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

| NCT Number | Study Titles | Interventions | Age Groups | Outcome Measures |
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| 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 ribavirin  Ribavirin 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 72  Efficacy endpoints  Safety endpoints  Economic 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 | SVR  Drop-out rate  Histologic response  Biochemical 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 | Adult  Senior | Efficacy - rapid virologic response, HCV RNA seronegative by PCR at week 4 SVR, HCV RNA seronegative by PCR throughout 24-week off-treatment period  Safety - 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-2b  Ribavirin | 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. | Placebo  Nitazoxanide | Adult | Assessment of efficacy of nitazoxanide as an add-on therapy in terms of achieving a SVR  Assessment of rapid virologic response  Assessment of early virologic response  Assessment of end-of-treatment response  Safety of nitazoxanide  Assessment 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  Telaprevir  Pegylated interferon alfa-2a | Adult  Senior | Proportion of patients achieving undetectable plasma HCV RNA levels  Safety and tolerability of the two dose regimens of telaprevir  Effect of IL28B genotype on viral response  Pharmacokinetics of telaprevir, pegylated interferonalpha-2a, and Ribavirin and pharmacokinetic-pharmacodynamic relationships for safety and efficacy  Changes 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-2a  Ribavirin  Pegylated interferon alfa-2a  Ribavirin | Adult  Senior | SVR  Change in health related quality as measured by Short Form 36 from baseline to 24 weeks after treatment completion  Sick 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  Ribavirin  Nitazoxanide | Adult | SVR  Rapid virologic response  Early virologic response  End-of-treatment response  Safety 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. | Simeprevir  Pegylated interferon alfa-2a  Ribavirin  Placebo | Adult  Senior | 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. | Simprevir  Pegylated interferon alfa-2a  Pegylated interferon alfa-2b  Ribavirin  Placebo | Adult  Senior | 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 alfa  Ribavirin | Adult  Senior | SVR: Plasma HCV RNA level <25 IU/mL, undetected 24 weeks after treatment completion  Occurrence of adverse events (overall, and classified into mild/moderate/severe)  Occurrence of adverse events leading to treatment discontinuation  Occurrence of serious adverse events  Occurrence of drug-related adverse events as assessed by the investigator  Occurrence of laboratory test abnormalities  Central tendency and changes from baseline in laboratory test values over time  SVR: 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 + DEB025  Standard of care + Placebo for 48 weeks | Adult  Senior | SVR, , defined as serum HCV RNA below limit of quantification 12 weeks after treatment completion  SVR 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 completion  Rapid 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 treatment  Treatment response at 12 weeks - defined as HCV RNA undetectable by limit of detection  End of treatment response - defined as HCV RNA undetectable by limit of detection, SVR 48 weeks after treatment completion  Change 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. | Simeprevir  Pegylated interferon alfa-  2a  Ribavirin | Adult  Senior | Proportion of participants with SVR 12  Proportion of participants with SVR 24  Number of participants with HCV RNA level >1000 IU/mL  Number of participants with viral breakthrough  Number of participants with viral relapse  Number of participants with normalized alanine aminotransferase levels  Number of participants with on-treatment failure  Number 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-2a  Ribavirin  BI 201335 | Adult  Senior | 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 8  Alanine 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 interferons  Ribavirin | Adult  Senior | Correlation between baseline patient characteristics and safety related dose reductions/treatment discontinuations of the long-acting interferon or Ribavirin  Correlation between safety related dose reductions/treatment discontinuations and SVR, defined as HCV RNA <50 IU/mL at 24 weeks after treatment completion  Correlation of on-treatment factors and dose reduction/treatment discontinuation  Correlation between degree of dose reductions/treatment interruptions (percentage of actual exposure/treatment administrations in relation to target exposure) and SVR  Comparison of on-treatment virological response (rapid virological response, early virological response) in treatment-naive and treatment experienced patients  Incidence 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 | Adult  Senior | Treatment efficacy  Safety and tolerability  Treatment adherence  Treatment 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-2b  Ribavirin | Adult  Senior | Proportion of patients achieving SVR  Proportion of patients achieving SVR 12 weeks after treatment completion  Proportion of participants achieving rapid virologic response  Proportion of participants achieving complete early virologic