Eiger Announces Peginterferon Lambda - Lonafarnib Combination Interim Results in Hepatitis Delta Virus (HDV) Infection from Phase 2 LIFT Study During Late-Breaker Oral Presentation at AASLD 2019

- 53% of Patients Achieve Undetectable or BLOQ HDV RNA at Week 24
- Median Decline of HDV RNA: -3.4 Log at Week 24
- 95% of Patients Achieve > 2 Log Decline in HDV RNA at Week 24

PALO ALTO, Calif., Nov. 12, 2019 /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 a late-breaker oral presentation at AASLD 2019 of interim end of treatment results of the Phase 2 LIFT Lambda combination study in HDV-infected patients. The LIFT 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. There is no approved treatment for HDV.

"We have previously presented promising results in 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 interim end of treatment results from the ongoing LIFT study are very encouraging and represent a potential foundational combination treatment for HDV. We look forward to presenting additional 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 twice daily boosted with ritonavir 100 mg twice daily for 24 weeks. Primary efficacy endpoint is > 2 log HDV RNA decline 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 (< 21 IU/mL) and log HDV RNA (4.74 IU/mL).

At the time of analysis, 19 of 26 patients had reached Week 24. Median HDV RNA decline was 3.4 log IU/mL (IQR: 2.9-4.5, $p<0.0001$) with 7 patients (37%) achieving undetectable HDV RNA and 3 patients (16%) BLOQ. 18 of 19 patients (95%) achieved > 2 log decline during 24 weeks of therapy. Subjects who achieved undetectable HDV RNA levels during therapy trended towards significance of having lower baseline HDV RNA levels compared to those who achieved > 2 log decline but not HDV RNA undetectable or BLOQ, suggesting that baseline viral load may be predictive of virologic response.

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. 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 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 InterFeron 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. 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.

About Eiger
Eiger is a late stage biopharmaceutical company focused on the development and commercialization of a pipeline of first-in-class, well-characterized drugs for serious rare and ultra-rare diseases for patients with high unmet medical needs and for which no approved therapies exist.

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 rapidly advancing peginterferon lambda, a first-in-class interferon, toward registration for the treatment of HDV. Eiger is preparing an NDA and MAA for lonafarnib to treat Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies with plans to submit an NDA by year-end 2019, followed by an MAA submission in the first quarter of 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 ongoing and planned clinical development, including planned NDA submission by year-end 2019, followed by submission of an MAA in first quarter 2020 for Progeria and Progeroid Laminopathies; our progression and enrollment of our Phase 3 D-LIVR study in HDV; our planned advancement of Lambda and Lonafarnib boosted with ritonavir for HDV; our plans to hold an end of Phase 2 meeting for Peginterferon Lambda in HDV in first quarter 2020; our plans for continued advancement of avexitide in registration trials; 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 the risks described in the "Risk Factors" sections in the Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 and Eiger's subsequent filings with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.

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

oral-presentation-at-aasld-2019-300956245.html

SOURCE Eiger BioPharmaceuticals, Inc.