Eiger Announces Peginterferon Lambda Combination Therapy for Treatment of Chronic Hepatitis Delta Virus (HDV) Infection to be Featured in a Late-Breaking Oral Presentation at AASLD 2019

- >50% 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., Oct. 21, 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 that a late-breaker oral presentation has been granted for interim end of treatment (Week 24) results of the Phase 2 LIFT (Peginterferon Lambda or Lambda) study at AASLD 2019 in Boston. 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 are pleased to now have combination data with Lambda and Lonafarnib, our two proprietary product candidates for the treatment of HDV, and that this data was selected for late-breaking oral presentation at the AASLD 2019 meeting," said David Cory, President and CEO. "We are very encouraged that interim end of treatment results with this combination indicate that >50% of patients were HDV RNA undetectable or BLOQ at Week 24 and 95% of patients achieved the primary endpoint of > 2 log decline in HDV RNA at Week 24. These data, combined with a favorable safety and tolerability profile, demonstrate the potential of this combination as a future foundational treatment for patients with HDV infection."

Publication Number: LO8
Session: Late-Breaking Abstract Oral Session II
Date: Tuesday, November 12, 2019, 8:00 AM ET
Presentation Time: 8:15 AM ET
Presenter: Christopher Koh, MD, Principal Investigator at NIDDK
Location: Auditorium, Hynes Convention Center

Abstract Summary: In a Phase 2a open-label study, 26 adult patients with chronic HDV and quantifiable HDV RNA in serum (lower limit of quantitation < 40 IU/mL) were treated with oral Lonafarnib 50 mg and Ritonavir 100 mg twice daily and subcutaneous Lambda 180 mcg once weekly for 24 weeks and then monitored post-therapy for 24 weeks. Tenofovir or Entecavir was started prior to therapy. Primary efficacy endpoint was greater than 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). Serial assessments of safety parameters, liver tests, pharmacokinetics, histology, and virologic (HDV RNA and HBV DNA) markers were collected.

In this ongoing study, after 12 weeks of therapy (21 of 26 subjects), the median HDV RNA decline from baseline was 3.6 log IU/mL (IQR: 2.6-4.2, p<0.0001) with 5 patients (24%) achieving undetectable HDV RNA and 5 patients (24%) with HDV RNA below the lower limit of quantification (BLOQ). At the end of therapy (19 of 26 subjects), the 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. Adverse events were mostly mild to moderate and included GI related side effects, weight loss, hyperbilirubinemia, and anemia. Therapy was dose reduced in 3 patients and discontinued in 4 patients.

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 Designation by FDA for Lambda in HDV.

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 Study
LIFT (Lambda InterFeron combo-Therapy) 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).

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 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 fourth quarter 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 submission of an NDA for Progeria and progeroid laminopathies in fourth quarter 2019 and progressing our Phase 3 D-LIVR 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. 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 June 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.

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