS-5885 and GS-9451 when administered in combination with PEG and RBV|Emergence of Viral Resistance
URL: http://ClinicalTrials.gov/show/NCT01371578

Study 8:
NCT Number: NCT01434498

Title: GS-5885, GS-9451, Tegobuvir and Ribavirin (RBV) in Interferon Ineligible or Intolerant Subjects With Chronic Genotype 1a or 1b Hepatitis C Virus (HCV) Infection
Recruitment: Completed
Study Results: No Results Available
Conditions: Chronic Genotype 1a or 1b HCV Infection
Interventions: Drug: GS-5885 tablet|Drug: GS-9451 tablet|Drug: tegobuvir capsule|Drug: ribavirin tablet|Drug: placebo matching ribavirin tablet|Device: placebo matching tegobuvir capsule
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 163
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Other IDs: GS-US-248-0132
First Received: September 9, 2011
Start Date: September 2011
Completion Date: January 2013
Last Updated: November 26, 2013
Last Verified: November 2013
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: January 2013
Outcome Measures: Safety and Tolerability|Antiviral Activity|Viral Dynamics|Composite (or Profile) of Pharmacokinetics
URL: http://ClinicalTrials.gov/show/NCT01434498

Study 9:
NCT Number: NCT01701401
Title: Safety and Efficacy of Ledipasvir/Sofosbuvir Fixed-Dose Combination (FDC) With and Without Ribavirin for the Treatment of HCV
Recruitment: Completed
Study Results: No Results Available
Conditions: Chronic Hepatitis C Virus
Interventions: Drug: LDV/SOF|Drug: RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 3
Enrollment: 870
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label

Other IDs: GS-US-337-0102|2012-003387-43
First Received: October 2, 2012
Start Date: September 2012
Completion Date: April 2014
Last Updated: May 12, 2014
Last Verified: May 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: February 2014
Outcome Measures: Proportion of participants with sustained virologic response (SVR) 12 weeks after discontinuation of study drug|Incidence of any AE leading to permanent discontinuation of study|Proportion of participants with SVR at 4 and 24 weeks after discontinuation of study drug|Proportion of participants with HCV RNA < LLOQ on treatment|Change from baseline in HCV RNA|Proportion of participants with virologic failure
URL: http://ClinicalTrials.gov/show/NCT01701401

Study 10:
NCT Number: NCT01384383
Title: GS-5885, GS-9451 With Peginterferon Alfa 2a (PEG) and Ribavirin in Treatment-Naïve Subjects With Chronic Genotype 1 Hep C Virus Infection and IL28B CC Genotype
Recruitment: Terminated
Study Results: No Results Available
Conditions: Chronic Hepatitis C
Interventions: Drug: GS-5885|Drug: GS-9451|Drug: RBV|Drug: PEG
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 248
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-248-0121
First Received: June 22, 2011
Start Date: August 2011
Completion Date: June 2013
Last Updated: January 2, 2014
Last Verified: January 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: June 2013
Outcome Measures: Sustained virologic response (SVR)|Safety and tolerability of therapy|Virologic response|Compare SVR|Viral resistance
URL: http://ClinicalTrials.gov/show/NCT01384383

Study 11:

NCT Number: NCT01878799
Title: Study of A Combination Pill With GS-7977 and GS-5885 for Hepatitis C in People With HIV
Recruitment: Completed
Study Results: No Results Available
Conditions: Hepatitis C|HIV
Interventions: Drug: GS-7977/GS- 5885 FDC
Sponsor/Collaborators: National Institute of Allergy and Infectious Diseases (NIAID)|National Institutes of Health Clinical Center (CC)
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 63
Funded Bys: NIH
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Single Group Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: 130159|13-I-0159
First Received: June 14, 2013
Start Date: June 2013
Completion Date: September 2014
Last Updated: September 20, 2014
Last Verified: September 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: September 2014
Outcome Measures: To assess the safety, tolerability and efficacy of a fixed dose combination (FDC) of GS-7977/GS-5885 tablets for 12 weeks in HIV/HCV GT-1 coinfected subjects who are IFN-treatment na(SqrRoot) ve.|To assess the fitness of NS5A/B viral mutants in vivo in the presence or absence of a fixed dose combination of GS-7977/ GS-5885 in vitro by performing NS5A/B site directed mutagenesis.|To compare HCV quasispecies evolution from baseline and throughout 12 weeks of treatment (especially during relapse or viral breakthrough) and assess the influence on virologic response to treatment in HIV/HCV GT-1 coinfected patients.|To compare the immunologic, virologic and host genetic/proteomic predictors of response to treatment with a fixed dose combination of GS-7977/GS-5885 in subjects treated for 12 weeks.
URL: http://ClinicalTrials.gov/show/NCT01878799