response  Proportion 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 2a  Ribavirin | Adult  Senior | Proportion of subjects with SVR 12 weeks after treatment completion, defined as HCV RNA < limit of quantification (detectable or undetectable) for each cohort  Frequency of serious adverse events and discontinuations due to adverse events for each cohort and overall  Proportion of subjects with CC, CT, or TT genotype at the IL28B rs12979860 single nucleotide polymorphism who achieves SVR 12 weeks after treatment completion  Proportion of subjects who achieve HCV RNA < limit of quantification  Proportion 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 Intervention  No Intervention | Adult  Senior | Treatment duration compliance rate  Dose exposure  SVR defined as undetectable plasma HCV RNA at followup week 24  Quality of life  Number 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 duration  Boceprevir plus pegylated interferon alfa-2a and Ribavirin per label response guided treatment | Adult  Senior | Proportion of patients that discontinue study drug or require dose reduction or dose interruption due to treatment-emergent adverse events  Proportion of patients with emergence of resistant mutations in each treatment arm  Proportion 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-2a  Ribavirin | Adult  Senior | Rate of SVR (undetectable HCV RNA 24 weeks after treatment completion) in relation to Interleukin 28B (IL28-b) expression  Incidence of anemia  Response rate (rapid/early/end of treatment) in relation to IL28-b expression  Correlation between SVR and anemia (hemoglobin levels) during the first month of treatment  Correlation between SVR and anemia (hemoglobin levels) after the first month of treatment  Correlation 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-790052  Pegylated interferon alfa-2a  Ribavirin | Adult  Senior | 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/Ribavirin  Proportion of subjects who achieve HCV RNA < limit of quantification  Proportion of subjects who achieve HCV RNA undetectable  Frequency of serious adverse events and discontinuations due to adverse events for each cohort on treatment  Proportion 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 alfa  Ribavirin  Boceprevir | Child  Adult  Senior | Improvement of SVR in previous treatment failure or naive HCV-positive menopausal women  Early 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. | Telaprevir  Pegylated interferon alfa-2a  Ribavirin | Adult  Senior | 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 completion  Proportion of subjects who have SVR at week 72  Proportion of subjects who have relapse overall and by treatment completion status  Proportion of subjects who have on-treatment virologic failure  Safety as indicated by adverse events, clinical laboratory results, electrocardiograms, and vital signs  Amino 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. | Telaprevir  Boceprevir | Adult  Senior | Proportion of subjects who have SVR 12 weeks after treatment completion  Proportion of subjects who have SVR 24 weeks after treatment completion  Virological breakthrough  Management 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-2a  Ribavirin | Adult  Senior | Proportion of genotype 1b patients with SVR, defined as HCV RNA < limit of quantification at followup week 12 in each group  Proportion of genotype 1b patients with hemoglobin value < 10 g/dL  Proportion of genotype 1b patients with rash events  Proportion of genotype1b patients with HCV RNA undetectable at week 12  Proportion of genotype 1b patients with HCV RNA undetectable at week 4  Proportion of genotype 1b patients with HCV RNA undetectable at Wweeks 4 and 12  Proportion of genotype 1b patients with SVR, defined as HCV RNA < limit of quantification at followup week 24 for each cohort  Proportion 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 | Adult  Senior | Efficacy 12 weeks after treatment completion  Description of Safety with PSI-7977 and Ribavirin  SVR 24 weeks after treatment completion  Amount of circulating HCV RNA  Alaine aminotransferase normalization  Number of subjects with virologic failure  Characterization 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) | Adult  Senior | Antiviral activity, as determined by the proportion of subjects with SVR 24 weeks after treatment completion  Antiviral activity, as determined by the proportion of subjects who achieve HCV RNA < limit of quantification  Antiviral activity, as determined by the proportion of subjects who achieve undetectable HCV RNA  Safety, as measured by the frequency of severe adverse events, discontinuations due to adverse events, adverse effects by intensity and laboratory abnormalities by toxicity grade  Proportion 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-2a  Ribavirin | Adult  Senior | 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 alfa  Ribavirin | Adult  Senior | 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 | Adult  Senior | Overall number of participants achieving SVR at followup week 24  Number 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 | Adult  Senior | Overall number of participants achieving SVR at followup week 24  Number 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-2a  Simeprevir | Adult  Senior | Proportion of participants achieving