Appendix D. Ongoing Clinical Trials of Interventions for Hepatitis C Infection

| NCT Number | Study Titles | Interventions | Age Groups | Outcome Measures |
| --- | --- | --- | --- | --- |
| NCT00485342 | Multicentric, Controlled and Randomised Open Clinical Trial Investigating the Efficacy and Safety of Dose Adaptation of Ribavirin Using Pharmacologic Measures of Ribavirin Exposition During Combination Peginterferon Alfa-2 and Ribavirin Treatment in Naive Patients With Chronic Hepatitis C of Genotype 1 on a First Combination Therapy. | Pegylated interferon alfa-2a and ribavirinRibavirin with adaptation dose | Adult | Inter group comparison of SVR rates as defined by the proportion of subjects with a negative PCR HCV RNA test at Week 72Efficacy endpointsSafety endpointsEconomic endpoints |
| NCT00491244 | Pegylated Interferon Alfa-2a Plus Low Dose Ribavirin Versus Pegylated Interferon Alfa-2a Alone for Treatment-naïve Dialysis Patients With Chronic Hepatitis C. | Pegylated interferon alfa-2a Low-dose ribavirin  | Adult | SVRDrop-out rateHistologic responseBiochemical response |
| NCT00540345 | Four Arms, Multicenter, Open Label Study of Tailored Regimens With Peginterferon Plus Ribavirin for Genotype 2 Chronic Hepatitis C. | Pegylated interferon alfa-2a Ribavirin  | AdultSenior | Efficacy - rapid virologic response, HCV RNA seronegative by PCR at week 4 SVR, HCV RNA seronegative by PCR throughout 24-week off-treatment periodSafety - adverse event rate and profile |
| NCT00780416 | A Phase 3 Study of MP-424 in Combination With Peginterferon Alfa-2b and Ribavirin, in Treatment-Naïve Subjects With Genotype 1 Hepatitis C. | MP-424 Pegylated interferon alfa-2bRibavirin  | Adult | The percentage of subjects achieving undetectable HCV RNA at 24 weeks after treatment completion (SVR) |
| NCT01197157 | Impact of Nitazoxanide on Virologic Responses in Chronic HCV Infected Patients With Genotype 4: A Placebo-controlled Randomized Trial. | PlaceboNitazoxanide | Adult | Assessment of efficacy of nitazoxanide as an add-on therapy in terms of achieving a SVRAssessment of rapid virologic responseAssessment of early virologic responseAssessment of end-of-treatment responseSafety of nitazoxanideAssessment of the efficacy of nitazoxanide monotherapy following the lead-in phase |
| NCT01241760 | A Randomized, Open-label, Phase 3 Study of Telaprevir Administered Twice Daily or Every 8 Hours in Combination With Pegylated Interferon Alfa-2a and Ribavirin in Treatment-naive Subjects With Genotype 1 Chronic Hepatitis C Virus Infection. | Ribavirin TelaprevirPegylated interferon alfa-2a | AdultSenior | Proportion of patients achieving undetectable plasma HCV RNA levelsSafety and tolerability of the two dose regimens of telaprevirEffect of IL28B genotype on viral responsePharmacokinetics of telaprevir, pegylated interferonalpha-2a, and Ribavirin and pharmacokinetic-pharmacodynamic relationships for safety and efficacyChanges from baseline in the amino acid sequence of the HCV non-structural 3-4A region |
| NCT01263860 | A Randomized Trial of 24-Week Versus 48-Week Courses of Peginterferon Plus. | Pegylated interferon alfa-2aRibavirin Pegylated interferon alfa-2aRibavirin | AdultSenior | SVRChange in health related quality as measured by Short Form 36 from baseline to 24 weeks after treatment completionSick leave in patients treated for 24 or 48 weeks treatment |
| NCT01276756 | Randomized Study for the Assessment of Nitazoxanide in the Treatment of Chronic Hepatitis C Genotype 4. | Pegylated interferon alfa-2a RibavirinNitazoxanide | Adult | SVRRapid virologic responseEarly virologic responseEnd-of-treatment responseSafety of nitazoxanide (occurrence of adverse events) |
| NCT01289782 | A Phase III, Randomized, Double-blind, Placebo-controlled Study to Investigate the Efficacy, Safety, and Tolerability of Simeprevir vs. Placebo as Part of a Treatment Regimen Including Peginterferon Alfa-2a and Ribavirin in Treatment-naive, Genotype 1 Hepatitis C-infected Subjects. | SimeprevirPegylated interferon alfa-2aRibavirinPlacebo | AdultSenior | Proportion of patients with a SVR 12 weeks after treatment completion |
