Eiger Announces Results of Investigator Sponsored Study in Outpatients with Mild and Uncomplicated COVID-19

Palo Alto, Calif., September 28, 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 an investigator sponsored study of Peginterferon Lambda-1a (Lambda) in outpatients with mild and uncomplicated COVID-19.

The primary endpoint was duration of viral shedding, determined by time to first of two consecutive negative tests for SARS-CoV-2 by qRT-PCR. The secondary endpoint was reducing duration of symptoms and hospitalization in patients with mild COVID-19. A total of 120 patients were randomized 1:1 to a single subcutaneous dose of Lambda or normal saline placebo. Patients were followed for 28 days.

No difference was demonstrated in duration of SARS-CoV-2 viral shedding and time to symptom resolution when compared with placebo. Median time to cessation of viral shedding in both groups was 7 days. Lambda was well-tolerated with few adverse events, which included elevated transaminases which self-resolved.

The study was co-led by Stanford University School of Medicine researchers 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.

“We now know that untreated patients with mild COVID-19 clear virus quickly. Published reports have demonstrated evidence of a therapeutic benefit of interferons in hospitalized patients with more advanced COVID-19 disease,” said Colin Hislop, MD, Senior Vice President of Clinical and Development Operations at Eiger. “We look forward to the results of the four on-going peginterferon lambda investigator sponsored studies in hospitalized patients with more advanced COVID-19, as well as the prophylaxis study of exposed or at-risk patients.”

“Lambda is in late stage development for the treatment of Hepatitis Delta Virus (HDV), the most severe form of human viral hepatitis, and HDV is our lead clinical program,” said David Cory, President and CEO of Eiger. “We have previously generated positive results in two Phase 2 studies in HDV-infected patients and have concurrence with FDA and EMA on a single, Phase 3 study of Lambda monotherapy in patients infected with chronic HDV. We look forward to initiating this study.”

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.

This study is one of six international, investigator sponsored studies evaluating Lambda in COVID-19. Other sites include patients with more advanced COVID-19 at University of Toronto (Toronto), Soroka University (Israel), Mount Sinai Hospital (New York), Massachusetts General Hospital (Boston), and Johns Hopkins University (Baltimore). Collectively, up to 520 patients are expected be enrolled and dosed across international sites.

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.

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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