Eiger Announces Completion of Dosing in Phase 2 LOWR HDV – 4 Study at Hannover Medical School

PALO ALTO, Calif., September 7, 2016 /PR Newswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a clinical-stage biopharmaceutical company focused on the development and commercialization of targeted therapies for rare diseases, today announced the completion of dosing of LOWR HDV – 4 (LOnafarnib With Ritonavir in Hepatitis Delta Virus – 4) at Hannover Medical School in Hannover, Germany. LOWR HDV – 4 is a 15 patient, 24-week open-label study designed to evaluate the efficacy and tolerability of lonafarnib combined with ritonavir administered twice daily, and includes the option of dose escalation at the discretion of the investigator.

“We are very pleased to conduct our first study with lonafarnib combined with ritonavir in HDV-infected patients,” said Heiner Wedemeyer, MD, Research Group Leader in the Department of Gastroenterology, Hepatology and Endocrinology at Hannover Medical School. “Many drugs are dose-escalated or titrated to allow patients to acclimate to therapy and optimize treatment. The LOWR HDV - 4 protocol enabled us to investigate lonafarnib in combination with ritonavir in HDV-infected patients with dose escalation or titration at pre-specified times during the 24-week dosing period to assess the potential of this treatment approach.”

“Hepatitis delta causes the most aggressive form of human viral hepatitis, with fast progression to cirrhosis and other life-threatening complications, and there is no approved treatment,” said Eduardo Martins, MD, DPhil, Senior Vice President of Liver and Infectious Diseases Drug Development at Eiger BioPharmaceuticals. “As part of the Phase 2 LOWR HDV program, including LOWR HDV – 2, – 3, – 4 studies, the LOWR HDV – 4 study was designed to help elucidate the antiviral potential of lonafarnib in combination with ritonavir with dose escalation. We look forward to analysis and presentation of results in conjunction with the entire LOWR HDV program.”

About Sarasar® (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, this compound may present a higher barrier to development of viral resistance mutations during therapy. Lonafarnib has been dosed in over 100 HDV-infected patients across international research centers and is in Phase 2 development for HDV. 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, and is licensed from Merck Sharp & Dohme Corp. (known as MSD outside of the United States and Canada).

About Hepatitis Delta Virus (HDV)

Hepatitis Delta (or Hepatitis D) is caused by infection with HDV and is considered to be one of the most severe forms 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, and due to migration, may affect up to approximately 15 million people worldwide. The prevalence of HDV varies among different parts of the world. Globally, HDV infection is reported to be present in approximately 5-6% of chronic Hepatitis B carriers. The prevalence of HDV in patients infected with chronic HBV is even higher in certain regions, including certain parts of Mongolia, China, Russia, Central Asia, Pakistan, Turkey, Africa, and South America, with an HDV prevalence as high as 60% being reported in HBV-infected patients in Mongolia and Pakistan.

About Eiger

Eiger is a clinical-stage biopharmaceutical company committed to bringing to market novel products for the treatment of rare diseases. The company has built a diverse portfolio of well-characterized product candidates with the potential to address diseases for which the unmet medical need is high, the biology for treatment is clear, and for which an effective therapy is urgently needed.

Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding our strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives, intentions, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “project,” “target,” “will” and other words and terms of similar meaning. Examples of such statements include, but are not limited to, whether or not pegylated interferon lambda-1a or lonafarnib or ubenimex or exendin (9-39) may be further developed and approved, statements relating to the availability of cash for Eiger’s future operations, Eiger’s ability to develop its drug candidates for potential commercialization, the timing of the commencement and number and completion of Phase 2 trials and whether the products can be successfully developed or commercialized. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including the risks described in the “Risk Factors” sections in the

Annual Report on Form 10-K for the period ended December 31, 2015 and Eiger's periodic reports filed with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.

SOURCE Eiger Bio, Inc.

Investors: Jim Shaffer, Eiger Bio, Inc., 919-345-4256, jshaffer@eigerbio.com