

Eiger Bio Receives Orphan Designation for Lonafarnib, a First In Class, Investigational Treatment for Hepatitis Delta Virus (HDV) Infection

Palo Alto, Calif., December 22, 2014 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. today announced that lonafarnib has been granted Orphan Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). The U.S. Orphan Drug Act (ODA) provides for granting special status to a drug or biological product ("drug") to treat a rare disease or condition. Orphan Designation qualifies the sponsor of the drug for various development incentives. Orphan designation also provides for a period of market exclusivity or protection against generic entry. Lonafarnib is a first in class, investigational treatment for patients infected with hepatitis delta virus (HDV).

"We are committed to developing a therapy for the most insidious form of viral hepatitis, Hepatitis Delta, particularly as no FDA-approved therapies are currently available," said David Cory, President and Chief Executive Officer of Eiger. "We are pleased that the FDA and EMA have granted Orphan Designation to lonafarnib as a first in class, potential new therapy for HDV, a disease with great unmet medical need."

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 HDV

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.



SOURCE Eiger Bio, Inc.

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