



Eiger Announces Sub-Analysis of Phase 2 Results Demonstrating High Response Rates to "All-Oral" Lonafarnib-Ritonavir Regimen in Low Viral Load HDV-Infected Patients at The International Liver Congress™ 2018

PALO ALTO, Calif., April 17, 2018 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc., (NASDAQ: EIGR) today announced additional positive lonafarnib (LNF) data from the LOWR HDV (Lonafarnib With Ritonavir in Hepatitis Delta Virus) Program presented at The International Liver Congress™ 2018, in Paris, France. A subanalysis of the LOWR-2 study reveals high response rates to LNF all-oral therapy in patients with low baseline viral loads ≤ 4 logs. After 24 weeks of treatment, all-oral lonafarnib-based regimens (LNF 50 mg BID + Ritonavir, or RTV) suppressed HDV-RNA below the limit of quantitation (BLQ) in 100% of patients with low baseline viral loads ≤ 4 logs. In addition, HDV-infected patients with high baseline viral loads > 4 logs responded well to combination therapy of LNF + RTV + PEG IFN-a-2a, where 50% were BLQ and 88% achieved ≥ 2 log decline at Week 24.

"This new sub-analysis demonstrates high response rates with all-oral lonafarnib / ritonavir therapy in HDV-infected patients with baseline viral loads ≤ 4 logs. Our data indicate that this will be relevant in approximately 30% of HDV-infected patients who present with this low baseline viral load profile," said David Apelian, MD, PhD, MBA, Chief Operating Officer and Executive Medical Officer at Eiger. "In addition, we have demonstrated good response rates in patients with higher baseline viral loads > 4 logs with the addition of pegylated interferon-alfa to lonafarnib / ritonavir therapy. We are focused on developing the first approved therapy for HDV-infected patients with multiple lonafarnib-based regimens to provide options for practitioners and patients."

About LOWR-2

LOWR HDV – 2 was a dose-finding study to identify combination regimens of lonafarnib and ritonavir \pm 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 were enrolled to date into 10 groups of different doses of lonafarnib in combination with ritonavir \pm 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 was conducted at Ankara University in Ankara, Turkey, and this study has completed.

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 virus life cycle at the stage of assembly. Lonafarnib has been dosed in over 120 HDV-infected patients across international academic centers and has completed Phase 2 development for HDV. Our lead program in Hepatitis Delta Virus (HDV) infection, is moving into Phase 3 with a single, pivotal trial planned to initiate by the end of the year. 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 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, Middle East 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 focused on the development and commercialization of targeted therapies for rare diseases. We are committed to translational innovation and the development of well-characterized drugs acting on newly identified or novel targets. Our mission is to systematically reduce the time and cost of the drug development process to more rapidly deliver important medicines to patients with rare diseases. Our lead program in Hepatitis Delta Virus (HDV) infection, is moving into Phase 3 with a single, pivotal trial planned to initiate by the end of the year. For additional information about Eiger and its clinical programs, please visit www.eigerbio.com.

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, including statements regarding our future financial condition, timing for and outcomes of clinical results, business strategy and plans and objectives for future operations, are forward looking statements. These forward-looking statements include terminology such as "believe," "will," "may," "estimate," "continue," "anticipate," "contemplate," "intend," "target," "project," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms. Forward looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned clinical development, the timing of and our ability to initiate or enroll clinical trials, and our ability to make regulatory filings and obtain and maintain regulatory approvals for lonafarnib, ubenimex, PEG IFN lambda, exendin 9-39 and our other product candidates, our intellectual property position, the potential safety, efficacy, reimbursement, convenience clinical and pharmaco-economic benefits of our product candidates, commercial opportunities, including potential market sizes and segments, our ability to commercialize, expectations regarding clinical trial data and FDA outcomes, including whether we will be able to reach agreement on a single pivotal study for lonafarnib and the nature and scope of any such study to support approval, our results of operations, cash needs, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

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 year ended December 31, 2017 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.

Investors: Ingrid Choong, PhD

Email: ichoong@eigerbio.com

Phone: 1-650-619-6115

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