Interim results from Trek Therapeutics' Phase 2 study show triple combination therapy achieves 100% SVR4 in genotype 4 HCV patients

Cambridge, MA (September 15, 2016)-- Trek Therapeutics (TREKtx), a private, clinical stage public benefit corporation developing affordable and accessible treatment regimens for serious infections, today announced the first results from an open-label Phase 2a study of faldaprevir (FDV) plus TD-6450 and ribavirin (RBV). The sustained viral response (SVR) rate four weeks after the completion of treatment (SVR4) was 100 percent (16 of 16) in treatment naïve patients with chronic genotype 4 (GT 4) hepatitis C virus (HCV) who received 120 mg of FDV and RBV in combination with 60 mg or 120 mg of TD-6450 for 12 weeks.

"The results of this study are very encouraging, and consistent with preliminary data from our ongoing Phase 2a study in patients with genotype 1b (GT 1b) HCV," said Robert Hindes, M.D., Chief Medical Officer at Trek Therapeutics. "Our goal is to develop regimens with the potential to play an important role in the treatment of hepatitis C in middle income countries where affordable and accessible treatments for HCV are not readily available."

About the Phase 2a Study
The results announced today are from an open-label Phase 2a study that evaluated two doses of TD-6450, 60 mg or 120 mg QD, in combination with FDV 120 mg QD and RBV for 12 weeks in non-cirrhotic treatment-naïve patients with chronic GT 4 HCV. In this study, there were no serious adverse events or treatment discontinuations, and the majority of adverse events were mild. The most common adverse events observed in greater than 10 percent of patients across the study were fatigue, headache, and nausea. Efficacy results for the two arms of the study were similar, and are combined in the summary below:

One hundred percent (100%, 16/16) of patients had HCV RNA below the lower limit of quantitation (<LLOQ, 15 IU/mL) after 3 weeks of treatment, and all 16 patients achieved SVR 4. To date, the 11 patients who have been followed for 12 weeks post-treatment have all achieved a sustained viral response (SVR12). No patients have experienced virologic breakthrough or relapse. Trek Therapeutics is currently conducting studies evaluating FDV plus TD-6450 with and without RBV in patients with GT 1b HCV in New Zealand and the United States. Phase 2b studies are planned in 2017.

About Faldaprevir
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 TD-6450
TD-6450 is a multivalent NS5A inhibitor licensed from Theravance Biopharma, Inc.

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. TREKtx is currently conducting Phase 2 clinical trials in patients with chronic HCV infection using a combination of direct acting antivirals, and is also evaluating treatments for other infectious diseases. For further information, please visit www.trektx.com.

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