

The Lancet Infectious Diseases Journal Publishes Results of Phase 2 Study of Lonafarnib in Hepatitis Delta Virus (HDV) Infected Patients

Palo Alto, Calif., July 20, 2015 / PRNewswire/ — Eiger BioPharmaceuticals Incorporated announced today the publication of results of the first Phase 2a study of lonafarnib in patients with chronic hepatitis delta virus (HDV) infection. The study was conducted at the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland. The double-blinded, randomized, placebo-controlled, dose ascending study evaluated two doses of lonafarnib, 100 mg twice daily and 200 mg twice daily for 28 days.

“The NIH Clinical Center has completed a study with significant implications for treatment of chronic hepatitis D, which often leads to cirrhosis and other life-threatening conditions,” said Theo Heller, MD, a Principal Investigator at the National Institute of Diabetes and Digestive and Kidney Diseases, part of the NIH. “We are proud to have the results of this study published in The Lancet Infectious Diseases.”

A decrease in HDV RNA viral levels was observed after treatment with lonafarnib for 28 days compared with placebo, including a statistically significant dose-dependent difference in decline in HDV RNA virus between the 100 mg twice daily and 200 mg twice daily doses compared with placebo ($p = 0.03$ and <0.0001 , respectively). The decline in HDV RNA viral levels significantly correlated with serum lonafarnib drug levels, providing further evidence for the antiviral activity of lonafarnib in chronic HDV. In the study, lonafarnib was generally well tolerated, with the most common adverse events in the treatment group being gastrointestinal related.

“This is the first study evaluating lonafarnib, an oral therapy, in patients infected with HDV, and we are very pleased with the results,” said David Cory, President and Chief Executive Officer of Eiger. “HDV is the most severe form of human viral hepatitis. Our goal is cure.”

About Lonafarnib

Lonafarnib is a well-characterized, late-stage, orally active inhibitor of farnesyl transferase, an enzyme involved in modification of proteins through a process called prenylation. HDV uses this host cell process inside liver cells to complete a key step in its life cycle. Lonafarnib inhibits the prenylation step of HDV replication inside liver cells and blocks the virus life cycle at the stage of assembly. Since prenylation is carried out by a host enzyme, there is a theoretical higher barrier to develop viral resistance mutations to lonafarnib therapy. Lonafarnib has been granted Orphan Drug Designation by the US FDA and European Medicines Agency (EMA), and Fast Track Designation by US FDA. Lonafarnib is not approved for any indication. Lonafarnib is licensed from Merck Sharpe & Dohme Corp. (known as MSD outside of the United States and Canada).

About Hepatitis Delta

Hepatitis Delta is caused by infection with the hepatitis delta virus (HDV) and is considered to be the most severe form of viral hepatitis in humans. Hepatitis D occurs only as a co-infection in individuals harboring hepatitis B (HBV). Hepatitis D leads to more severe liver disease than HBV alone and is associated with accelerated liver fibrosis, liver cancer, and liver failure. Hepatitis D is a disease with a significant impact on global health affecting ~15 million people worldwide. The prevalence of HDV varies between different parts of the world. Globally, HDV infection is reported to be 5-6% of chronic hepatitis B carriers. In some parts of the world, including certain areas of China, Mongolia, Russia, Central Asia, Turkey, Africa, and South America, HDV prevalence as high as 70% has been reported in HBV infected patients.

About Eiger

Eiger is a privately held biotechnology company focused on the research, development and commercialization of innovative therapies in viral hepatitis. The company is focused on developing lonafarnib for the treatment of hepatitis delta virus (HDV), the most severe form of viral hepatitis. For additional information about Eiger and its R&D pipeline, please visit www.eigerbio.com.



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