



## **Eiger Announces Positive Phase 2 Interim 24-Week Data with Pegylated Interferon Lambda in Hepatitis Delta Virus (HDV) Infection at the American Association for the Study of Liver Diseases (AASLD) Meeting**

PALO ALTO, Calif., Oct. 23, 2017 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc., (NASDAQ: EIGR) today announced positive interim 24-week data with pegylated interferon lambda (Lambda) in the Phase 2 LIMT HDV (Lambda Interferon MonoTherapy in Hepatitis Delta Virus) Study presented at the American Association for the Study of Liver Diseases (AASLD) meeting in Washington DC. LIMT HDV is a 1:1 randomized, open-label study of Lambda 120 or 180 microgram subcutaneous injections administered weekly for 48 weeks in patients with chronic HDV. A total of 33 patients were enrolled.

### **Interim 24-Week Results:**

- Ten of 33 patients reached 24 weeks of treatment at time of analysis
- Five of 10 (50%) patients achieved  $\geq 2$  log decline in HDV RNA by Week 24
- Four of 10 (40%) patients achieved HDV PCR-negativity by Week 24
- Lambda is well tolerated in the majority of patients through Week 24

"At the time of this analysis, Lambda interferon demonstrates similar efficacy as previously seen with Alfa interferon in the treatment of HDV infection and importantly, is better tolerated," said LIMT HDV Study Co-Lead Investigators, Saeed Hamid, MD, Chairman and Professor in Section of Gastroenterology, Department of Medicine, Aga Khan University and Ohad Etzion, MD, Senior Physician in the Department of Gastroenterology and Liver Diseases at Soroka University Medical Center. "Lambda has demonstrated encouraging results in HDV-infected patients, and we look forward to reporting additional data from this study next year."

"Interim 24 week results with Lambda in HDV are consistent with viral load endpoints that we believe should be meaningful in future regulatory discussions and study design to advance in clinical development," said David Cory, President and CEO at Eiger. "In addition to lonafarnib, our lead compound in Phase 2 development to treat HDV, Lambda represents a second product in our pipeline, with a differentiated mechanism of action, for development in HDV. Eiger now has two complementary anti-HDV agents in the pipeline, to develop alone and in combination for the future treatment of HDV."

### **Presentations at AASLD 2017:**

- *Hamid, S. et al; "A Phase 2 Randomized Clinical Trial to Evaluate the Safety and Efficacy of Pegylated Interferon Lambda Monotherapy in Patients with Chronic Hepatitis Delta Virus Infection. Interim Results From the LIMT HDV Study." Abstract #927, Poster Presentation, Session – Hepatitis B: New and Approved Treatment, October 21, 5:30 pm – 7:00 pm.*
- *Dahari, H. et al; "Modeling Hepatitis Delta Virus Dynamics during Ritonavir Boosted Lonafarnib Treatment—the LOWR HDV-3 Study." Abstract #38, Oral Presentation, Session – Parallel 5: Hepatitis B: New Therapies, October 22, 10:15 am, Room 207.*
- *Cornberg, M.; "Treatment in On-going Hepatitis Delta Trials." Oral Presentation, Hepatitis Delta International Network (HDIN) Meeting, October 21, 9:25 pm – 9:50 pm, Marriott Marquis Hotel, Chinatown Room.*

### **About Pegylated Interferon Lambda 1a (Lambda) and the LIMT HDV Study**

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 may 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.

LIMT HDV is a 1:1 randomized, open-label study of Lambda 120 or 180 microgram 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 LonaFarnib and the LOWR HDV – 3 Study**

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).

The LOWR HDV program was a multi-center, international Phase 2 program, designed to identify dosing regimens and durations of lonaFarnib (LNF) with ritonavir (RTV) ± pegylated interferon (PEG IFN) to move forward in development for the treatment of hepatitis delta infection (HDV). LOWR HDV – 3 was part of the LOWR HDV program. LOWR HDV – 3 was 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. This study has completed.

#### **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 orphan diseases. We are committed to realizing the full value of promising research from academic research and collaborations, independent investigators, and the pharmaceutical industry to efficiently translate programs into the clinic. Through the repurposing of drugs for orphan diseases, our mission is to systematically reduce the time and cost of the drug development process to more rapidly deliver important medicines to patients. For additional information about Eiger and its clinical programs, please visit [www.eigerbio.com](http://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, 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 viral load endpoints will continue to be consistent with prior study results, whether the viral load endpoints would be supported by the FDA as the basis for approval or further development the product and whether pegylated interferon lambda-1a or lonaFarnib may be further developed and approved and whether promising earlier clinical study results will obtain in larger, later clinical studies, 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 most recent Quarterly Report on Form 10-Q for the period ended June 30, 2017 and Eiger's other periodic reports and filings with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.

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