Study 12:
NCT Number: NCT01924949
Title: An Open-Label Study of Ledipasvir/Sofosbuvir Fixed-Dose Combination in Subjects With Nosocomial Genotype 1 HCV Infection.
Recruitment: Completed
Study Results: No Results Available
Conditions: Hepatitis C
Interventions: Drug: LDV/SOF
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior

Phases: Phase 2
Enrollment: 5
Funded Bys: Industry
Study Types: Interventional
Study Designs: Endpoint Classification: Safety/Efficacy Study|Intervention Model: Single Group Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-0125
First Received: August 14, 2013
Start Date: July 2013
Completion Date: August 2014
Last Updated: August 20, 2014
Last Verified: August 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: May 2014
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Proportion of participants who permanently discontinue study drug due to an adverse event|Proportion of participants with sustained virologic response at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)|Proportion of participants with HCV RNA < LLOQ while on treatment|HCV RNA change from Baseline|Proportion of participants with virologic failure
URL: http://ClinicalTrials.gov/show/NCT01924949

Study 13:
NCT Number: NCT01851330
Title: Safety and Efficacy of Ledipasvir/Sofosbuvir Fixed-Dose Combination ± Ribavirin for the Treatment of HCV (ION-3)
Recruitment: Completed
Study Results: No Results Available
Conditions: Chronic Hepatitis C Virus
Interventions: Drug: LDV/SOF|Drug: RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 3
Enrollment: 647
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-0108
First Received: May 3, 2013
Start Date: May 2013
Completion Date: March 2014
Last Updated: March 10, 2014
Last Verified: March 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: November 2013

Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Incidence of adverse events leading to permanent discontinuation of study drug(s)|Proportion of participants with sustained virologic response at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)|Proportion of participants with HCV RNA < LLOQ on treatment|Change in HCV RNA from Baseline|Proportion of participants with virologic failure
URL: http://ClinicalTrials.gov/show/NCT01851330

Study 14:
NCT Number: NCT01984294
Title: Ledipasvir/Sofosbuvir Fixed-Dose Combination With Ribavirin or GS-9669 in Subjects With Chronic Genotype 1 HCV Infection
Recruitment: Completed
Study Results: No Results Available
Conditions: Chronic HCV Infection
Interventions: Drug: LDV/SOF|Drug: RBV|Drug: GS-9669
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 101
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-0133
First Received: November 8, 2013
Start Date: October 2013
Completion Date: July 2014
Last Updated: August 1, 2014
Last Verified: August 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: April 2014
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Proportion of participants who discontinue study drug due to an adverse event|Proportion of participants with sustained virologic response (SVR) at 2, 4, 8, and 24 weeks after discontinuation of therapy (SVR2, SVR4, SVR8, and SVR24)|Proportion of participants experiencing viral breakthrough|Proportion of participants experiencing viral relapse
URL: http://ClinicalTrials.gov/show/NCT01984294

Study 15:
NCT Number: NCT01726517
Title: Safety and Efficacy of LDV/SOF Fixed-Dose Combination (FDC) ± Ribavirin in HCV Genotype 1 Subjects
Recruitment: Completed
Study Results: No Results Available
Conditions: Chronic Hepatitis C Virus

Interventions: Drug: LDV/SOF|Drug: RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 100
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-0118
First Received: November 10, 2012
Start Date: October 2012
Completion Date: January 2014
Last Updated: March 17, 2014
Last Verified: March 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: July 2013
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Incidence of adverse events leading to permanent discontinuation of study drug(s)|Proportion of participants with sustained virologic response at 2, 4, 8, and 24 weeks after discontinuation of therapy (SVR2, SVR4, SVR8, and SVR24)|Proportion of participants experiencing viral breakthrough|Proportion of participants experiencing viral relapse
URL: http://ClinicalTrials.gov/show/NCT01726517

