Viral Hepatitis Center

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http://www.hopkinsmedicine.org/Medicine/viralhep/research/clintrials.html

Enrolling Studies

Hepatitis C

GS-US-256-0148: Phase 2B

To evaluate the antiviral efficacy as measured by SVR of response guided therapy (RGT) with GS-5885 + GS-9451 + PEG/RBV, GS-5885 + GS-9256 + PEG/RBV or GS-5885 + PEG/RBV in **treatment naïve subjects with GT 1 chronic HCV**

Treatment	
1	RGT with GS-5885 30mg QD + GS-9451 200mg QD + GS-9256 placebo BID + PEG/RBV
2	RGT with GS-5885 10mg QD + GS-9256 125mg BID+GS-9451 placebo QD + PEG/RBV
3	RGT with GS-5885 30mg QD + GS-9256 placebo BID+GS-9451 placebo QD + PEG/RBV

Duration of therapy is based on patient response and randomization. There is the potential to stop therapy at week 12, 24, or 48

Key Inclusion:

- Male or female 18-70 with Chronic hepatitis C,Genotype1
- HCV RNA > 10,000 IU/mL at screening;
- Liver biopsy within 2 years; with no evidence of cirrhosis

Key Exclusion:

- No prior HCV treatment

Upcoming Studies

Hepatitis C

GS-US-256-124: Phase 2B

Expected to begin enrollment in one to two weeks

To evaluate antiviral efficacy as measured by SVR of response guided therapy (RGT) with GS-9451 + tegobuvir, GS-9451 + GS-5885, or GS-5885 + tegobuvir when treated **with PEG IFN alfa-2a and ribavirin (RBV) in GT 1treatment experienced (**non-responder, relapse, or breakthrough) subjects

Treatment	
1	RGT with GS-5885 placebo QD + GS-9451 200mg QD+ tegobuvir 30mg BID+ PEG/RBV
2	RGT with GS-5885 30mg QD +GS-9451 200mg QD+ tegobuvir placebo BID +PEG/RBV
3	RGT with GS-5885 30mg QD +GS-9451 placebo QD+ tegobuvir 30mg BID +PEG/RBV

Subjects who achieve eRVR are re-randomized (1:1) at week 24 to stop therapy or continue PEG/RBV

Key Inclusion:

- Male or female 18-70 with Chronic hepatitis C,Genotype1
- HCV RNA > 10,000 IU/mL at screening;
- Prior treatment and adherence (completing 80% of prescribed treatment) with PEG and RBV
- Liver biopsy within 3 years; with no evidence of cirrhosis

Key Exclusion:

- No prior treatment of oral HCV antiviral, exclusive of RBV

Upcoming Studies

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Hepatitis C

The Quantum Study (P2938-0721): Phase 2

Expected to begin enrollment in one to two weeks

450 **Treatment-naïve** patients will be stratified for HCV Genotype(**GT 1a versus 1b versus all other genotypes)**, baseline HCV RNA (< 6 log10IU/mL or ≥ 6 log10IU/mL), and the **presence of cirrhosis (present or absent)**, will initially be randomized in 2 consecutive cohorts to receive:

Treatment	
A	PSI-352938 for 12 weeks
B	PSI-352938 and PSI-7977 for 12 weeks
C	PSI 7977 and RBV for 12 weeks
D	PSI-352938 and PSI-7977 with RBV for 12 weeks
E	PSI-352938 for 24 weeks
F	PSI-352938 and PSI-7977 for 24 weeks
G	PSI-7977 and RBV for 24 weeks
H	PSI-352938 and PSI-7977 with RBV for 24 weeks
I	Deferred start (Placebo) for 24 weeks, then re-randomized to an active arm

Key Inclusion:

• Male or female18 years or older with documented chronic HCV

• Liver biopsy or Fibrosure testing (**cirrhosis included, capped at 10% of all patients randomized**)

• HCV RNA > 50,000 IU/mL at screening

•**Naïve to prior IFN based therapy, ribavirin, or any antiviral drug for acute or chronic HCV**

Key Exclusion:

• Co-infection with HIV or HBV

• Evidence of liver decompensation

• Clinically significant ECG findings

Upcoming Studies

Hepatitis C

GS-US-248-131: Phase 2

Expected to begin enrollment in one to two weeks

To evaluate the antiviral efficacy as measured by SVR of combination therapy with GS-5885, GS-9451, tegobuvir and RBV compared with GS-5885, GS-9451 and tegobuvir or

GS-5885, GS-9451 and RBV in **GT 1a or 1b treatment experienced (**non-responder, relapse, or breakthrough) subjects

Treatment	
1	GS-5885 90mg QD + GS-9451 200mg QD + tegobuvir 30mg BID + RBV BID
2	GS-5885 90mg QD + GS-9451 200mg QD + tegobuvir 30mg BID + RBV placebo BID
3	GS-5885 90mg QD + GS-9451 200mg QD + tegobuvir placebo BID + RBV BID

Subjects who achieve vRVR (HCV RNA < LOQ at week 2) will stop therapy at week 24

Key Inclusion:

• Male or female ≥18 years with Chronic hepatitis C,Genotype1

• HCV RNA > 10,000 IU/mL at screening

• Prior treatment and adherence with PEG and RBV

• Liver biopsy within 3 years; with no evidence of cirrhosis

Key Exclusion:

• No prior treatment of oral HCV antiviral (exclusive of RBV