| NCT01290679 | Phase III, Double-blind, Placebo-controlled Study to Investigate the Efficacy, Safety, and Tolerability of Simeprevir vs Placebo as Part of a Treatment Regimen Including Peginterferon a-2a and Ribavirin or Peginterferon a-2b and Ribavirin in Treatment-naive, Genotype 1 Hepatitis C-infected Subjects. | SimprevirPegylated interferon alfa-2aPegylated interferon alfa-2bRibavirinPlacebo | AdultSenior | Proportion of patients with SVR 12 weeks after treatment completion |
| NCT01297270 | A Phase III, Randomized, Double Blind and Placebo Controlled Study of Once Daily BI 201335 120 mg for 24 Weeks and BI 201335 240 mg for 12 Weeks in Combination With Pegylated Interferon Alpha and Ribavirin in Treatment Naive Patients With Genotype 1 Chronic Hepatitis C Infection. | BI201335 Pegylated interferon alfaRibavirin | AdultSenior | SVR: Plasma HCV RNA level <25 IU/mL, undetected 24 weeks after treatment completionOccurrence of adverse events (overall, and classified into mild/moderate/severe)Occurrence of adverse events leading to treatment discontinuationOccurrence of serious adverse eventsOccurrence of drug-related adverse events as assessed by the investigatorOccurrence of laboratory test abnormalitiesCentral tendency and changes from baseline in laboratory test values over timeSVR: Plasma HCV RNA level < 25 IU/mL, undetected 12 weeks after treatment completion Early treatment success: - Plasma HCV RNA level < 25 IU/mL (detected or undetected) at week 4 and HCV RNA < 25 IU/mL, undetected at week 8 Alanine aminotransferase normalization: in normal range 24 weeks after treatment completion |
| NCT01318694 | A Randomized, Double-blind, Placebo-controlled Trial of the Efficacy and Safety of DEB025/Alisporivir in Combination With Peg-IFNα2a and Ribavirin in Hepatitis C Genotype 1 Treatment-naïve. | Standard of care (Pegylated interferon alfa-2a once weekly + Ribavirin twice daily) + DEB025 Standard of care + DEB025 400 mg Standard of care + DEB025Standard of care + Placebo for 48 weeks | AdultSenior | SVR, , defined as serum HCV RNA below limit of quantification 12 weeks after treatment completionSVR week 24 - -duration of DEB025+Ribavirin+ pegylated interferon alfa-2a therapy followed by Ribavirin+pegylated interferon alfa-2a therapy for up to 48 weeks needed to achieve SVR 12 weeks after treatment completionRapid virologic response by limit of detection, rapid virologic response by limit of quantification, - defined as serum HCV RNA below limit of detection or limit of quantification respectively after 4 weeks of treatmentTreatment response at 12 weeks - defined as HCV RNA undetectable by limit of detectionEnd of treatment response - defined as HCV RNA undetectable by limit of detection, SVR 48 weeks after treatment completionChange in liver enzyme (alainine aminotransferase and bilirubin) and hematological patient profiles (platelets, neutrophils, hemoglobin) during treatment phase |
| NCT01323244 | A Phase III, Open-Label, Single Arm, Rollover Trial of Simeprevir in Combination With Peginterferon Alpha-2A and Ribavirin for HCV Genotype-1 Infected Subjects Who Participated in the Placebo Group of a Phase II/III Simeprevir Study, or Who Received DAA Treatment in a Tibotec-Sponsored Phase I Study. | SimeprevirPegylated interferon alfa-2aRibavirin | AdultSenior | Proportion of participants with SVR 12Proportion of participants with SVR 24Number of participants with HCV RNA level >1000 IU/mLNumber of participants with viral breakthroughNumber of participants with viral relapseNumber of participants with normalized alanine aminotransferase levelsNumber of participants with on-treatment failureNumber of participants affected by an adverse event |
