Research Specialists of Texas List of Ongoing Studies

No.	Sponsor	Protocol #	Protocol Title:	Status
1	Abbott	M12-114	A Blinded Randomized, Placebo-Controlled, Dose-Ranging study to Evaluate the Safety, Pharmacokinetics, and Antiviral Activity of ABT-267 in Combination with Peginterferon a-2a and Ribavirin (pegINF/RBV) in Treatment-Naïve Subjects with Genotype 1 Chronic Hepatitis C Virus (HCV) Infection.	Open/Follow Up
2	Hoffman-La Roche, Inc.	598-505	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Ascending Multiple Dose Trial of Safety, Efficacy, and Pharmacokinetics of ANA598 Administered with Pegylated Interferon and Ribavirin in Treatment-Naïve Genotype 1 Patients with Chronic Hepatitis C Infection.	Open/Follow Up
3	Bristol Myers S	AI444-038	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.	Open/Follow Up
4	Bristol Myers S	AI444-052	A Phase 3 Evaluation of BMS-790052 (Daclatasvir) Compared With Telaprevir In combination with Peg-Interferon Alfa-2a and Ribavirin in Treatment- Naïve Patients with Chronic Hepatitis-C	Open/ Follow Up
5	Bristol Myers S	AI443-1014	Open-Label, Multiple Dose, Dose Escalation Study to Evaluate the Pharmacodynamics, Pharmacokinetics, and Safety of Co administration of BMS-650032, BMS-7900052, and BMS-791325 when administered for 24 or 12 weeks in Treatment-Naïve Subjects Infected with Hepatitis C Virus Genotype 1	Open/Enrolling
5	Gilead	GS-US-337-0102	A Phase 3, Multicenter, Randomized, Open-Label Study to Investigate the Efficacy and Safety of Sofosbuvir /GS-5885 Fixed-Dose Combination + Ribavirin for 12 or 24 Weeks in Treatment-Naïve Subjects with Chronic HCV Genotype 1 Infection	Open/ On drug Treatment/FU
6	Gilead	GS-US-334-0110	A Phase 3, Multicenter, Open Label Study to Investigate the Efficacy and Safety of GS-7977 With Peginterferon Alfa 2a and Ribavirin for 12 Week in Treatment-Naïve Subjects with Chronic Genotype 1,4, 5, or 6 HCV Infection	Open/ Follow Up

7	Gilead	GS-US-248-0121	A Phase 2 Randomized, Open-Label, Exploratory Trial of GS-5885, GS-9451 with Peginterferon Alfa 2a (PEG) and Ribavirin (RBV) in Treatment-Naïve Subjects with Chronic Genotype 1 Hepatitis C Virus Infection and IL28B CC Genotype	Open/Follow UP
8	Gilead	GS-US-248-0122 (Registry Study)	A Long Term Follow Up Registry for Subjects Who Achieve a Sustained Virologic Response to Treatment in Gilead Sponsored Trials in Subjects with Chronic HepatitisC Infection	Open
9	Gilead	GS-US-248-0123 (Registry Study)	A Long Term Follow up Registry Study of Subjects Who Did Not Achieve Sustained Virologic Response in Gilead Sponsored Trials in Subjects with Chronic Hepatitis C	Open
10	Gilead	GS-US-256-0124	A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating Response Guided Therapy using Combinations of 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	Open/ subjects completed study.
11	Gilead	GS-US-196-0140	A Phase 2b, Randomized, Double-Blind, Placebo Controlled Trial Evaluating 16 and 24 Weeks of a Four-Drug Regimen and 24 Weeks of a Three-Drug Regimen of GS-9451, Peginterferon Alfa 2a (PEG, Pegasys®and Ribavirin (RBV, Copegus®) With and Without Tegobuvir (GS-9190) Followed by Response Guided PEG and RBV in Treatment Naïve Subjects with Chronic Genotype 1 Hepatitis C Virus Infection	Open/ Subjects finished Study.
12	Gilead	GS-US-256-0148	A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating Response Guided Therapy with GS 5885 Alone or in Combination with GS-9451 or GS-9256 with Peginterferon Alfa 2a and Ribavirin in Treatment Naïve Subjects with Chronic Genotype 1 Hepatitis C	Open/ Follow up 2 Subjects
13	Gilead	GS-US- 337-0109	A Phase 3, Randomized, Open-Label Study to Investigate the Efficacy and Safety of Sofosbuvir/GS-5885 Fixed Dose Combination <u>+</u> Ribavirin for 12 and 24 Weeks in Treatment-Experience Subjects with Chronic Genotype 1 HCV Infection	Open/ Screening
14	Gilead	P7977-1231	A Phase III 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 2or 3 HCV Infection	Open/ Follow Up
15	U. Florida/U. NC	HCV-TARGET	Hepatitis C Therapeutic Registry and Research Network- A Longitudinal, Observational Study	Open/ Ready for Screening
16	Beckman Coulter	HCV-01-11	Multicenter, Prospective Evaluation of the Beckman Coulter DxN-HCV Viral Load Assay as an Aid in the Management of HCV-Infected Individual Undergoing Antiviral	Open/Ready for Screening

