

Eiger BioPharmaceuticals Announces Positive Phase 2 LIMT Study End of Treatment Data with Pegylated Interferon Lambda Monotherapy in Hepatitis Delta Virus (HDV) Infection

- **Lambda Antiviral Activity Demonstrated in HDV Infection**
- **Currently Dosing Lambda in Combination with Lonafarnib in HDV Infection**

PALO ALTO, Calif., October 17, 2018 -- Eiger BioPharmaceuticals, Inc., (NASDAQ: EIGR) today announced positive data with Pegylated Interferon Lambda (Lambda) in the Phase 2 LIMT HDV (Lambda Interferon MonoTherapy in Hepatitis Delta Virus) Study. LIMT HDV enrolled a total of 33 patients, randomized to Lambda 180 µg (N=16) or Lambda 120 µg (N=17), respectively, with weekly subcutaneous injections for 48 weeks in patients with chronic HDV. Lambda is a first in class, type III interferon, in development for the treatment of HDV.

At Week 48, patients in the 180 µg Lambda treated group experienced a -2.4 log₁₀ mean decline in HDV-RNA, with 6 of 10 (60%) experiencing ≥2 log₁₀ decline, 4 of 10 (40%) patients were HDV-RNA negative at end of treatment. At Week 48, patients in the 120 µg Lambda treated group experienced a -1.5 log₁₀ mean decline in HDV RNA, with 6 of 14 (42.9%) experiencing ≥2 log₁₀ decline, 2 of 14 (14.3%) patients were HDV-RNA negative at end of treatment. The most common adverse events included mild to moderate flu-like symptoms and elevated transaminase levels.

“Lambda interferon demonstrated better tolerability in HDV-infected patients who were previously treated with Alfa interferon,” said LIMT HDV Study Co-Lead Investigators, Ohad Etzion, MD, Director in the Department of Gastroenterology and Liver Diseases at Soroka University Medical Center and Saeed Hamid, MD, Chairman and Professor in Section of Gastroenterology, Department of Medicine, Aga Khan University. “Fewer episodes of cytopenia, flu-like symptoms, and psychiatric events in this study make Lambda interferon particularly attractive for further development as a monotherapy or in combination with other treatments for HDV.”

“Lambda is the second proprietary product in the Eiger pipeline for development as a monotherapy or combination therapy in HDV,” said David Apelian, COO and Executive Medical Officer at Eiger. “Lambda is now dosing in combination with Lonafarnib boosted with Ritonavir in HDV-infected patients in the Phase 2 LIFT study at the National Institutes of Health (NIH). We look forward to end of treatment data from this proprietary Lambda-Lonafarnib combination in 2019.”

The company plans to share additional details from the Lambda LIMT study at the following AASLD 2018 events in San Francisco in November:

- *Liver Institute and Foundation for Education and Research (L.I.F.E.R.) Meeting: The Search for HBV/HDV Cure: Challenges for Industry; “Eiger Phase 3 HDV Lonafernib ‘D-LIVR’ Study and Phase 2 HDV Lambda ‘LIFT’ Study,” November 9*
- *Eiger Phase 3 D-LIVR Study Investigator Reception, November 9*
- *Hepatitis Delta International Network (HDIN) Meeting; “HDV Program Update: Lonafernib Boosted with Ritonavir and Pegylated Interferon Lambda”; November 10*

About Pegylated Interferon Lambda (Lambda)

Lambda is a well-characterized, late-stage, first in class, type III interferon (IFN) that stimulates immune responses that are critical for the development of host protection during viral infections. Lambda targets type III IFN receptors which are distinct from the type I IFN receptors targeted by IFN alfa. These type III receptors are highly expressed on hepatocytes with limited expression on hematopoietic and central nervous system cells, which reduce off-target effects and improve tolerability of Lambda. Although Lambda does not use the IFN alfa receptor, signaling through either the IFN Lambda or IFN alfa receptor complexes results in the activation of the same Jak-STAT signal transduction cascade.

Eiger licensed worldwide rights to Lambda from Bristol-Myers Squibb in April 2016. Lambda has been administered in HBV / HCV clinical trials involving over 3,000 subjects. Lambda has not been approved for any indication. Eiger has received Orphan Designation and Fast Track Designation for Lambda in HDV.

About LIMT (Lambda Monotherapy) Study

LIMT HDV is a 1:1 randomized, open-label study of Lambda 120 or 180 µg subcutaneous injections administered weekly for 48 weeks in 33 patients with chronic HDV. End of treatment will be followed by a treatment-free 24-week observation period. The primary objective of the Phase 2 study is to evaluate the safety, tolerability, and efficacy of treatment with two dose levels of Lambda monotherapy in patients with chronic HDV infection. All patients are administered an anti-hepatitis B virus nucleos(t)ide analog throughout the study. LIMT HDV is an international study with sites in New Zealand, Israel and Pakistan.

About LIFT (Lambda Combo Therapy) Study

LIFT (Lambda InterFeron combo-Therapy) is an open-label, Phase 2 study evaluating Lambda + LNF + RTV in approximately 26 HDV-infected patients. Patients will be dosed for 24 weeks + undergo follow up for 24 weeks. Primary endpoint will be ≥ 2 log decline in HDV RNA at end of treatment. Secondary endpoints will include histology (> 2 point improvement in histological activity index and no progression in fibrosis) at end of treatment. LIFT is being conducted

within the National Institutes of Health (NIH) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

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. There is no approved therapy for HDV infection.

About Eiger

Eiger is a clinical-stage biopharmaceutical company focused on the accelerated development and commercialization of targeted therapies for rare and ultra-rare diseases. We innovate by developing well-characterized drugs acting on newly identified or novel targets in rare diseases. Our mission is to systematically reduce the time and cost of the drug development process to more rapidly deliver important medicines to patients. Lonafarnib is our lead compound advancing into Phase 3 with a single, pivotal trial to treat HDV to initiate by the end of the year. Lonafarnib is also advancing toward an NDA for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) in 2019. 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, including whether the D-LIVR study will be successful as a single, pivotal study to support registration; the timing of and our ability to initiate or enroll clinical trials, including

whether our D-LIVR study can be advanced by the end of this year; the timing for completion and potential filing for registration for our clinical candidates; whether lambda interferon will be further developed as monotherapy in HDV; whether PREVENT Phase 2 study results of avexitide will be repeated in larger, more advanced clinical trials and the timing and costs of such trials; our ability to make timely regulatory filings and obtain and maintain regulatory approvals for lonafarnib as a single agent or in combination, ubenimex, PEG IFN lambda, avexitide and our other product candidates; our intellectual property position; and the potential safety, efficacy, reimbursement, convenience clinical and pharmaco-economic benefits of our product candidates as well as the commercial opportunities, including potential market sizes and segments; our ability to finance the continued advancement of our development pipeline products, including our results of operations, cash available, financial condition, liquidity, prospects, growth and strategies; and the potential for success of any of our product candidates.

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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 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 BioPharmaceuticals, Inc.

Investors: Ingrid Choong, PhD

Phone: 650-619-6115

Email: ichoong@eigerbio.com