| NCT01343888 | A Phase III, Randomised, Double-blind and Placebo-controlled Study of Once Daily BI 201335 120 mg for 12 or 24 Weeks or BI 201335 240 mg for 12 Weeks in Combination With Pegylated interferon-a and Ribavirin in Treatment-naïve Patients With Genotype 1 Chronic Hepatitis C Infection. | Pegylated interferon alfa-2aRibavirinBI 201335 | AdultSenior | SVR after 12 weeks of treatment completion: Plasma HCV RNA level < 25 IU/mL, undetected SVR after 24 weeks of treatment completion: Plasma HCV RNA level < 25 IU/mL, undetected Early treatment success: Plasma HCV RNA level < 25 IU/mL (detected or undetected) at week 4 and HCV RNA < 25 IU/mL undetected at week 8Alanine aminotransferase and aspartate aminotransferase normalization: in normal range at end of treatment and post-treatment |
| NCT01344889 | Global Observational Cohort Study on the Prediction of Unwanted Adverse Effects in Individuals Infected With Chronic Hepatitis C Receiving a Long Acting Interferon Plus Ribavirin. | Long-acting interferonsRibavirin | AdultSenior | Correlation between baseline patient characteristics and safety related dose reductions/treatment discontinuations of the long-acting interferon or RibavirinCorrelation between safety related dose reductions/treatment discontinuations and SVR, defined as HCV RNA <50 IU/mL at 24 weeks after treatment completionCorrelation of on-treatment factors and dose reduction/treatment discontinuationCorrelation between degree of dose reductions/treatment interruptions (percentage of actual exposure/treatment administrations in relation to target exposure) and SVRComparison of on-treatment virological response (rapid virological response, early virological response) in treatment-naive and treatment experienced patientsIncidence of adverse events |
| NCT01364090 | A Phase IV, Open-label, Multicentre, International Trial of Response Guided Treatment With Directly Observed Pegylated Interferon Alfa 2b and Self Administered Ribavirin for Patients With Chronic HCV Genotype 2 or 3 and Ongoing Injection Drug Use. | Pegylated interferon alfa-2b Ribavirin | AdultSenior | Treatment efficacySafety and tolerabilityTreatment adherenceTreatment response, (end of treatment and SVR 12 weeks after treatment completion)Behavioral and quality of Life |
| NCT01370642 | A Phase III Randomized, Placebo-controlled Study to Evaluate the Safety, Tolerability, and Efficacy of MK-7009 When Administered Concomitantly With Peginterferon Alfa-2b and Ribavirin in Japanese Treatment-Naïve Patients With Chronic Hepatitis C Infection. | Vaniprevir Placebo Pegylated interferon alfa-2bRibavirin | AdultSenior | Proportion of patients achieving SVRProportion of patients achieving SVR 12 weeks after treatment completionProportion of participants achieving rapid virologic responseProportion of participants achieving complete early virologic responseProportion of participants achieving undetectable HCV RNA at the end of treatment |
| NCT01389323 | Open-Label, Single Arm Evaluation of BMS-790052 in Combination With Peg-Interferon Alfa-2a and Ribavirin in Black-African Americans, Latinos and White-Caucasians With Chronic Hepatitis C Genotype 1 Infection. | BMS-790052 (NS5A Replication Complex Inhibitor)Pegylated interferon alfa 2aRibavirin | AdultSenior | Proportion of subjects with SVR 12 weeks after treatment completion, defined as HCV RNA < limit of quantification (detectable or undetectable) for each cohortFrequency of serious adverse events and discontinuations due to adverse events for each cohort and overallProportion of subjects with CC, CT, or TT genotype at the IL28B rs12979860 single nucleotide polymorphism who achieves SVR 12 weeks after treatment completionProportion of subjects who achieve HCV RNA < limit of quantificationProportion of subjects who achieve HCV RNA undetectable |
| NCT01405027 | Boceprevir in Community Practice: Assessing Safety, Efficacy, Compliance and Quality of Life, Impact of an Education Program. | Educational InterventionNo Intervention | AdultSenior | Treatment duration compliance rateDose exposureSVR defined as undetectable plasma HCV RNA at followup week 24 Quality of lifeNumber of participants with adverse events |