Study 16:
NCT Number: NCT01965535
Title: Efficacy and Safety of Sofosbuvir/Ledipasvir Fixed-Dose Combination ± Ribavirin in Cirrhotic Subjects With Chronic Genotype 1 HCV Infection
Recruitment: Active, not recruiting
Study Results: No Results Available
Conditions: HCV Infection
Interventions: Drug: SOF/LDV|Drug: RBV|Drug: Placebo to match SOF/LDV|Drug: Placebo to match RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 150
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Other IDs: GS-US-337-0121|2013-002296-17
First Received: October 16, 2013
Start Date: October 2013

Completion Date: December 2014
Last Updated: June 19, 2014
Last Verified: June 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: September 2014
Outcome Measures: Proportion of participants with sustained virologic response (SVR) at 12 weeks post-treatment (SVR12)|Proportion of participants with HCV RNA < LLOQ at 4 weeks (SVR4) and 24 weeks (SVR24) post-treatment.|Proportion of participants with HCV RNA < LLOQ while on treatment|Change in HCV RNA|The proportion of patients with virologic failure
URL: http://ClinicalTrials.gov/show/NCT01965535

Study 17:
NCT Number: NCT02249182
Title: Safety and Efficacy of Ledipasvir/Sofosbuvir Fixed Dose Combination in Adolescents and Children With Chronic HCV-Infection
Recruitment: Not yet recruiting
Study Results: No Results Available
Conditions: Hepatitis C Virus Infection
Interventions: Drug: LDV/SOF
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Child
Phases: Phase 2
Enrollment: 200
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-1116
First Received: September 23, 2014
Start Date: October 2014
Completion Date: June 2018
Last Updated: September 23, 2014
Last Verified: September 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: June 2018
Outcome Measures: For the PK Lead-in Phase, PK parameters of GS-331007 and LDV as measured by AUCtau to determine the appropriate LDV/SOF FDC dose.|For the Treatment Phase, any adverse event leading to permanent discontinuation of study drug(s)|For the Treatment Phase, proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|For the PK Lead-in Phase, early viral kinetics and PK profiles of GS-331007, sofosbuvir, and ledipasvir|For the PK Lead-in Phase, adverse events leading to permanent discontinuation of study drug(s)|For the Treatment Phase, growth and development measurements such as height, weight, and Tanner Stage Assessment|For the Treatment Phase, proportion of participants with sustained virologic response (SVR) at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)|For

the Treatment Phase, proportion of participants experiencing viral breakthrough|For the Treatment Phase, proportion of participants experiencing viral relapse|For the Treatment Phase, HCV RNA change from baseline|For the Treatment Phase, alanine aminotransferase (ALT) normalization|For the Treatment Phase, viral kinetic parameters
URL: http://ClinicalTrials.gov/show/NCT02249182

Study 18:
NCT Number: NCT02226549
Title: Ledipasvir/Sofosbuvir Fixed-Dose Combination and Vedroprevir With or Without Ribavirin in Treatment-Experienced Participants With Chronic Genotype 1 HCV Infection and Cirrhosis
Recruitment: Active, not recruiting
Study Results: No Results Available
Conditions: Hepatitis C Virus Infection
Interventions: Drug: LDV/SOF|Drug: VDV|Drug: RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 50
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-1512
First Received: August 25, 2014
Start Date: July 2014
Completion Date: July 2015
Last Updated: October 7, 2014
Last Verified: October 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: July 2015
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Incidence of any adverse event leading to permanent discontinuation of study drug(s)|Proportion of participants with sustained virologic response 4 weeks after discontinuation of therapy (SVR4)
URL: http://ClinicalTrials.gov/show/NCT02226549

Study 19:
NCT Number: NCT02251717
Title: Safety and Efficacy of Ledipasvir/Sofosbuvir (LDV/SOF) Fixed Dose Combination (FDC) for 12 or 24 Weeks in Kidney Transplant Recipients With Chronic HCV Infection
Recruitment: Not yet recruiting
Study Results: No Results Available
Conditions: Hepatitis C Virus Infection
Interventions: Drug: LDV/SOF
Sponsor/Collaborators: Gilead Sciences

Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 150
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-1406|2014-002121-35
First Received: September 25, 2014
Start Date: September 2014
Completion Date: March 2016
Last Updated: September 25, 2014
Last Verified: September 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: January 2016
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Incidence of any adverse events leading to permanent discontinuation of study drug|Proportion of participants with sustained virologic response 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)|Proportion of participants with virologic failure
URL: http://ClinicalTrials.gov/show/NCT02251717

