Eiger BioPharmaceuticals Announces First COVID-19 Patients Dosed with Peginterferon Lambda

- **Six International, Investigator Sponsored Studies Initiating and Enrolling**

PALO ALTO, Calif. April 30, 2020 -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today announced that the first patients have been dosed in a Phase 2 study of peginterferon lambda (Lambda) in outpatients with mild COVID-19 at the Stanford University School of Medicine.

Approximately 120 patients will be randomized 1:1 to a single subcutaneous dose of Lambda or normal saline placebo to evaluate the efficacy of Lambda in reducing the duration of viral shedding of SARS-CoV-2 virus and in reducing duration of symptoms and hospitalization in patients with mild COVID-19. Patients will be followed for 28 days.

The Stanford study is co-led by Upinder Singh, MD, Professor of Medicine and Infectious Diseases and Geographic Medicine and Microbiology and Immunology and Prasanna Jagannathan, MD, Assistant Professor of Medicine and Infectious Diseases.

Lambda interferon plays a key role in the targeted innate immune response against viral pathogens that infect the respiratory tract. Upon infection of airway epithelial cells, type III IFNs, like lambda interferon, are produced first and act as the initial line of defense to limit virus spread at the epithelial barrier without triggering inflammation. The study will investigate the hypothesis that Lambda may be most effective in patients who have confirmed infection with mild symptoms in order to reduce duration and severity of COVID-19.

“SARS-CoV-2 induces very weak expression of interferons in infected cells,” said Colin Hislop, MD, Senior Vice President of Clinical and Development Operations. “Absence of interferon production likely hampers the early innate immune response to SARS-CoV-2 infection and suggests stimulation of antiviral immunity with exogenous lambda interferon might be successful for treating SARS-CoV-2 infection.”

The Stanford study is one of six international, investigator sponsored studies evaluating Lambda in COVID-19. Other sites include Soroka University (Israel), Mount Sinai Hospital (New York), Massachusetts General Hospital (Boston), Johns Hopkins University (Baltimore), and University of Toronto (Toronto). Eiger has been involved in protocol development, regulatory interactions and is providing Lambda clinical drug supply. Collectively, up to 400 patients are expected be enrolled and dosed across international sites. These studies will assess Lambda’s ability to reduce COVID-19 replication and limit virus transmission.

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.

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 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.

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, for which no approved therapies exist.

Eiger has completed an NDA and MAA submission for lonafarnib for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies. Eiger has also established a global Managed Access Program, expected to span greater than 40 countries, to ensure all children and young adults with Progeria and Progeroid Laminopathies have access to treatment.

The company's lead program is in Phase 3, developing lonafarnib, a first-in-class oral prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. The company is also advancing peginterferon lambda, a first-in-class interferon, toward registration for the treatment of HDV. 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, the timing of our ongoing and planned clinical development, including the potential for approval of our lonafarnib product candidate in the US and EU for Progeria and Progeroid Laminopathies; our progression and enrollment of our Phase 3 D-LIVR study in HDV; our ability to complete enrollment of D-LIVR in 2021; our ability to maintain supply of our clinical trial materials; our announcement of data from the trial of peginterferon lambda and lonafarnib boosted with ritonavir for HDV (LIFT); our plans to advance peginterferon lambda in HDV in the US and EU; our plans to initiate clinical studies of peginterferon lambda in coronavirus; 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; that the company's expectations regarding the effects of COVID-19 on the Company’s trials and development may be incorrect, 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 Annual Report on Form 10-K for the year ended December 31, 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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