| NCT01446250 | A Randomized, Open Label Trial of the Safety and Efficacy of DEB025/Alisporivir in Combination With Pegylated Interferon-α2a and Ribavirin (Peg-INFα2a/RBV) and Boceprevir in Combination With Peg-INFα2a/RBV in African American Treatment-naϊve Patients With Chronic Hepatitis C Genotype 1. | DEB025 plus pegylated interferon alfa-2a and Ribavirin fixed duration treatment DEB025 plus pegylated interferon alfa-2a and Ribavirin response guided treatment durationBoceprevir plus pegylated interferon alfa-2a and Ribavirin per label response guided treatment | AdultSenior | Proportion of patients that discontinue study drug or require dose reduction or dose interruption due to treatment-emergent adverse eventsProportion of patients with emergence of resistant mutations in each treatment armProportion of patients that achieve SVR, defined as serum HCV RNA undetectable by limit of detection 24 weeks after treatment completion |
| NCT01447420 | Clinical Study to Compare Sustained Virological Response in Function of Expression Profile of IL28-b in naïve Patients With Chronic Infection by HCV Genotype 1, With Hepatitis C, Receiving Pegasys and Ribavirin. | Pegylated interferon alfa-2aRibavirin  | AdultSenior | Rate of SVR (undetectable HCV RNA 24 weeks after treatment completion) in relation to Interleukin 28B (IL28-b) expressionIncidence of anemiaResponse rate (rapid/early/end of treatment) in relation to IL28-b expressionCorrelation between SVR and anemia (hemoglobin levels) during the first month of treatmentCorrelation between SVR and anemia (hemoglobin levels) after the first month of treatmentCorrelation between viral load (HCV RNA levels) 12 weeks after treatment completion and SVR |
| NCT01448044 | A Phase 3 Evaluation of BMS-790052 in Combination With Peg-Interferon Alfa-2a and Ribavirin in Treatment Naive Subjects With Chronic Hepatitis C Genotype 4. | BMS-790052 (NS5A Replication Complex Inhibitor)Placebo matching BMS-790052Pegylated interferon alfa-2aRibavirin | AdultSenior | Compare rates of SVR 12 weeks after treatment completion for HCV genotype 4 subjects treated with either BMS-790052 or placebo in combination with pegylated interferon ± alfa2a/RibavirinProportion of subjects who achieve HCV RNA < limit of quantificationProportion of subjects who achieve HCV RNA undetectableFrequency of serious adverse events and discontinuations due to adverse events for each cohort on treatmentProportion of subjects with SVR 12 or 24 weeks after treatment completion by rs12979860 single nucleotide polymorphism in the IL28B gene |
| NCT01457937 | Boceprevir/Peginterferon Alfa (PegIFN α)-2b/Ribavirin (Riba) in Difficult-to-Treat Menopausal Women With Chronic Hepatitis C Genotype 1 (Gt 1), Either Deemed Nonresponders to Peginterferon/Ribavirin or Treatment-naives (MEN\_BOC). | Pegylated interferon alfaRibavirinBoceprevir | ChildAdultSenior | Improvement of SVR in previous treatment failure or naive HCV-positive menopausal womenEarly virologic response |
| NCT01459913 | A Phase 3b Study of 2 Treatment Durations of Telaprevir, Peg-IFN (Pegasys®), and Ribavirin (Copegus®) in Treatment-Naive and Prior Relapser Subjects With Genotype 1 Chronic Hepatitis C and IL28B CC Genotype. | TelaprevirPegylated interferon alfa-2a Ribavirin | AdultSenior | Proportion of subjects assigned to the 12-week regimen of telaprevir, pegylated interferon, and Ribavirin who have SVR 12 weeks after treatment completion Proportion of subjects who have SVR 24 weeks after treatment completionProportion of subjects who have SVR at week 72Proportion of subjects who have relapse overall and by treatment completion statusProportion of subjects who have on-treatment virologic failureSafety as indicated by adverse events, clinical laboratory results, electrocardiograms, and vital signsAmino acid sequence of the HCV non-structural 3-4A protease domain |