17	Merck	5172-003	A Dose Ranging Study to Test the Safety, Tolerability and Effectiveness of Different Doses of MK-5172 When Given with Peginterferon alfa-2b and Ribavirin in Patients with Hepatitis C Virus Infection	Open/ Follow Up	
18	Merck	7009-028	A Phase 2 Open Label Study of MK 7009 Administered Concomitantly with Pegylated Interferon Alfa 2a and Ribavirin to Patients with Chronic Hepatitis C Infection After Participation in Other MK-7009 Clinical Trials	Open/ Follow Up	
19	Merck	5172-017 (Roll Over)	A Long Term Follow Up Study to Evaluate the Durability of Virologic Response and /or Viral Resistance Patterns of Subjects With Chronic Hepatitis C Who Have been Previously Treated with MK5172 in a Prior Clinical Trial	IRB Approved. Sponsor Site Activation.	
20	Novartis	CDEB025A2301	A Randomized Double Blind, Placebo- Controlled Trial of the Efficacy and Safety of DEB025/Alisporivir in Combination with Peginterferon alpha 2a (PEG-IFN) and Ribavirin in hepatitis C Genotype 1 treatment naïve patients.	Open/ Follow Up	
21	Novartis	CDEB025A2312 (Roll Over)	A Multi-Centre 3 Year Follow Up Study to assess the Durability of Sustained Virologic response in Alisporivir treated Chronic Hepatitis C patients	Open/ Follow Up	
22	Novartis	CDEB025A2313 (Roll Over)	A Multi-Centre 3 Year follow up study to assess the viral activity in patients Who failed to achieve sustained virologic response in Novartis sponsored Alisporivir –studies for chronic Hepatitis C patients	Open	
23	Schering-Plough	P05063	Term Follow Up of Subjects in a Phase 1,2,or 3 Clinical Trial in Which Boceprevir or Narlaprevir was administer red for the treatment of Chronic Hepatitis C Open		
24	Schering-Plough	P05514	A single Arm Study to Provide Boceprevir Treatment in Subjects with Chronic Hepatitis C Genotype 1 Deemed Nonresponders to Peginterferon/Ribavirin in PREVIOUS Schering-Plough Boceprevir Studies	Open/ Subjects Completed study	
25	Tibotec	TMC435-TiD16- C213	A Phase III Open Label Trial of TMC435 In Combination with Peginterferon And Ribavirin for HCV Genotype 1 infected Subjects who Participated in the placebo group of a Phase II/III TMC435 study (C201, C205, C206, C208, C216 or HPC3007) or who received short term (up to 14 days) direct acting antiviral treatment for hepatitis C infection in a selected Jansen R&D Ireland-Sponsored phase I Study.	Open	

26	Tibotec	TMC435-TidP16- C216	A Phase III, randomized, double-blind, placebo-controlled study to investigate the efficacy, safety and tolerability of TMC435 versus placebo as part of a treatment regimen including peginterferon α -2a (Pegasys®) and ribavirin (Copegus®) or peginterferon α -2b (PegIntron®) and ribavirin (Rebetol®) in treatment-naïve, genotype 1, hepatitis C-infected subjects.	Open/ Subjects Completed study
27	Tibotec	TMC435HPC3007	A Phase III, randomized, double-blind, placebo-controlled study to investigate the efficacy, safety and tolerability of TMC435 vs. placebo as part of a treatment regimen including peginterferon alfa-2a and ribavirin in hepatitis C, genotype 1 infected subjects who relapsed after previous interferon-based therapy. Open/ Sub Completed	
28	Tibotec	VX-950-C211	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-naïve subjects with genotype 1 chronic hepatitis C virus infection.	Open/Subjects Completed Study Close out visit on 1/31/13
29	Salix Pharmaceuticals, Inc.	RFHE4044	A Multicenter, Randomized, Open, Label, Active Controlled, Trial To Evaluate The Safety And Efficacy If Rifaximin 550 MG With and Without Lactulose In Subjects With A History Of Recurrent Overt Hepatic Encephalopathy	IRB Approved Waiting Site Activation.