FDA Grants Fast Track Designation to Eiger Bio's Lonafarnib for Hepatitis Delta Virus (HDV) Infection

PALO ALTO, Calif., April 20, 2015 /PRNewswire/ -- Eiger BioPharmaceuticals, Incorporated today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its lead product candidate, lonafarnib, in combination with ritonavir for treatment of hepatitis delta virus (HDV) infection. Lonafarnib is currently in Phase 2 clinical trials for this indication.

The FDA grants Fast Track status to facilitate the development of drugs intended to treat serious or life-threatening conditions and which demonstrate the potential to address unmet medical needs. Interim results of the **LO**nafarnib **W**ith **R**itonavir (LOWR – 1 and LOWR – 2) studies will be presented publicly for the first time this week at the European Association for the Study of the Liver (EASL) meeting in Vienna, Austria.

"We are very pleased to receive Fast Track designation for lonafarnib to address a serious unmet medical need. It provides us with an outstanding opportunity to expeditiously develop lonafarnib for HDV infection," said Joanne Quan, MD, Chief Medical Officer. "The granting of Fast Track status is an important achievement that can facilitate accelerated review of an NDA submission based on the expected data from our development program with the goal of bringing the first approved treatment to HDV patients as quickly as possible."

About Lonafarnib
Lonafarnib is a well-characterized, late stage, orally active agent targeting farnesyltransferase, an enzyme involved in modification of proteins through a process called prenylation. HDV uses this host cellular 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 carried out by a host enzyme there is also a theoretical higher barrier to develop viral resistance mutations with lonafarnib therapy.

Lonafarnib has been granted Orphan Drug Designation by the US FDA and the European Medicines Agency (EMA). Lonafarnib is an investigational product and its safety and efficacy have not yet been established 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. 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, 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 for orphan diseases. The company's lead program 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, please visit www.eigerbio.com.

EIGER
Leader in HDV

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