| NCT01474811 | HCV-TARGET: Hepatitis C Therapeutic Registry and Research Network - A Longitudinal, Observational Study. | TelaprevirBoceprevir | AdultSenior | Proportion of subjects who have SVR 12 weeks after treatment completionProportion of subjects who have SVR 24 weeks after treatment completionVirological breakthroughManagement of adverse events |
| NCT01492426 | A Phase 3 Evaluation of BMS-790052 (Daclatasvir) Compared With Telaprevir in Combination With Peginterferon Alfa-2a and Ribavirin in Treatment-Naive Patients With Chronic Hepatitis C. | BMS-790052 (Daclatasvir) Telaprevir Pegylated interferon alfa-2aRibavirin | AdultSenior | Proportion of genotype 1b patients with SVR, defined as HCV RNA < limit of quantification at followup week 12 in each groupProportion of genotype 1b patients with hemoglobin value < 10 g/dLProportion of genotype 1b patients with rash eventsProportion of genotype1b patients with HCV RNA undetectable at week 12Proportion of genotype 1b patients with HCV RNA undetectable at week 4Proportion of genotype 1b patients with HCV RNA undetectable at Wweeks 4 and 12Proportion of genotype 1b patients with SVR, defined as HCV RNA < limit of quantification at followup week 24 for each cohortProportion of genotype 1b patients with SVR at followup week 12 based on IL28B rs12979860 single nucleotide polymorphism genotype (CC or non-CC)Proportion of genotype 1a patients with SVR, defined as HCV RNA < limit of quantification at followup week 12 for each cohort |
| NCT01497366 | 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. | PSI-7977 in combination with ribavirin Pegylated interferon in combination with ribavirin | AdultSenior | Efficacy 12 weeks after treatment completionDescription of Safety with PSI-7977 and RibavirinSVR 24 weeks after treatment completionAmount of circulating HCV RNAAlaine aminotransferase normalizationNumber of subjects with virologic failureCharacterization of drug resistance |
| NCT01497834 | A Phase 3 Japanese Study of BMS-790052 Plus BMS-650032 Combination Therapy in Chronic Hepatitis C Genotype 1b Infected Subjects Who Are Non Response to Interferon Plus Ribavirin and Interferon Based Therapy Ineligible Naive/Intolerant. | BMS-790052 (Daclatasvir)BMS-650032 (Asunaprevir) | AdultSenior | Antiviral activity, as determined by the proportion of subjects with SVR 24 weeks after treatment completionAntiviral activity, as determined by the proportion of subjects who achieve HCV RNA < limit of quantificationAntiviral activity, as determined by the proportion of subjects who achieve undetectable HCV RNASafety, as measured by the frequency of severe adverse events, discontinuations due to adverse events, adverse effects by intensity and laboratory abnormalities by toxicity gradeProportion of subjects with SVR 24 weeks after treatment by IL28B status (CC, CT, or TT genotype at the IL28B rs12979860 single nucleotide polymorphisms) |
| NCT01498068 | Open-Label, Bridging Study to Determine Efficacy and Safety of Telaprevir, Pegylated-Interferon-alfa-2a and Ribavirin in Treatment- Naïve and Treatment-Experienced Russian Subjects With Genotype 1 Chronic Hepatitis C. | Telaprevir Pegylated interferon alfa-2aRibavirin | AdultSenior | Proportion of patients having undetectable plasma HCV RNA levels |
| NCT01508286 | Multicenter, Open-label, Early Access Program of Telaprevir in Combination With Peginterferon Alfa and Ribavirin in Genotype 1 Chronic Hepatitis C Subjects With Severe Fibrosis and Compensated Cirrhosis. | Telaprevir Pegylated interferon alfaRibavirin | AdultSenior | Not reported |
| NCT01544920 | A Phase 3, Safety and Efficacy Study of Boceprevir/Peginterferon Alfa-2a/Ribavirin in Chronic HCV Genotype 1 IL28B CC Subjects. | Pegylated interferon alfa-2a Ribavirin Boceprevir | AdultSenior | Overall number of participants achieving SVR at followup week 24Number of participants achieving SVR at followup week 24 among those participants who had achieved rapid virologic response |
