



## **Eiger Announces U.S. IND Filing of Pegylated Interferon Lambda for Hepatitis Delta Virus Infection**

### **- LIMT HDV: Lambda Interferon MonoTherapy in HDV Study Enrolling**

PALO ALTO, Calif., May 3, 2017 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq: EIGR), focused on the development and commercialization of targeted therapies for rare diseases, announced today that the U.S. IND has been filed for Pegylated Interferon Lambda in the treatment of hepatitis delta virus (HDV) infection. U.S. sites are planned for the ongoing Phase 2 LIMT HDV (Lambda Interferon MonoTherapy in HDV) study, a monotherapy trial of pegylated interferon lambda 1a ("Lambda") as a potential treatment for chronic hepatitis D virus (HDV) infection.

"Filing the U.S. IND for Lambda in the treatment of HDV is a strategic imperative for Eiger," said Shelly Xiong, PhD, RAC, Senior Vice President of Regulatory Affairs at Eiger. "This filing should facilitate discussions with the agency regarding potential Lambda development and registration pathways for HDV as well as expanding the program to U.S. investigators and U.S. patients."

"Over recent years, patients with chronic hepatitis B and hepatitis C have benefited from huge advances in antiviral therapy for both diseases. Unfortunately HDV remains a large unmet medical need because of the lack of any effective therapy for this most aggressive form of viral hepatitis. In many countries, HDV presents a real public health challenge," said Eduardo Martins, MD, DPhil, Senior Vice President of Liver and Infectious Diseases Development at Eiger. "We look forward to expanding our HDV development program to include Lambda monotherapy and potential combinations, including Isoniazid."

#### **About the LIMT HDV Phase 2 Study**

LIMT HDV is a 1:1 randomized, open-label study of Lambda 120 or 180 microgram subcutaneous injections administered weekly for 48 weeks in approximately 30-40 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 will also be administered an anti-hepatitis B virus nucleos(t)ide analog throughout the study. LIMT HDV is an international study currently enrolling at sites in New Zealand, Israel and Pakistan.

#### **About Pegylated Interferon Lambda 1a**

Pegylated interferon lambda 1a ("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 the off-target effects associated with other IFNs and improve the 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.

#### **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.

**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 or ubenimex or exendin 9-39 may be further developed and approved, 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 Annual Report on Form 10-K for the period ended December 31, 2016 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.

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