# Eiger Announces Case Studies Demonstrating Regression of Liver Fibrosis Following 48 Weeks of Therapy with Peginterferon Lambda in Patients with Chronic Hepatitis Delta Virus (HDV) Infection Presented at The Liver Meeting Digital Experience™ 2020

Palo Alto, Calif., November 16, 2020 / PRNewswire / — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of first-in-class therapies for serious rare and ultra-rare diseases, today announced a poster presentation of two case studies from the completed Phase 2 LIMT (Lambda Interferon MonoTherapy in HDV) trial at The Liver Meeting Digital Experience™ 2020. Peginterferon lambda (Lambda) is a first-in-class type III interferon in development for hepatitis delta virus (HDV) infection, the most severe form of human viral hepatitis.

The LIMT study enrolled a total of 33 patients with chronic HDV, randomized to monotherapy Lambda 180 µg (N=14) or Lambda 120 µg (N=19), weekly subcutaneous injections for 48 weeks (EOT) with 24 weeks of follow-up (EOFU). Recently, administration of Lambda for 48 weeks was shown to induce a durable virologic response (HDV RNA below limit of quantification at 24 weeks post-treatment) in 36% of patients with HDV and compensated liver disease. Impact of Lambda therapy on liver histology was not assessed in the LIMT study.

Two patients who had liver biopsies prior to participation (pre-treatment) in the LIMT study, were re-biopsied 18 months after the last Lambda injection (post-treatment). Liver biopsies were staged according to the ISHAK scoring system, ranging from F0 (no fibrosis) to F6 (cirrhosis) and evaluated.

- Patient 1: a 64-year-old male, HDV RNA level was 3.7 $\log_{10}$ at baseline, became HDV RNA undetectable at Lambda EOT with rebound to 2.6 $\log_{10}$ at EOFU. ALT was 169 U/L, declined to 55 U/L at EOT and remained at 54 U/L at EOFU. A reduction in liver fibrosis score from F5 (incomplete cirrhosis) to F1 (mild portal fibrosis) was observed.
- Patient 2: a 37-year-old female, HDV RNA level was 4.9 $\log_{10}$ at baseline, became HDV RNA undetectable at Lambda EOT with rebound to 3.6 $\log_{10}$ at EOFU. ALT was 159 U/L, declined to 44 U/L at EOT and peaked to 162 U/L at EOS. A reduction in liver fibrosis score from F4 (marked bridging fibrosis) to F1 (mild portal fibrosis) was observed.

The most commonly reported adverse events in LIMT included mild to moderate flu-like symptoms and elevated transaminase levels which resolved post-treatment. Patients previously treated with peginterferon alfa noted significantly less side effects on Lambda.

“This the first report demonstrating fibrosis regression following finite duration therapy with Lambda in patients with chronic HDV, the most severe form of hepatitis for which there is no approved treatment,” said Ohad Etzion, MD, LIMT Principal Investigator and Director of the Department of Gastroenterology and Liver Diseases at Soroka University Medical Center. “These case studies suggest clinical benefit in the liver after 48 weeks of Lambda therapy. We look forward to next steps for Lambda as it enters Phase 3 of clinical development.”

**About Peginterferon 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, resulting in activation of the same Jak-STAT signal transduction cascade. Lambda type III receptors are highly expressed on hepatocytes with limited expression on hematopoietic and central nervous system cells, which may reduce off-target effects and improve tolerability of Lambda.

Eiger licensed worldwide rights to Lambda from Bristol-Myers Squibb. Eiger is developing Lambda as a monotherapy and in combination with Lonafarnib boosted with ritonavir. Lambda is an investigational agent and not yet approved for any indication. Eiger has received Orphan Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), and Fast Track and Breakthrough Therapy Designation by FDA for Lambda in HDV.

**About LIMT (Lambda Monotherapy) Study**

LIMT HDV enrolled a total of 33 patients with chronic HDV, randomized to monotherapy Lambda 180 µg (N=14) or Lambda 120 µg (N=19), weekly subcutaneous injections for 48 weeks with 24 weeks of follow-up. At Week 48, LIMT study patients randomized to with Lambda 180 µg group experienced a mean decline in HDV-RNA of 2.3 log, with 7 of 14 (50%) experiencing ≥ 2 log decline and 5 of 14 (36%) patients achieving HDV-RNA below the limit of quantification (BLQ), comparable to historical peginterferon alfa. At Week 72, a durable virologic response (DVR = HDV RNA below limit of quantitation) at 24 weeks post-treatment for Lambda 180 µg was achieved in 5 of 14 (36%). LIMT HDV was an international study with sites in New Zealand, Israel and Pakistan.

**About Hepatitis Delta Virus (HDV)**

Hepatitis Delta is caused by infection with the hepatitis delta virus and leads to the most severe form of viral hepatitis. 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. Approved nucleos(t)ide treatments for HBV only suppress HBV DNA, do not affect HBsAg and have no impact on HDV.

Hepatitis delta is a disease with a significant impact on global health, which may affect up to 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.

**About Eiger**

Eiger is a late-stage biopharmaceutical company focused on the development and commercialization of first-in-class, well-characterized drugs for serious rare and ultra-rare diseases for patients with high unmet medical needs.

Eiger's lead clinical programs target Hepatitis Delta Virus (HDV) infection, the most serious form of human viral hepatitis. Eiger is developing two complementary treatments for HDV. Lonafarnib is a first-in-class, oral prenylation inhibitor in a global Phase 3 trial. Peginterferon lambda is a first-in-class, well-tolerated type III interferon entering Phase 3.

Eiger has filed an NDA and MAA for lonafarnib for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies. FDA PDUFA date is November 20, 2020.

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 anticipating significant milestones in 2020 and 2021, the timing of our ongoing and planned clinical development, including the potential for approval of our lonafarnib product candidate in the U.S. and EU for Progeria and Progeroid Laminopathies; our progression and enrollment of our Phase 3 D-LIVR study in HDV; our ability to maintain supply of our clinical trial materials; our announcement of data from the trial of Lambda and lonafarnib boosted with ritonavir for HDV (LIFT); our plans to advance Lambda in HDV in the U.S. and EU; our ability to

transition into a commercial stage biopharmaceutical company; our ability to finance the continued advancement of our development pipeline products; and the potential for success of any of our product candidates. These statements concern product candidates that have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). No representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including additional applicable risks and uncertainties described in the "Risk Factors" sections in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 and Eiger's subsequent filings with the SEC. The forward-looking statements contained in this press release are based on information currently available to Eiger and speak only as of the date on which they are made. Eiger does not undertake and specifically disclaims any obligation to update any forward-looking statements, whether as a result of any new information, future events, changed circumstances or otherwise.


SOURCE Eiger BioPharmaceuticals, Inc.
Investors: Ingrid Choong, PhD
Email: ichoong@eigerbio.com
Phone: 1-650-619-6115