Eiger BioPharmaceuticals Announces Second Positive Interim Analysis and Continuation of Dosing of Peginterferon Lambda in Phase 3 *TOGETHER* Study of Newly Diagnosed COVID-19 Patients

- Interim analysis of 1,003 patients, randomized to Peginterferon Lambda vs placebo
- Variants of SARS-CoV-2 will be determined on all patients

Palo Alto, Calif., December 15, 2021 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure Hepatitis Delta Virus (HDV) and other serious rare diseases, today announced that the Data Safety Monitoring Board (DSMB) for the Phase 3 *TOGETHER* study has conducted a second interim futility analysis and recommended continuation of the study. This analysis was based on a sample size of 1,003 patients, randomized to active or placebo. The primary endpoint compares number of extended emergency setting visits, hospitalizations, and/or deaths in treated patients versus placebo. *TOGETHER* is expected to enroll up to 1,600 patients at high risk for developing complications from progression of COVID-19.

"We are pleased that the DSMB has now completed a second interim futility analysis on a larger sample of Peginterferon Lambda treated patients and recommended to continue enrollment," said Edward Mills, PhD, Principal Investigator, Professor of Health Research Methods, Evidence, and Impact at McMaster University Hamilton, Canada, who is leading the study with Gilmar Reis, MD, PhD, Co-Investigator, Associate Professor of Medicine, Pontifical Catholic University of Minas Gerais, Brazil. “The COVID-19 pandemic continues to be a global public health emergency and treatments with novel mechanisms that can be easily administered to newly diagnosed patients are urgently needed."

“Peginterferon Lambda stimulates immune responses critical to innate defenses with a mechanism of action agnostic to variants of SARS-CoV-2 and resistance concerns with other treatments,” said David Cory, President and Chief Executive Officer at Eiger. “A single subcutaneous injection of Peginterferon Lambda administered to newly diagnosed COVID-19 patients may reduce complications and prevent hospitalizations, with or without other treatments. We look forward to reporting results of the *TOGETHER* study.”

TOGETHER is a multi-center, investigator-sponsored, randomized, placebo-controlled adaptive platform Phase 3 study evaluating therapeutics in newly diagnosed, high-risk, non-hospitalized patients with COVID-19. Peginterferon Lambda is currently the only therapeutic being investigated in *TOGETHER*. The primary endpoint compares number of emergency setting visits, hospitalizations, and/or deaths in treated patients versus placebo through Day 28. The DSMB provides independent oversight for the trial and has previously discontinued five other therapeutics due to observed futility. *TOGETHER* is expected to enroll as many as 1,600 patients (1:1 Peginterferon Lambda vs placebo) at high risk for developing complications from progression of COVID-19. *TOGETHER* is currently recruiting at twelve sites in Brazil.

For more information about *TOGETHER*, please click here.

About Peginterferon Lambda

Peginterferon 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. Peginterferon 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 'cytokine storm' from developing.

Eiger is developing Peginterferon Lambda for the treatment of hepatitis delta virus (HDV) infection. Peginterferon Lambda has been administered to over 3,000 subjects in 23 clinical trials of HBV, HCV, HDV and COVID-19. Peginterferon 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 Peginterferon Lambda in HDV.

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

About Eiger

Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure Hepatitis Delta Virus (HDV) and other serious rare diseases. The Eiger HDV platform includes two first-in-class therapies in Phase 3 that target critical host processes involved in viral replication. All five Eiger rare disease programs have been granted FDA Breakthrough Therapy Designation.

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 within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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. Forward-looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our anticipated significant milestones in 2021 and 2022; the timing of our ongoing and planned clinical development; the sufficiency of our cash, cash equivalents and investments to fund our operations; and the potential of Lambda to be an effective therapy for newly diagnosed outpatients with COVID-19. 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 September 30, 2021 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.

SOURCE Eiger BioPharmaceuticals, Inc. Investors and Media:
Sri Ryali
Chief Financial Officer
Email: sryali@eigerbio.com
Phone: 1-650-272-6138