SVR 12 weeks after treatment completion  Efficacy of simeprevir with respect to proportion of participants achieving SVR 24 weeks after treatment completion  On-treatment virologic response  On-treatment virologic failure  Evaluation of the viral breakthrough rate  Evaluation of viral relapse rate  Evaluation 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 dose  BI201335 low dose  Pegylated interferon alfa-2b  Ribavirin | Adult  Senior | SVR, defined as plasma HCV RNV undetectable at 24 weeks after treatment completion  SVR, defined as plasma HCV RNA undetectable at 12 weeks after treatment completion  Early treatment success, defined as plasma HCV RNA <25 IU/mL at week 4 and HCV RNA undetectable at week 8  Alanine 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 Asunaprevir  Placebo matching Daclatasvir  Pegylated interferon alfa-2a  Ribavirin | Adult  Senior | 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-naïve  Proportion 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 Ribavirin  On treatment safety, as measured by frequency of serious adverse events and discontinuations due to adverse events  Differences in rates of selected grade 3-4 laboratory abnormalities during the first 12 weeks between treatments (Asunaprevir + Daclatasvir vs. placebo) for naive subjects  Proportion 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 cohort  Proportion of genotype 1b subjects with HCV RNA undetectable  Proportion 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. | Boceprevir  Pegylated interferon alfa-2a (Pegasys)  Ribavirin (Copegus) | Adult  Senior | SVR 12 weeks after treatment completion  SVR 24 weeks after treatment completion  Level of HCV RNA  End of treatment response  Virologic relapse rate  Safety: 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-1a  Pegylated interferon alfa-2a  Ribavirin  Telaprevir | Adult  Senior | 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 events  Proportion of subjects achieving efficacy as measured by SVR 12 weeks after treatment completion, defined as HCV RNA < 25 IU/ml  Proportion of subjects who achieve efficacy as measured by SVR 12 weeks after treatment completion, defined as HCV RNA < 25 IU/ml  Proportion of subjects who achieve efficacy as measured by SVR 24 weeks after treatment completion, defined as HCV RNA < 25 IU/ml  Proportion of subjects who achieve efficacy as measured by SVR 12 weeks after treatment completion, defined as HCV RNA < 25 IU/ml in treatment-naive subjects  Proportion of subjects who achieve efficacy as measured by extended rapid virologic response, defined as HCV RNA undetectable  Proportion of subjects who achieve efficacy as measured by SVR 24 weeks after treatment completion, defined as HCV RNA < 25 IU/ml  Number 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-2a  Ribavirin  Drug BI 201335 | Adult  Senior | 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, 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 8  Alanine 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-2a  Ribavirin | Adult  Senior | Percentage of patients with undetectable HCV RNA 24 weeks after treatment completion  Percentage 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 events  Incidence 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  Ribavirin  Daclatasvir  Placebo | Adult  Senior | Proportion of subjects who achieve SVR 12 weeks after treatment completion  Proportion of subjects with rapid virologic response, undetectable HCVRNA  Proportion 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 events  Proportion of subjects with dose reductions  Proportion of subjects who discontinue due to adverse events  Proportion of subjects with SVR 12 weeks after treatment completion in subjects with genotype-3 chronic HCV infection  Proportion 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 | Adult  Senior | The rate of SVR measured by PCR 24 weeks after treatment completion  Frequency of adverse events  Virologic 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-2a  Ribavirin | Adult  Senior | Efficacy 12 weeks after treatment completion  Safety and tolerability of GS-7977+Ribavirin+pegylated interferon alfa-2a when given for 12 weeks  Efficacy 4 and 24 weeks after treatment completion  Amount of circulating HCV RNA  Characterization 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. | Boceprevir  Pegylated interferon alfa-2b  Ribavirin | Adult  Senior | Efficacy  Week 8 response  Week 12 response  IL-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-2a  Pegylated interferon alfa-2b  Ribavirin | Adult  Senior | Predictive values of SVR  Correlation of patient characteristics and SVR  Overall treatment duration  Treatment duration after SVR  Correlation of treatment dose and SVR  SVR  Incidence 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-7977  Ribavirin  Placebo | Adult  Senior | Efficacy 12 weeks after treatment completion  Safety and tolerability of GS-7977 + Ribavirin  Efficacy 4 and 24 weeks after treatment completion  Efficacy of treatment with GS-7977 + Ribavirin based on prior treatment history  Kinetics of circulating HCV RNA during and after treatment completion  Viral 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--2a  Ribavirin | Adult  Senior | SVR  Requirement of blood-related products |

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