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Hepatitis C Case Study 1

A Phase 1, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of Escalating, Multiple, Oral Doses of XXXX in Treatment Naïve Subjects with Chronic Genotype 1 Hepatitis C Virus Infection

Daniel Gruener, MD

Key Elements:
- 100% Retention
- Highest Enrolling Site
- Rapid start site

Phase: 1
First-in-Human Indication: Hepatitis C
Study Population: Treatment-naïve, chronically-infected HCV subjects
# of Subjects: 19 randomized and completed – highest enrolling of 13 total study sites, with 27% of total subjects

Cohorts: 6 unique dosing cohorts:
- Cohort 1: Genotype 1a
- Cohort 2: Genotype 1a
- Cohort 3: Genotype 1a
- Cohort 4: Genotype 1a
- Cohort 5: Genotype 1b
- Cohort 6: Genotype 1b

Study Duration: 5 months
In-patient Period: 5 days

Objectives
Primary
- To evaluate the safety and tolerability of escalating, multiple, oral doses of XXXX in subjects with chronic genotype 1 Hepatitis C Virus (HCV) infection.
- To evaluate the antiviral activity of XXXX against genotype 1 HCV following administration of multiple oral doses.

Secondary
- To characterize the plasma pharmacokinetics of XXXX following administration of escalating, multiple, oral doses in genotype 1 HCV-infected subjects.
- To assess the PK/PD relationship between HCV viral load change and XXXX plasma concentrations following multiple dose administration.
- To compare XXXX antiviral activity in genotype 1a versus 1b infections.
- To evaluate genotypic changes from baseline in the NS5A coding region of HCV following multiple dose administration of XXXX and for up to 48 weeks thereafter.

Lab Assessments - 95 per subject
Hematology, Serum Chemistry, Lipids
HBV, HCV, and HIV Serology
HCV Genotype
Prothrombin time/INR
Serial Plasma HCV RNA
Serial Pharmacokinetic Analysis
Plasma for Resistance Surveillance
IL28B Genotyping
Plasma/Serum for Storage

Safety Assessments - 10 per subject
Time point specific Vitals Signs and 12-Lead ECG