| NCT01544920 | A Phase 3, Safety and Efficacy Study of Boceprevir/Peginterferon Alfa-2a/Ribavirin in Chronic HCV Genotype 1 IL28B CC Subjects. | Pegylated interferon alfa-2a Ribavirin Boceprevir | AdultSenior | Overall number of participants achieving SVR at followup week 24Number of participants achieving SVR at followup week 24 among those participants who had achieved rapid virologic response |
| NCT01567735 | An Open-Label, Single-Arm Phase III Study to Evaluate the Efficacy, Safety and Tolerability of Simeprevir in Combination With PegIFN Alfa-2a (Pegasys) and Ribavirin (Copegus) in Treatment-Naïve or Treatment-Experienced, Chronic Hepatitis C Virus Genotype-4 Infected Subjects. | Pegylated interferon alfa-2aSimeprevir | AdultSenior | Proportion of participants achieving SVR 12 weeks after treatment completionEfficacy of simeprevir with respect to proportion of participants achieving SVR 24 weeks after treatment completionOn-treatment virologic responseOn-treatment virologic failureEvaluation of the viral breakthrough rateEvaluation of viral relapse rateEvaluation the safety and tolerability |
| NCT01579474 | Safety, Efficacy and Pharmacokinetics of BI 201335 NA in Patient With Genotype 1 Chronic Hepatitis C Virus Infection in Combination With Pegylated Interferon Alfa-2b and Ribavirin - Cohort 1 for Treatment-naive Patients: Randomised, Double-blind Part of BI 201335 NA for 12 or 24 Weeks - Cohort 2 for Treatment-experienced Patients: Open-label Part of BI 201335 NA for 24 Weeks. | BI 201335 high doseBI201335 low dosePegylated interferon alfa-2bRibavirin | AdultSenior | SVR, defined as plasma HCV RNV undetectable at 24 weeks after treatment completionSVR, defined as plasma HCV RNA undetectable at 12 weeks after treatment completionEarly treatment success, defined as plasma HCV RNA <25 IU/mL at week 4 and HCV RNA undetectable at week 8Alanine aminotransferase normalization, defined as normal at 24 weeks after treatment completion |
| NCT01581203 | A Phase 3 Study With Asunaprevir and Daclatasvir (DUAL) for Null or Partial Responders to Peginterferon Alfa and Ribavirin (P/R), Intolerant or Ineligible to P/R Subjects and Treatment-Naive Subjects With Chronic Hepatitis C Genotype 1b Infection. | Asunaprevir Daclatasvir Placebo matching AsunaprevirPlacebo matching DaclatasvirPegylated interferon alfa-2a Ribavirin  | AdultSenior | Proportion of treated subjects with SVR, defined as HCV RNA < limit of quantification at 12 weeks after treatment completion, for all subjects who are prior null or partial responders to pegylated interferon alfa-2a and Ribavirin or are treatment-naïveProportion of treated subjects with SVR, defined as HCV RNA < limit of quantification 12 weeks after treatment completion, for subjects who are intolerant or ineligible to pegylated interferon alfa-2a and RibavirinOn treatment safety, as measured by frequency of serious adverse events and discontinuations due to adverse eventsDifferences in rates of selected grade 3-4 laboratory abnormalities during the first 12 weeks between treatments (Asunaprevir + Daclatasvir vs. placebo) for naive subjectsProportion of genotype 1b subjects with SVR (defined as HCV RNA < limit of quantification at 12 weeks after treatment completion) by the rs12979860 single nucleotide polymorphisms in the IL28B gene for each cohortProportion of genotype 1b subjects with HCV RNA undetectableProportion of genotypes 1b subjects with HCV RNA < limit of quanitifcation |
| NCT01591460 | An International, Multicenter, Open-Label Study Evaluating Sustained Virological Response and Safety With Boceprevir in Triple Combination Therapy With Peginterferon Alfa-2a (40KD) and Ribavirin in Treatment-Naïve Patients With Genotype 1 Chronic Hepatitis C. | BoceprevirPegylated interferon alfa-2a (Pegasys) Ribavirin (Copegus)  | AdultSenior | SVR 12 weeks after treatment completionSVR 24 weeks after treatment completionLevel of HCV RNAEnd of treatment responseVirologic relapse rateSafety: incidence of adverse events |
