Eiger BioPharmaceuticals Announces Positive Results of Investigator Sponsored Randomized Controlled Trial at University of Toronto with Peginterferon Lambda in Outpatients with Mild to Moderate COVID-19

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PALO ALTO, Calif., Oct. 15, 2020 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc (Nasdaq: EIGR), focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today announced results of the ILIAD Study (**I**nterferon **L**ambda for **I**mmediate **A**ntiviral Therapy at **D**iagnosis in COVID-19), an investigator sponsored randomized trial of Peginterferon Lambda (Lambda) in outpatients with mild to moderate COVID-19 conducted at Toronto General Hospital, University Health Network in Toronto, Canada.

The main efficacy outcomes were viral load decline and the proportion of individuals with a negative nasopharyngeal swab for SARS-CoV-2 at Day 7. A total of 60 patients were randomized 1:1 to a single subcutaneous dose of Lambda 180 mcg or normal saline placebo. Patients were followed for 14 days.

The SARS-CoV-2 RNA viral load decline from baseline was significantly greater in the Lambda group than in the placebo group from Day 5 onwards. After controlling for baseline viral load, those treated with Lambda were 4.1-fold (95% CI 1.2-16.7, p=0.029) more likely to clear by Day 7 than those in the placebo arm. For those with baseline viral load > 6 log copies/mL, the proportion negative at Day 7 in the Lambda group was 15 of 19 (79%) compared to 6 of 16 (38%) in the placebo group (p=0.013). This difference translated into a median time to clearance of 7 days with Lambda compared to 10 days in the placebo group (p=0.038). Consistent with recently reported studies, there was no difference in time to clearance in patients with low baseline viral loads < 6 log copies/mL: 9 of 11 (82%) in the Lambda arm and 13 of 14 (93%) in the placebo arm were negative by Day 7 (p=0.40). Across all patients, by Day 7, 24 of 30 patients (80%) in the Lambda group were negative compared to 19 of 30 (63%) in the placebo arm (p=0.15).

Participants with low viral loads also had milder symptoms at baseline with symptoms improving over time in both groups. Lambda was well-tolerated with few adverse events, which included minimal elevations of transaminases which self-resolved.

"This is one of the first randomized controlled trials showing a significant effect on COVID-19 in an ambulatory setting. We are excited about these results showing that peginterferon lambda accelerates viral load decline in outpatients with mild to moderate COVID-19," said Jordan Feld, MD, MPH, Associate Professor of Medicine at University of Toronto and Senior Scientist at Toronto Centre for Liver Disease and Toronto General Hospital Research Institute. "Lambda works particularly well in patients with high baseline viral loads. Our cutoff of 6 log copies/mL was prospectively chosen as this correlates with the threshold for infectivity and the likely need for treatment. Importantly, all Lambda-treated patients were below levels of shedding infectious virus by Day 7. We look forward to the results of our ongoing Lambda investigator sponsored studies in hospitalized patients with more advanced COVID-19."

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. Binding leads to activation of JAK-STAT signaling pathway and upregulation of numerous IFN-stimulated genes (ISGs). IFN lambda receptors are largely restricted to cells and tissues of epithelial origin, including respiratory epithelial cells.

IFN lambdas are critical for maintaining a balanced antiviral response in the respiratory tract. They are induced at lower viral burden before type I IFNs to limit the initial infection by inducing viral resistance to cells and helping them deal with the virus load. IFN lambda lacks the strong pro-inflammatory effects of type I IFNs and are tissue-protective and anti-inflammatory. Administration of IFN lambda has been shown to suppress viral replication while stopping the 'cytokine storm' from developing.

The ILIAD Study (**I**nterferon **L**ambda for **I**mmediate **A**ntiviral Therapy at **D**iagnosis in COVID-19) is one of several international, investigator sponsored studies evaluating Lambda in COVID-19.

Eiger is developing Lambda as a monotherapy and in combination with lonafarnib boosted with ritonavir for the treatment of hepatitis delta virus (HDV) infection. Lambda has been administered to over 3,000 subjects in 19 clinical trials of HBV, HCV and HDV. 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.

Eiger licensed worldwide rights to Lambda from Bristol-Myers Squibb.

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 ready to enter 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.

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 complete the investigator sponsored studies of Lambda in COVID-19; 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.

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