

Eiger Bio Announces Positive Data in Patients Infected with Hepatitis Delta Virus (HDV) Treated with Lonafarnib – Results Presented at American Association for the Study of Liver Diseases (AASLD) Meeting

Palo Alto, Calif., December 22, 2014 /PRNewswire/ -- Eiger BioPharmaceuticals Incorporated announced the positive results of a 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. “This proof-of-concept study is the first ever to evaluate lonafarnib, the first of a class of novel antiviral agents known as prenylation inhibitors, in patients infected with HDV”, said David Cory, President and Chief Executive Officer of Eiger. “Hepatitis Delta is the most severe form of human viral hepatitis and a therapy is sorely needed.”

A significant 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. The decline in HDV RNA viral levels significantly correlated with serum lonafarnib drug levels, providing further evidence for the efficacy 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. “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 NIH. “We look forward to continued collaboration to potentially deliver an approved therapy to patients.”

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 ability of the virus to multiply. Since prenylation is a host process, not under control of HDV, and lonafarnib inhibits prenylation, there is also a theoretical higher barrier to resistance with lonafarnib therapy. Virus mutation, a common pathway to drug resistance, is not expected to be a potential pathway to lonafarnib resistance by HDV.

Lonafarnib is not approved for sale for any indication.

About Hepatitis Delta

Hepatitis Delta is caused by infection with the hepatitis D 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 with hepatitis B (HBV), leads to more severe liver disease than HBV alone, and is associated with accelerated liver fibrosis, liver cancer, and liver failure. HDV 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. HDV meets criteria for Orphan Designation in the United States (less than 200,000 people), Europe (less than 5 in 100,000 people), and Japan (less than 50,000 people). Globally, HDV infection is reported to be present in approximately 4% - 6% of chronic hepatitis B carriers. In some parts of the world, including certain areas of China, Russia, Central Asia, Turkey, Africa, and South America, prevalence as high as 40% 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. Lonafarnib is not approved for sale. Eiger's research programs are focused on the discovery of targeted, small-molecule therapeutics and biomarkers to treat and monitor serious liver diseases. For additional information about Eiger and its R&D pipeline, please visit www.eigerbio.com.



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