



Eiger Late-Breaker Oral Presentation of Peginterferon Lambda Phase 2 LIMT Study at The International Liver Congress™ 2019

- 36% Durable Virologic Response at 24 Weeks Post-Treatment

PALO ALTO, Calif., March 13, 2019 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today announced a late-breaker oral presentation of Phase 2 LIMT HDV (Lambda Interferon MonoTherapy in Hepatitis Delta Virus) end of study 24 week post-treatment results will be presented at The International Liver Congress™ 2019 in Vienna, Austria, April 10 to 13. Peginterferon Lambda is a first-in-class, type III interferon in development for the treatment of HDV, the most severe form of human viral hepatitis for which there is no approved therapy.

Accepted abstract to The International Liver Congress™:

- Etzion, O. et al; "End of Study Results from LIMT HDV Study: 36% Durable Virologic Response at 24 Weeks Post-Treatment with Pegylated Interferon Lambda Monotherapy in Patients with Chronic Hepatitis Delta Virus Infection", Oral Presentation, PS-052, Parallel Session: Hepatitis B/D/E – Clinical Aspects of Viral Hepatitis, April 11, 4:45 pm – 5:00 pm CET

Other HDV events during The International Liver Congress™:

- 17th Hepatitis Delta International Network (HDIN) Meeting
Apelian et al; "Lonafarnib: An Oral, First-in-Class, Prenylation Inhibitor in Phase 3 D-LIVR Study for HDV and Pegylated Interferon Lambda: A Better Tolerated Interferon in Phase 2 LIMT / LIFT Studies for HDV"; Oral Presentation, April 10, 4:30 pm – 7:30 pm CET, Room Lehar 2 – Congress Venue
- Eiger Phase 3 D-LIVR Study Reception, April 11, 8:30-10:30 pm CET

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. 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. The LIMT (Lambda Interferon Monotherapy) study in HDV-infected patients has completed dosing across international centers. Lambda is an investigational agent and not yet approved for any indication. Eiger has received Orphan Designation and Fast Track Designation by the U.S. Food and Drug Administration (FDA) 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 was followed by a treatment-free 24-week observation period. The primary objective of the Phase 2 study was to evaluate the safety, tolerability, and efficacy of treatment with two dose levels of Lambda monotherapy in patients with chronic HDV infection. All patients were administered an anti-hepatitis B virus nucleos(t)ide analog throughout the study. LIMT HDV was an international study with sites in New Zealand, Israel and Pakistan.

About Lonafarnib

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, a vital process in the life cycle of HDV. Blocking prenylation of the large delta hepatitis antigen (LDHAg) reduces HDV replication. Currently approved nucleos(t)ide treatments for HBV only suppress HBV DNA, do not affect HBsAg, and have no impact on HDV infection.

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 designation by 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 (Lambda and Lonafarnib Combo-therapy) Study

LIFT is an open-label, Phase 2 study evaluating Lambda + Lonafarnib + Ritonavir in 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). End of treatment data is expected end of 2019.

About D-LIVR Study

D-LIVR (Delta Liver Improvement and Virologic Response in HDV) is an international, multi-center, Phase 3 study of approximately 300 lonafarnib (LNF)-treated patients (total N=400 patients including controls) to evaluate an all-oral arm of LNF boosted with ritonavir (RTV) and a combination arm of LNF boosted with RTV combined with pegylated interferon-alfa (PEG IFN-alfa), with each arm to be compared to a placebo arm (background HBV nucleos(t)ide only), in HDV-infected patients. A PEG IFN-alfa alone arm will be dosed to demonstrate contribution of effect only. The LNF containing arms will not be required to demonstrate superiority over PEG IFN-alfa alone. A combined primary endpoint of ≥ 2 log₁₀ decline in HDV RNA and ALT normalization at end of 48 weeks of treatment will be used to assess activity of LNF-based regimens versus placebo in the D-LIVR study.

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. Investigational agents in development for HBV target functional cure, are not expected to eliminate extra-hepatic reservoirs of HBsAg and are thus not expected to impact HDV infection.

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. 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 late-stage biopharmaceutical company focused on the accelerated development and commercialization of a pipeline of targeted, first-in-class therapies for serious rare and ultra-rare diseases. The company's lead program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. The company is also preparing an NDA with plans to file in 2019 for lonafarnib in the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies. For additional information about Eiger, 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 plans to file an NDA for Progeria in 2019 and progress our Phase 3 study in HDV; 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.

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 September 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.

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