CENTER FOR THE STUDY OF HEPATITIS C

A COOPERATIVE ENDEAVOR OF THE ROCKEFELLER UNIVERSITY, WEILL CORNELL MEDICAL COLLEGE AND NEWYORK-PRESBYTERIAN HOSPITAL

Weill Cornell Medical College — NewYork-Presbyterian Hospital / Weill Cornell Medical Center

Division of Gastroenterology and Hepatology

Currently Enrolling HCV Clinical Trials

Research study contact: 646-962- HepC (4372)

Sponsor	Description	Key Information
Merck	A Phase 1b Randomized Placebo-Controlled Clinical Trial to Study the Safety and Efficacy of MK-7009 in Hepatitis C Infected Patients	Genotype 1, Treatment Naïve, Stage ≤ 2, males age 18-55, study period 22 days with study drug/placebo for 7 days, compensation provided.
Novartis	A randomized, double-blind, placebo-controlled, multicenter, time-lagged, parallel, multiple-dose, escalating dose study to assess safety/tolerability, pharmacokinetic and pharmacodynamic profiles following administration of NIM811(cyclosporin analogs) in patients with viral hepatitis C genotype 1	Phase I, Genotype 1, Treatment relapser, Stage ≤ 3, age 18-69 males and females with non child bearing potential, study period is 14 days of study drug/placebo with pegylated interferon with the option to continue on pegylated interferon and ribavirin for up to 48 weeks, compensation provided.
Intarcia	Phase Ib Dose Escalation Study of the Safety, Tolerability, Pharmacokinetics and Antiviral Activity of Omega DUROS® (Implantable device to deliver Omega Interferon) and Ribavirin in Subjects with Chronic Hepatitis C Previously Treated with Pegylated Interferon and Ribavirin	Genotype 1, Relapsers to previous pegylated interferon and ribavirin, compensated cirrhosis allowed, age 18-65 males and females, study period 72 up to weeks.
Romark	Phase II, Randomized, Double-Blind, Placebo-Controlled Study Of Nitazoxanide In Combination With Peginterferon a-2a And Ribavirin In Treatment-Naïve Patients With Hepatitis C	Genotype 1, Treatment Naïve, male/female age ≥18, BMI < 34, no diabetes, Randomized to receive study drug/placebo with Pegasys and Copegus for study period of 48 weeks. Compensation provided.
Schering	A Phase 3 Safety and Efficacy Study of Boceprevir in Subjects With Chronic Hepatitis C Genotype 1 Who Failed Prior Treatment With Peginterferon/Ribavirin (P05101)	Genotype 1, Relapsers or partial responders (no null responders), male/female age ≥18, must have had at least 12 weeks of Pegylated Interferon and Ribavirin, must have had ≥ 2 log ↓ in HCV RNA by treatment week 12 or detectable HCV RNA after end of treatment. 20% chance of placebo, can rollover to active treatment at TW12 if not responding, treatment period 36-48 weeks, Methadone program patients okay.
Schering	Boceprevir in Previously Untreated Subjects with Chronic Hepatitis C Infected with Genotype 1. A Phase 3 Safety and Efficacy Study (P05216)	Genotype 1, Treatment Naïve (never received any treatment for HCV), males/females age ≥18, 20% chance of placebo, can Rollover to active treatment at TW24 if not responding. Treatment period 28-48 weeks, Methadone program patients okay.

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Currently Enrolling HBV Clinical Trials

Research study contact: 646-962- HepC (4372)

Sponsor	Description	Key Information
Pharmasset	A Multi-center, Randomized, Double-Blind, Active-Control, 96 Week, Phase III Trial of the Efficacy and Safety of Clevudine Compared with Adefovir at Weeks 48 and 96 in Nucleoside Treatment-Naive Patients with HBeAg Positive Chronic Hepatitis due to Hepatitis B Virus	HBeAG positive, persistent ALT elevation, HBV DNA > 100,000 copies/mL , Naive with no prior Nucleoside treatment, age ≥ 16, treatment duration up to 126 weeks.
Pharmasset	A Multi-center, Randomized, Double-Blind, Active-Control, 96 Week, Phase III Trial of the Efficacy and Safety of Clevudine Compared with Adefovir at Weeks 48 and 96 in Nucleoside Treatment-Naive Patients with HBeAg Negative Chronic Hepatitis due to Hepatitis B Virus	HBeAG negative, persistent ALT elevation, HBV DNA > 100,000 copies/mL , Naive with no prior Nucleoside treatment, age ≥ 16, treatment duration up to 126 weeks.