Study 20:
NCT Number: NCT02219685
Title: Ledipasvir/Sofosbuvir Fixed-Dose Combination on Cerebral Metabolism and Neurocognition in Treatment-Naive and Treatment-Experienced Participants With Chronic Genotype 1 HCV Infection
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Hepatitis C Virus Infection
Interventions: Drug: LDV/SOF|Drug: Placebo to match LDV/SOF
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult
Phases: Phase 2
Enrollment: 40
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Other IDs: GS-US-337-1445
First Received: August 15, 2014
Start Date: August 2014
Completion Date: February 2016
Last Updated: October 6, 2014
Last Verified: October 2014

Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: November 2015
Outcome Measures: Change from pretreatment assessment in MRS metabolic ratios at 4 weeks after discontinuation of therapy|Change from pretreatment assessment in neurocognitive function at 4 weeks after discontinuation of therapy|Proportion of participants with sustained virologic response (SVR) at 4, 12, and 24 weeks after discontinuation of therapy (SVR4, SVR12, and SVR24)|Change from pretreatment assessment in neurocognitive function at 24 weeks after discontinuation of therapy|Change from pretreatment assessment in health-related quality of life at 4 and 24 weeks after discontinuation of therapy|Change from pretreatment assessment in mood-related assessment at 4 and 24 weeks after discontinuation of therapy
URL: http://ClinicalTrials.gov/show/NCT02219685

Study 21:
NCT Number: NCT01938430
Title: Ledipasvir/Sofosbuvir Fixed-Dose Combination + Ribavirin in Subjects With Chronic HCV With Advanced Liver Disease or Post-Liver Transplant
Recruitment: Active, not recruiting
Study Results: No Results Available
Conditions: Chronic HCV Infection
Interventions: Drug: LDV/SOF FDC|Drug: RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 400
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-0123
First Received: September 5, 2013
Start Date: September 2013
Completion Date: February 2015
Last Updated: May 15, 2014
Last Verified: May 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: November 2014
Outcome Measures: Proportion of participants with sustained virologic response (SVR12), defined as HCV RNA < lower limit of quantitation (LLOQ) 12 weeks after last dose of study drug|Proportion of participants who discontinue study drug due to an adverse event|Proportion of participants with sustained virologic response (SVR) at 2, 4, 8 and 24 weeks after discontinuation of therapy (SVR2, SVR4, SVR8 and SVR24)|Proportion of participants who have HCV RNA < LLOQ by visit while on treatment|HCV RNA levels and change from Day 1 through Week 8|Proportion of participants with virologic failure|Change in model for end-stage liver disease (MELD) and Child-Pugh-Turcotte (CPT) scores|Proportion of participants with post-transplant virologic response

URL: http://ClinicalTrials.gov/show/NCT01938430

Study 22:
NCT Number: NCT02010255
Title: Ledipasvir/Sofosbuvir Fixed-Dose Combination Plus Ribavirin in Subjects With Chronic HCV With Advanced Liver Disease or Post-Liver Transplant
Recruitment: Active, not recruiting
Study Results: No Results Available
Conditions: Chronic HCV Infection
Interventions: Drug: LDV/SOF|Drug: RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 400
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-0124|2013-002802-30
First Received: December 9, 2013
Start Date: January 2014
Completion Date: August 2015
Last Updated: September 29, 2014
Last Verified: September 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: May 2015
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after last dose of study drug (SVR12)|Proportion of participants who discontinue study drug due to an adverse event|Proportion of participants with sustained virologic response (SVR) 2, 4, 8, and 24 weeks after last dose of study drug (SVR2, SVR4, SVR8 and SVR24)|Proportion of participants who have HCV RNA < LLOQ by visit while on treatment|HCV RNA levels and change from Day 1 through Week 8|Proportion of participants with virologic failure|Change in model for end-stage liver disease (MELD) and Child-Pugh-Turcotte (CPT) scores|Proportion of participants with post-transplant virologic response
URL: http://ClinicalTrials.gov/show/NCT02010255

Study 23:
NCT Number: NCT02021656
Title: Efficacy and Safety of Ledipasvir/Sofosbuvir Fixed-Dose Combination in Korean and Taiwanese Participants With Chronic Genotype 1 HCV Infection
Recruitment: Active, not recruiting
Study Results: No Results Available
Conditions: Chronic HCV Infection
Interventions: Drug: LDV/SOF
Sponsor/Collaborators: Gilead Sciences
Gender: Both

