



## **Eiger Announces Peginterferon Lambda - Lonafarnib Combination End of Treatment Results from Phase 2 LIFT HDV Study in Late Breaker Session at The Digital International Liver Congress™ 2020**

August 31, 2020

**- 96% of Patients Achieve Primary Endpoint of > 2 Log Decline in HDV RNA**

**- 58% of Patients Below Limit of Quantitation or Undetectable at Week 24**

PALO ALTO, Calif., Aug. 31, 2020 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted, first-in-class therapies for serious rare and ultra-rare diseases, today announced results from a late-breaker poster presentation at The Digital International Liver Congress™ 2020 of end of treatment results of the Phase 2 LIFT Lambda – Lonafarnib combination study in patients infected with hepatitis delta virus (HDV). The LIFT (Lambda InterEeron combo-Therapy) study is being conducted within the National Institutes of Health (NIH) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Lambda is a first-in-class type III interferon in clinical development for HDV, the most severe form of human viral hepatitis.



"We have previously presented promising results from multiple studies at NIDDK that Lonafarnib reduces HDV RNA viral load in patients infected with HDV," said Christopher Koh, MD, Principal Investigator at the NIDDK. "Lambda and Lonafarnib combination Week 24 end of treatment results from the ongoing LIFT study represent a potential foundational combination treatment for HDV. We will present Week 48 end of follow-up results from the LIFT study in the future."

LIFT is a Phase 2a open-label study of 26 adult patients with chronic HDV treated with Lambda 180 mcg once weekly in combination with Lonafarnib 50 mg boosted with ritonavir 100 mg twice daily for 24 weeks. Primary efficacy endpoint is > 2 log decline in HDV RNA at end of treatment. Median baseline evaluations included: ALT (64 IU/mL), AST (47 IU/mL), Ishak Fibrosis (3), modified HAI inflammation (9), HBV DNA (< 20 IU/mL) and log HDV RNA (4.74 IU/mL).

At Week 24 end of treatment, 25 of 26 patients (96%) achieved the Primary Endpoint of > 2 log decline in HDV RNA, 58% of patients were either Below Limit of Quantitation or Undetectable, and median HDV RNA decline was 3.2 log IU/mL (CI: 2.50-3.93, p<0.0001). Combination therapy with Lambda and Lonafarnib in chronic HDV patients appears to be well tolerated for up to 6 months in most patients. LIFT end of treatment results support continued exploration of this therapeutic combination in HDV.

Adverse events were mostly mild to moderate and included GI-related side effects, weight loss, hyperbilirubinemia, and anemia. Per-protocol dose reductions occurred in 3 patients and discontinued in 4 patients, and were mostly due to known side effects related to peginterferon lambda.

### **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 Lonafarnib**

Lonafarnib is a well-characterized, late-stage, orally active, first-in-class inhibitor of farnesyl transferase, an enzyme involved in modification of proteins through a process called prenylation, a vital process in the life cycle of HDV. Blocking prenylation of the large delta hepatitis antigen (LDHAg) reduces HDV replication.

Lonafarnib has been dosed in over 120 HDV-infected patients across international academic centers and is in Phase 3 with a single, international, pivotal trial (D-LIVR Study). Lonafarnib has been granted Orphan Drug designation by the U.S. FDA and European Medicines Agency (EMA), Fast Track and Breakthrough Therapy Designation by the U.S. FDA and PRIME designation by the EMA. 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 LIFT Study**

LIFT (Lambda InterEeron combo-Therapy) is an open-label, Phase 2 study evaluating Lambda + Lonafarnib + Ritonavir in 26 HDV-infected patients. Patients with quantifiable HDV RNA in serum (lower limit of quantitation < 40 IU/mL) were dosed for 24 weeks with follow up for 24 weeks. Primary endpoint is > 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 follow-up. Tenofovir or Entecavir was started prior to therapy. Serial assessments of safety parameters, liver tests, pharmacokinetics, histology, and virologic (HDV RNA and HBV DNA) markers were collected. 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 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](http://www.eigerbio.com).


The research described here is conducted by the Division of Intramural Research at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health. The content of this news release is solely the responsibility of the authors and does not necessarily represent the official views or imply endorsement of the National Institutes of Health.

#### **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 June 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.

Investors: Ingrid Choong, PhD  
Email: [ichoong@eigerbio.com](mailto:ichoong@eigerbio.com)  
Phone: 1-650-619-6115

 View original content to download multimedia: <http://www.prnewswire.com/news-releases/eiger-announces-peginterferon-lambda-lonafarnib-combination-end-of-treatment-results-from-phase-2-lift-hdv-study-in-late-breaker-session-at-the-digital-international-liver-congress-2020-301120774.html>

SOURCE Eiger BioPharmaceuticals, Inc.