Eiger Announces Abstracts and Presentations of LOWR HDV Program at the European Association for the Study of the Liver (EASL) Meeting

PALO ALTO, Calif., April 6, 2017 -- Eiger BioPharmaceuticals, Inc., (NASDAQ: EIGR) today announced that abstracts from its LOWR HDV (Lonafarnib With Ritonavir in Hepatitis Delta Virus) Program will be presented at the European Association for the Study of the Liver (EASL) meeting in Amsterdam, Netherlands, April 19 to 23, 2017. Forty-eight week data from the Phase 2 LOWR HDV Program will be presented.

Accepted EASL abstracts are listed below:

- Wedemeyer, H. et al; “A Phase 2 Dose-Escalation Study of Lonafarnib Plus Ritonavir in Patients With Chronic Hepatitis D: Final Results from The Lonafarnib With Ritonavir in HDV-4 (LOWR HDV-4) Study”; Abstract #PS-039, Oral Presentation, April 20, 4:00 pm – 4:15 pm, Forum.

- Yurdaydin, C. et al; “A Phase 2 Dose-Optimization Study of Lonafarnib with Ritonavir for the Treatment of Chronic Delta Hepatitis—End of Treatment Results from the LOWR HDV-2 Study”; Abstract #GS-008, Oral Presentation, April 21, 8:45 am – 9:00 am, Hall 5.

- Koh, C. et al; “Phase 2 study exploring once daily dosing of ritonavir boosted lonafarnib for the treatment of chronic delta hepatitis – end of study results from the LOWR HDV-3 study”; Abstract #LBP-519, Poster Presentation, April 20-22, 8:00 pm – 6:00 pm, Hall 1.

- Yurdaydin, C. et al; “The Prenylation Inhibitor Lonafarnib (LNF) Can Induce Post-Treatment Viral Clearance in Patients with Chronic Delta Hepatitis (CDH) Resulting in ALT Normalization and Regression of Fibrosis”; Abstract #THU-161, Poster Presentation, April 20, 8:00 pm – 6:00 pm, Hall 1; Oral ePoster Presentation, April 20, 1:00 pm – 2:00 pm, Booth 2, Hall 1.

Other HDV events during EASL:

- 13th Hepatitis Delta International Network (HDIN) Meeting – April 19, 5:30 pm - 8:00 pm
  Yurdaydin, C. et al; “Results from Retreatment of a Subset of Patients with Lonafarnib”; Oral Presentation, 7:30 pm – 7:40 pm, Room D201+D202.
LOWR HDV Studies:

- LOWR HDV – 2 is a dose-finding study to identify combination regimens of lonafarnib and ritonavir ± PEG-IFN-α, with efficacy and tolerability for longer term dosing to enable HDV RNA clearance. In this open-label study, 58 HDV-infected patients have been enrolled to date into 10 groups of different doses of lonafarnib in combination with ritonavir ± PEG-IFN-α for dosing durations of 12 to 48 weeks. Lonafarnib doses range from 25 mg bid to 100 mg bid. LOWR HDV – 2 is being closed at Ankara University in Ankara, Turkey.

- LOWR HDV – 3 is a double-blinded, randomized, placebo-controlled study designed to evaluate the efficacy and tolerability of once-daily doses of lonafarnib – 50 mg, 75 mg and 100 mg – each combined with ritonavir 100 mg once daily for 12 or 24 weeks. Twenty-one patients with chronic hepatitis delta were randomized into one of six treatment groups. LOWR HDV – 3 was conducted at the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland, and the study has completed.

- LOWR HDV – 4 is an open-label study to evaluate the efficacy and tolerability of dose escalation of lonafarnib combined with ritonavir administered twice daily for dosing durations of 24 weeks. Fifteen patients were initiated at lonafarnib 50 mg and ritonavir 100 mg twice daily, and dose-escalated up to lonafarnib 100 mg twice daily as tolerated. LOWR HDV – 4 was conducted at Hannover Medical School in Hannover, Germany, and the study has completed.

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. Lonafarnib has been dosed in over 120 HDV-infected patients across international academic centers and is in Phase 2 development for HDV. Lonafarnib has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), and Fast Track Designation by U.S. 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 delta occurs only as a co-infection in individuals harboring Hepatitis B Virus (HBV). Hepatitis delta leads to more severe liver disease than HBV alone and is associated with accelerated liver fibrosis, liver cancer, and liver failure. Hepatitis delta is a disease with a significant impact on global health, which may affect up to approximately 15-20 million people worldwide. The prevalence of HDV varies among different parts of the world. Globally, HDV infection is reported to be present in approximately 4.3% to 5.7% 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.

Investors: Ingrid Choong, Eiger Bio, 650-619-6115, ichoong@eigerbio.com