Age Groups: Adult|Senior
Phases: Phase 3
Enrollment: 360
Funded Bys: Industry
Study Types: Interventional
Study Designs: Endpoint Classification: Safety/Efficacy Study|Intervention Model: Single Group Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-0131
First Received: December 20, 2013
Start Date: December 2013
Completion Date: June 2017
Last Updated: September 2, 2014
Last Verified: September 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: March 2017
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Incidence of adverse events leading to permanent discontinuation of study drug|Proportion of participants with sustained virologic response at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)|Proportion of participants experiencing viral breakthrough|Proportion of participants experiencing viral relapse|HCV RNA change from baseline
URL: http://ClinicalTrials.gov/show/NCT02021656

Study 24:
NCT Number: NCT01975675
Title: Efficacy and Safety of Sofosbuvir/Ledipasvir ± Ribavirin in Japanese Participants With Chronic Genotype 1 HCV Infection
Recruitment: Completed
Study Results: No Results Available
Conditions: Chronic HCV Infection
Interventions: Drug: SOF/LDV|Drug: RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 3
Enrollment: 341
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-0113
First Received: October 29, 2013
Start Date: October 2013
Completion Date: August 2014
Last Updated: October 10, 2014
Last Verified: October 2014
Acronym: null
Results First Received: No Study Results Posted

Primary Completion Date: June 2014
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Proportion of participants who permanently discontinue study drug due to an adverse event|Proportion of participants with sustained virologic response at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)|Proportion of participants experiencing viral breakthrough|Proportion of participants experiencing viral relapse
URL: http://ClinicalTrials.gov/show/NCT01975675

Study 25:
NCT Number: NCT02081079
Title: Efficacy and Safety of Ledipasvir/Sofosbuvir Fixed-Dose Combination in Treatment-Naïve and Treatment-Experienced Subjects With Chronic Genotype 4 or 5 HCV Infection
Recruitment: Active, not recruiting
Study Results: No Results Available
Conditions: Chronic Genotype 4 HCV|Chronic Genotype 5 HCV
Interventions: Drug: LDV/SOF
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 80
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-1119|2013-003978-27
First Received: March 5, 2014
Start Date: April 2014
Completion Date: March 2015
Last Updated: June 12, 2014
Last Verified: June 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: December 2014
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Incidence of adverse events leading to permanent discontinuation of study drug|Proportion of participants with sustained virologic response at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)|Proportion of participants experiencing viral breakthrough|Proportion of participants experiencing viral relapse|HCV RNA change from baseline
URL: http://ClinicalTrials.gov/show/NCT02081079

Study 26:
NCT Number: NCT02120300
Title: Efficacy and Safety of Ledipasvir/Sofosbuvir Fixed-Dose Combination and Sofosbuvir + Ribavirin for Subjects With Chronic Hepatitis C Virus (HCV) and Inherited Bleeding Disorders

Recruitment: Recruiting
Study Results: No Results Available
Conditions: Chronic HCV Infection
Interventions: Drug: LDV/SOF|Drug: Sofosbuvir|Drug: Ribavirin
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 125
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-334-1274
First Received: April 18, 2014
Start Date: April 2014
Completion Date: August 2015
Last Updated: October 20, 2014
Last Verified: October 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: August 2015
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Incidence of adverse events leading to permanent discontinuation of study drug(s)|Proportion of participants with sustained virologic response (SVR) at 4 weeks after discontinuation of therapy (SVR4)|Proportion of participants with HCV RNA < LLOQ on treatment|HCV RNA change from baseline|Proportion of participants with virologic failure|For HIV-1/HCV co-infected participants, the proportion of subjects that maintain HIV-1 RNA < 50 copies/mL while on HCV treatment|For HIV-1/HCV co-infected participants, change from baseline of serum creatinine at the end of treatment|For HIV-1/HCV co-infected participants, change from baseline of serum creatinine at posttreatment Week 12
URL: http://ClinicalTrials.gov/show/NCT02120300

Study 27:
NCT Number: NCT02073656
Title: Efficacy and Safety of Ledipasvir/Sofosbuvir Fixed-Dose Combination for 12 Weeks in Subjects With Chronic Genotype 1 or 4 HCV and HIV-1 Co-infection
Recruitment: Active, not recruiting
Study Results: No Results Available
Conditions: Hepatitis C Virus|HIV
Interventions: Drug: LDV/SOF|Drug: RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 3
Enrollment: 300
Funded Bys: Industry
Study Types: Interventional

Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Single Group Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-0115
First Received: February 25, 2014
Start Date: February 2014
Completion Date: June 2016
Last Updated: June 11, 2014
Last Verified: June 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: March 2015
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Incidence of adverse events leading to permanent discontinuation of study drug(s)|Proportion of participants with sustained virologic response at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)|Proportion of participants with HCV RNA < LLOQ on treatment|Change in HCV RNA from Baseline|Proportion of participants with virologic failure|For retreatment group only: Proportion of participants with sustained virologic response at 4, 12 and 24 weeks after discontinuation of therapy (SVR4, SVR12, and SVR24)|Proportion of participants that maintain HIV-1 RNA < 50 copies/mL while on treatment|Change from baseline of serum creatinine at end of treatment, posttreatment weeks 12 and 24
URL: http://ClinicalTrials.gov/show/NCT02073656

Study 28:
NCT Number: NCT01987453
Title: Efficacy and Safety of Ledipasvir/Sofosbuvir Fixed-Dose Combination ± Ribavirin in Subjects With Chronic Genotype 1 HCV Who Participated in a Prior Gilead-Sponsored HCV Treatment Study
Recruitment: Enrolling by invitation
Study Results: No Results Available
Conditions: HCV Infection
Interventions: Drug: LDV/SOF|Drug: RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 100
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-1118|2014-001245-24
First Received: November 12, 2013
Start Date: November 2013
Completion Date: January 2016
Last Updated: October 22, 2014
Last Verified: October 2014
Acronym: null

Results First Received: No Study Results Posted
Primary Completion Date: October 2015
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Incidence of adverse events leading to permanent discontinuation of study drug|Proportion of participants with sustained virologic response (SVR) at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)|Proportion of participants with HCV RNA < LLOQ while on treatment|Change in HCV RNA from Baseline|Proportion of participants with virologic failure
URL: http://ClinicalTrials.gov/show/NCT01987453

Study 29:
NCT Number: NCT01826981
Title: Sofosbuvir Containing Regimens for the Treatment of Chronic HCV Infection in Subjects With Chronic Genotype 1, 2, 3, or 6 HCV Infection
Recruitment: Active, not recruiting
Study Results: No Results Available
Conditions: Chronic Hepatitis C
Interventions: Drug: LDV/SOF FDC|Drug: SOF|Drug: RBV|Drug: PEG|Drug: GS-9669|Drug: GS-5816
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 410
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-0122
First Received: April 1, 2013
Start Date: April 2013
Completion Date: June 2015
Last Updated: August 14, 2014
Last Verified: August 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: March 2015
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Proportion of participants with adverse events leading to permanent discontinuation of study drug(s)|Proportion of participants with SVR through posttreatment Week 24|Proportion of participants with on-treatment virologic failure and relapse
URL: http://ClinicalTrials.gov/show/NCT01826981

Study 30:
NCT Number: NCT01805882
Title: Combination Therapy for Chronic Hepatitis C Infection
Recruitment: Recruiting
Study Results: No Results Available

Conditions: Hepatitis C, Chronic
Interventions: Drug: Fixed Dose GS-7977/GS-5885|Drug: FDC with GS-9451|Drug: FDC with GS-9669
Sponsor/Collaborators: National Institute of Allergy and Infectious Diseases (NIAID)|National Institutes of Health Clinical Center (CC)
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 325
Funded Bys: NIH
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: 130066|13-I-0066
First Received: March 5, 2013
Start Date: January 2013
Completion Date: December 2015
Last Updated: September 27, 2014
Last Verified: August 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: December 2015
Outcome Measures: The incidence and severity of adverse events (AEs) during and following treatment with GS-7977 in combination with GS-5885, GS-9669 or GS-9451 and the proportion of subjects who achieve SVR12.|Correlation and comparison of early viral kinetics with response to treatment; host and viral factors influencing response, comparison of HCV viral kinetics and pharmacodynamics in HCV treatment naive vs. null responders.
URL: http://ClinicalTrials.gov/show/NCT01805882