| NCT01598090 | A Phase 3 Blinded Randomized Study of Peginterferon Lambda-1a and Ribavirin Compared to Peginterferon Alfa-2a and Ribavirin, Each Administered With Telaprevir in Subjects With Genotype-1 Chronic Hepatitis C Who Are Treatment-naive or Relapsed on Prior Treatment With Peginterferon Alfa-2a and Ribavirin. | Peginterferon lambda-1aPegylated interferon alfa-2a RibavirinTelaprevir | AdultSenior | Proportion of subjects achieving efficacy as measured by extended rapid virologic response Safety as measured by the frequency of deaths, serious adverse events, drug related adverse events, dose reductions and discontinuations due to adverse eventsProportion of subjects achieving efficacy as measured by SVR 12 weeks after treatment completion, defined as HCV RNA < 25 IU/mlProportion of subjects who achieve efficacy as measured by SVR 12 weeks after treatment completion, defined as HCV RNA < 25 IU/mlProportion of subjects who achieve efficacy as measured by SVR 24 weeks after treatment completion, defined as HCV RNA < 25 IU/mlProportion of subjects who achieve efficacy as measured by SVR 12 weeks after treatment completion, defined as HCV RNA < 25 IU/ml in treatment-naive subjectsProportion of subjects who achieve efficacy as measured by extended rapid virologic response, defined as HCV RNA undetectableProportion of subjects who achieve efficacy as measured by SVR 24 weeks after treatment completion, defined as HCV RNA < 25 IU/mlNumber of incidence for Cytopenic abnormalities (anemia is defined by hemoglobin < 10 g/dL, neutropenia as defined by absolute neutrophil count < 750 mm3, thrombocytopenia as defined by platelets < 50,000 mm3)Number of incidence for flu-like symptoms (as defined by pyrexia or chills or pain)Number of incidence for musculoskeletal symptoms (as defined by arthralgia or myalgia or back pain) |
| NCT01608737 | A Phase III, Randomised, Double-blind and Placebo-controlled Study of Once Daily BI 201335 for 12 or 24 Weeks in Combination With Pegylated interferon-a and Ribavirin in Treatment-naive and Prior Relapser Patients With Genotype 1 Chronic Hepatitis C Infection. | Pegylated interferon alfa-2aRibavirinDrug BI 201335  | AdultSenior | SVR 12 weeks after treatment completion: Plasma HCV RNA <25 IU/mL undetected Virologic response\ 24 weeks after treatment completion: Plasma HCV RNA level <25 IU/mL, undetectedEarly treatment success: Plasma HCV RNA level <25 IU/mL (detected or undetected) at week 4 and HCV RNA <25 IU/mL, undetected at week 8Alanine Aminotransferase and Aspartate Aminotransferase normalization: normal at end of treatment and treatment completion |
| NCT01609049 | Open-label, Multicenter, Non-comparative, Prospective Observational Study to Evaluate Efficacy and Safety of Combined Ribavirin and Peginterferon Alfa-2a (40 kDa) Therapy in Patients With Chronic Hepatitis C (CHC) and Compensated Liver Cirrhosis in Real Clinical Practice. | Pegylated interferon alfa-2aRibavirin | AdultSenior | Percentage of patients with undetectable HCV RNA 24 weeks after treatment completionPercentage of patients with SVR and negative HCV RNA at week 4 and 12 (naive patients)Percentage of patients with SVR and negative HCV RNA at week 12 (previously treated patients) Percentage of patients with SVR and decrease in HCV RNA by > log 10 from baseline (previously treated and naive patients) Percentage of patients with SVR who had dose reduction of any drug (Ribavirin or Pegylated interferon alfa-2a) due to adverse eventsIncidence of adverse events |
