Eiger Bio Announces Interim Results of Lonafarnib in Combination with Ritonavir or Pegylated Interferon in Patients Infected with Hepatitis Delta Virus (HDV)

– Results Presented at European Association for the Study of the Liver (EASL) Meeting in Vienna, Austria

PALO ALTO, Calif., April 27, 2015 /PRNewswire/ -- Eiger BioPharmaceuticals, Incorporated today announced the presentation of interim results of Phase 2 data of lonafarnib in patients with chronic hepatitis delta viral (HDV) infection. Data were presented from the LOWR HDV program, enrolled at Ankara University Medical School, Turkey, in a country where HDV is endemic.

LOWR HDV - 1 (**LO**nafarnib **W**ith and without **R**itonavir-1) is a parallel dose comparison study which randomized subjects to receive different doses of lonafarnib with or without ritonavir or pegylated interferon for four to twelve weeks. Interim data from 15 subjects who received lonafarnib alone or with ritonavir boosting or in combination with pegylated interferon all led to decreased viral loads. High doses (200 mg twice daily or 300 mg twice daily) of lonafarnib resulted in 1.6 and 2.0 log decline in viral loads after 4 weeks of treatment, respectively. A lower dose of lonafarnib (100 mg twice daily) with 100 mg daily ritonavir boosting or in combination with 180 mcg once weekly of pegylated interferon resulted in a 2.2 and a 1.8 log decline in viral load at week 4, respectively. At week 8, the mean viral load declines were 3.2 and 3.0 logs for subjects on lonafarnib with ritonavir or lonafarnib with pegylated interferon, respectively.

The most frequently observed adverse events in LOWR-1 were anorexia, nausea, diarrhea, fatigue, and weight loss, and these appeared to be dose-dependent.

LOWR HDV - 2 (**LO**nafarnib **W**ith **R**itonavir-2) was recently initiated to test a range of doses of lonafarnib boosted by ritonavir, with the aim to identify optimal combination(s) for the next longer-term studies.

"The data generated thus far investigating lonafarnib combinations are very encouraging," said Cihan Yurdaydin, MD, Principal Investigator, Ankara University Medical School. "We continue to conduct dose finding with lonafarnib boosted by ritonavir to identify the optimal balance of efficacy and tolerability, with a goal of viral clearance."

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 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 the European Medicines Agency (EMA), and Fast Track designation by US FDA. Lonafarnib is an investigational product and its safety and efficacy have not yet been established for any indication. Lonafarnib is licensed from Merck Sharp & Dohme Corp. (known as MSD outside the United States and Canada).

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 harboring hepatitis B virus (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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Leader in HDV

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