



Trek Therapeutics Initiates Phase 2a Study of Faldaprevir and TD-6450, With and Without Ribavirin, in Patients with HCV GT 1b.

Cambridge, MA (June 21, 2016) — Trek Therapeutics (TREKtx), a private, clinical stage public benefit corporation developing affordable and accessible treatment regimens for chronic hepatitis C virus (HCV) infections has initiated a Phase 2a study evaluating TD-6450 plus faldaprevir (FDV) with and without ribavirin (RBV) in patients with genotype 1b (GT 1b) HCV infection in New Zealand and the United States. The GT 1b study was initiated following TREKtx analysis of interim results from a Phase 2a study evaluating FDV plus TD-6450 and RBV in patients with HCV GT 4. In that 16-patient study, all patients achieved HCV RNA <15 IU/mL by treatment Week 3, and all patients with post-treatment data (10/16) have achieved a sustained viral response 4 weeks after the end of treatment (SRV4). Of the 5 patients who have completed post-treatment follow-up, all have SVR12. Six patients still on treatment have maintained HCV RNA <15 IU/mL. Final results for the GT 4 study will be analyzed later this year.

About TD-6450

TD-6450, a multivalent NS5A inhibitor licensed from Theravance Biopharma, Inc., was designed to have improved antiviral activity against genotype 1 resistance-associated variants (RAV) resistant to first generation NS5A inhibitors. TD-6450 has successfully completed Phase 1 studies in both healthy volunteers and HCV patients.

About Faldaprevir

FDV is a well-characterized HCV protease inhibitor licensed from Boehringer Ingelheim. Phase 3 studies evaluating FDV in combination with pegylated interferon and RBV have been completed.

About HCV

Hepatitis C is an infectious disease of the liver. Worldwide, 130-150 million people have chronic HCV infection and most are undiagnosed. Three quarters of people with chronic HCV infection will develop chronic liver disease. Development of affordable therapies for HCV is a global health priority. In the United States, chronic HCV infection is the leading cause of cirrhosis and liver cancer, and the most common reason for liver transplantation. Multiple highly effective, safe, and well-tolerated regimens have been developed for chronic HCV. The creation of these drugs sets the stage for a *Campaign to Eradicate HCV*. The accessibility of HCV treatment is limited by the low diagnosis rate and the high cost of drugs.

About Trek Therapeutics

[Trek Therapeutics](#), PBC is a private, clinical stage public benefit corporation developing treatments for serious infections. Its mission is to profitably develop affordable and accessible medicines to treat infectious diseases and to commercialize them for global populations.

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