| NCT01616524 | A Phase 3, Randomized, Double-Blind, Controlled Study Evaluating the Efficacy and Safety of Peginterferon Lambda-1a, With and Without Daclatasvir, Compared to Peginterferon Alfa-2a, Each in Combination With Ribavirin, in the Treatment of Naïve Genotype 2 and 3 Chronic Hepatitis C Subjects. | Pegylated interferon lambda Pegylated interferon alfa-2a RibavirinDaclatasvirPlacebo  | AdultSenior | Proportion of subjects who achieve SVR 12 weeks after treatment completionProportion of subjects with rapid virologic response, undetectable HCVRNAProportion of subjects with treatment emergent cytopenic abnormalities (anemia as defined by hemoglobin < 10 g/dL, neutropenia as defined by absolute neutrophil count < 750 mm3 or thrombocytopenia as defined by platelets < 50,000 mm3)Proportion of subjects with on-treatment interferon-associated flu-like symptoms (as defined by pyrexia or chills or pain)Proportion of subjects with on-treatment musculoskeletal symptoms (as defined by arthralgia or myalgia or back pain)Proportion of subjects with SVR 24 weeks after treatment completion Proportion of subjects with on-treatment serious adverse eventsProportion of subjects with dose reductionsProportion of subjects who discontinue due to adverse eventsProportion of subjects with SVR 12 weeks after treatment completion in subjects with genotype-3 chronic HCV infectionProportion of subjects with on-treatment constitutional symptoms (fatigue or asthenia) |
| NCT01623336 | Safety and Efficacy of BIP48 (Peginterferon Alfa 2b 48kDa) Compared With Pegasys® (Peginterferon 2a 40kDa) for Treatment of Chronic Hepatitis C: Randomized, Multicentric Study With Blinded Analysis. | BIP 48 (Pegylated interferon alfa-2b 48kDA)Pegylated interferon alfa-2a 40kDA BIP 48  | AdultSenior | The rate of SVR measured by PCR 24 weeks after treatment completionFrequency of adverse eventsVirologic response at treatment completion |
| NCT01641640 | A Phase 3, Multicenter, Open-Label Study to Investigate the Efficacy and Safety of GS-7977 With Peginterferon Alfa 2a and Ribavirin for 12 Weeks in Treatment-Naïve Subjects With Chronic Genotype 1, 4, 5, or 6 HCV Infection. | GS 7977 in combination with Pegylated interferon alfa-2aRibavirin | AdultSenior | Efficacy 12 weeks after treatment completionSafety and tolerability of GS-7977+Ribavirin+pegylated interferon alfa-2a when given for 12 weeksEfficacy 4 and 24 weeks after treatment completionAmount of circulating HCV RNACharacterization of viral resistance |
| NCT01653236 | Pilot Study to Determine the Efficacy and Safety of Combining Boceprevir With Peginterferon Alfa-2b and Ribavirin in the Treatment-naive Patients Infected With Genotype 4 Chronic Hepatitis C Infection. | BoceprevirPegylated interferon alfa-2b Ribavirin | AdultSenior | EfficacyWeek 8 responseWeek 12 responseIL-28B polymorphism |
| NCT01659567 | Prospective Observational Study on Predictors of On-treatment Response and Sustained Virological Response in a Cohort of HCV-infected Patients Treated With Pegylated Interferons in Georgia. | Pegylated interferon alfa-2aPegylated interferon alfa-2bRibavirin | AdultSenior | Predictive values of SVRCorrelation of patient characteristics and SVROverall treatment durationTreatment duration after SVRCorrelation of treatment dose and SVRSVRIncidence of adverse events |
| NCT01682720 | A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of GS-7977+ Ribavirin for 12 Weeks in Treatment Naive and Treatment Experienced Subjects With Chronic Genotype 2 or 3 HCV Infection. | GS-7977RibavirinPlacebo  | AdultSenior | Efficacy 12 weeks after treatment completionSafety and tolerability of GS-7977 + RibavirinEfficacy 4 and 24 weeks after treatment completionEfficacy of treatment with GS-7977 + Ribavirin based on prior treatment historyKinetics of circulating HCV RNA during and after treatment completionViral resistance to GS-7977 during and after treatment completion |
| NCT01686789 | Randomized Controlled Open Label Trial of Peg Alpha 2a Interferon and Adjusted-dose of Ribavirin vs. Standard Therapy in the Treatment of Naive Chronic Hepatitis C Patients Infected With Genotype 4. | Pegylated interferon alfa--2aRibavirin | AdultSenior | SVRRequirement of blood-related products |

**Note:** HCV=hepatitis C virus; PCR=polymerase chain reaction; RNA=ribonucleic acid; SVR=sustain virologic response.
**Source:** Clinicaltrials.gov.