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

- Data Safety Monitoring Board recommends continuation of Peginterferon Lambda
- Interim analysis of 453 patients, randomized 1:1 Peginterferon Lambda vs placebo

Palo Alto, Calif., September 20, 2021 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today announced that the Data Safety Monitoring Board (DSMB) recommended that investigators continue enrollment of the Peginterferon Lambda arm in the Phase 3 *TOGETHER* platform study. The per protocol interim futility analysis was based on a sample size of 453 patients, randomized 1:1 active treatment to placebo.

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. The primary endpoint is a clinical outcome comparing emergency setting visits and/or hospitalization in each active arm versus placebo. The DSMB provides independent oversight for the trial and has previously discontinued five other therapeutics due to observed futility. The Peginterferon Lambda arm targets enrollment of up to 800 patients at high risk for developing complications from progression of COVID-19. The *TOGETHER* platform study is currently recruiting at twelve sites in Brazil.

"We are pleased that the DSMB has recommended to continue enrolling the Peginterferon Lambda arm in the *TOGETHER* study," said Edward Mills, PhD, Principal Investigator, Professor of Health Research Methods, Evidence, and Impact at McMaster University, Vancouver, 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 outpatient treatments that can be quickly and efficiently administered to newly diagnosed SARS-CoV-2 patients are desperately needed with a goal of reducing COVID-19 complications."

“Resistance due to variants or new strains of SARS-CoV-2 is an ongoing concern with approved treatments as well as vaccines,” said David Cory, President and Chief

Executive Officer at Eiger. “Peginterferon Lambda stimulates immune responses that we believe are critical for the development of host protection during viral infections and may be ideal for addressing variants of SARS-CoV-2. Peginterferon Lambda’s mechanism of action is agnostic to arising variants, and as such we believe may be ideally suited to treat newly diagnosed COVID-19 outpatients as a single subcutaneous injection. We look forward to reporting additional results in the future.”

For more information about the *TOGETHER* platform study, 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 and commercialization of targeted therapies for serious rare and ultra-rare diseases.

Eiger’s lead clinical programs are focused on the development of foundational therapies for Hepatitis Delta Virus (HDV) infection, the most serious form of viral hepatitis, with

two complementary HDV treatments. 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 entering Phase 3.

Zokinvy® for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and processing-deficient Progeroid Laminopathies is the Company's first FDA approved product. A Marketing Authorization Application (MAA) is under review by the European Medicines Agency (EMA).

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 "will," "may," "continue," "plan," "expect," "could," "potential" 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, the potential of Lambda to be an effective therapy for newly diagnosed outpatients with COVID-19; 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, 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.

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