Study 31:
NCT Number: NCT01260350
Title: Open-Labeled Study of PSI-7977 and RBV With and Without PEG-IFN in Treatment-Naïve Patients With HCV GT2 or GT3
Recruitment: Completed
Study Results: No Results Available
Conditions: Chronic Hepatitis C Infection
Interventions: Drug: SOF|Drug: RBV|Drug: PEG|Drug: LDV|Drug: GS-9669|Drug: LDV/SOF
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 292
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: P7977-0523|Medsafe

First Received: December 13, 2010
Start Date: December 2010
Completion Date: December 2013
Last Updated: May 28, 2014
Last Verified: May 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: October 2013
Outcome Measures: Safety and Tolerability|HCV RNA|Sustained Virologic Response (SVR)|Resistance|Duration of PEG-IFN therapy|Pharmacokinetics
URL: http://ClinicalTrials.gov/show/NCT01260350

Study 32:
NCT Number: NCT02202980
Title: Efficacy and Safety of Oral Regimens for the Treatment of Chronic HCV Infection
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Chronic Hepatitis C
Interventions: Drug: LDV/SOF|Drug: RBV
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 125
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: GS-US-337-1468
First Received: July 25, 2014
Start Date: August 2014
Completion Date: January 2016
Last Updated: August 14, 2014
Last Verified: August 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: August 2015
Outcome Measures: Proportion of participants with sustained virologic response 12 weeks after discontinuation of therapy (SVR12)|Incidence of any adverse events leading to permanent discontinuation of study drug(s)|Proportion of participants with sustained virologic response 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)|Proportion of participants with on treatment virologic failure and relapse
URL: http://ClinicalTrials.gov/show/NCT02202980

Study 33:
NCT Number: NCT01457755
Title: Gilead Sustained Virologic Response (SVR) Registry
Recruitment: Enrolling by invitation

Study Results: No Results Available
Conditions: Hepatitis C, Chronic
Interventions:
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases:
Enrollment: 4000
Funded Bys: Industry
Study Types: Observational
Study Designs: Observational Model: Cohort|Time Perspective: Prospective
Other IDs: GS-US-248-0122|2011-000945-19
First Received: October 4, 2011
Start Date: September 2011
Completion Date: July 2023
Last Updated: August 11, 2014
Last Verified: August 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: July 2023
Outcome Measures: Sustained Virologic Response|Subsequent detection of HCV RNA|Clinical Progression of liver disease|Development of hepatocellular carcinoma (HCC)
URL: http://ClinicalTrials.gov/show/NCT01457755

Study 34:
NCT Number: NCT01457768
Title: A Gilead Sequence Registry of Subjects Who Did Not Achieve Sustained Virologic Response
Recruitment: Enrolling by invitation
Study Results: No Results Available
Conditions: Hepatitis C, Chronic
Interventions:
Sponsor/Collaborators: Gilead Sciences
Gender: Both
Age Groups: Adult|Senior
Phases:
Enrollment: 800
Funded Bys: Industry
Study Types: Observational
Study Designs: Observational Model: Cohort|Time Perspective: Prospective
Other IDs: GS-US-248-0123|2011-000946-39
First Received: October 4, 2011
Start Date: September 2011
Completion Date: July 2023
Last Updated: August 11, 2014
Last Verified: August 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: July 2023

Outcome Measures: Viral Activity|Clinical progression of liver disease|Development of hepatocellular carcinoma (HCC)
URL: http://ClinicalTrials.gov/show/NCT01457768

Study 35:
NCT Number: NCT02064049
Title: Surveillance and Treatment of Prisoners With Hepatitis C
Recruitment: Not yet recruiting
Study Results: No Results Available
Conditions: Hepatitis C
Interventions: Drug: Sofosbuvir and ribavirin
Sponsor/Collaborators: Kirby Institute
Gender: Male
Age Groups: Adult|Senior
Phases: Phase 4
Enrollment: 650
Funded Bys: Other
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Open Label
Other IDs: VHCRP1302
First Received: February 12, 2014
Start Date: September 2014
Completion Date: December 2017
Last Updated: May 1, 2014
Last Verified: May 2014
Acronym: SToP-C
Results First Received: No Study Results Posted
Primary Completion Date: December 2017
Outcome Measures: Hepatitis C virus (HCV) incidence|Hepatitis C virus prevalence|SVR12|ETR|Rapid Virological Response (RVR)|Very rapid virological response (vRVR)|Treatment adherence|Number of patients with adverse events|Treatment uptake|On-treatment change in illicit drug use|HCV reinfection rate
URL: http://ClinicalTrials.gov/show/NCT02064049