Eiger BioPharmaceuticals Provides Update on Status of Planned Peginterferon Lambda COVID-19 Emergency Use Authorization Application

PALO ALTO, Calif., Sept. 6, 2022 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development of innovative therapies for hepatitis delta virus (HDV) and other serious diseases, today provided an update on the status of its planned request for emergency use authorization (EUA) of peginterferon lambda for the treatment of patients with mild-to-moderate COVID-19 based on its most recent communications with the U.S. Food and Drug Administration (FDA).

Following a cooperative and extensive pre-EUA information exchange with FDA regarding the Phase 3 *TOGETHER* study of peginterferon lambda for COVID-19, the agency has indicated that it is not yet able to determine whether the criteria for the submission of an application and issuance of an EUA are likely to be met. FDA has indicated that it will consider any new information and data from the *TOGETHER* study to support an EUA as well as the company's plans for the further development of peginterferon lambda for COVID-19. Eiger remains in active dialogue with FDA and will provide additional information to the agency that the company believes could be supportive of an EUA.

"We appreciate the active dialogue with FDA and remain committed to continued engagement with the agency to obtain the necessary alignment to submit our EUA application for peginterferon lambda," said David Cory, President and CEO, Eiger. "Given its unique mechanism of action and the ongoing need for effective COVID-19 therapeutics, making peginterferon lambda available for patients remains a priority for Eiger."

The company has recently generated new data and analyses from the *TOGETHER* study that it plans to discuss with FDA, including further statistical modeling and efficacy analyses of the study's primary and secondary endpoints in patients treated within three days of symptom onset. The endpoint of hospitalization due to COVID-19 and all-cause mortality for patients treated within three days of symptom onset is consistent with the endpoint used to authorize other therapeutics for emergency use and is summarized below:

	Patients Treated Within 3 Days of Symptom Onset		
Population	**Hospitalization due to COVID-19 / All-Cause Mortality**	**Hospitalization / Mortality due to COVID-19**	**Hospitalization due to COVID-19**
Intent to Treat (ITT) N=1,154[1]	RRR[2] 0.58 Pr[3] 0.991 p=0.026	RRR 0.62 Pr 0.996 p=0.014	RRR 0.62 Pr 0.996 p=0.014

[1] n=567 (peginterferon lambda), n=587 (placebo)

[2] Relative Risk Reduction

[3] Probability of superiority; threshold for superiority = 0.976

The original efficacy analysis of the data generated from the *TOGETHER* study was based on dosing peginterferon lambda within seven days of symptom onset.

In addition, Eiger plans to provide new additional analyses of long-term follow-up data, including rates of rebound and incidence of long COVID, as well as an indirect comparative analysis of mortality and hospitalizations in vaccinated patients when treated with peginterferon lambda compared to other therapeutics authorized for emergency use.

The company is working with the *TOGETHER* investigators on the publication of a manuscript in a peer reviewed journal.

About Peginterferon Lambda
Peginterferon lambda is an investigational 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 and has been well-tolerated in clinical studies.

Peginterferon lambda is to be administered as a single subcutaneous injection so that it can be prescribed and administered at the first sign of infection or at first awareness of an exposure, potentially helping patients avoid severe illness that can lead to

hospitalization and death.

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 HDV infection. Peginterferon lambda has been administered to over 4,000 subjects in 28 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, 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 *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. *TOGETHER* is the largest placebo-controlled study in COVID-19 and has evaluated 11 different therapeutic agents for non-hospitalized COVID-19 patients. This evaluation of peginterferon lambda versus placebo was the second largest study to date of a COVID-19 therapeutic. Eligibility criteria required that all patients had laboratory-confirmed mild-to-moderate COVID-19, and were randomized within seven days of symptom onset. High-risk criteria were defined by patients having at least one of the following, including but not limited to: > age 50, diabetes, hypertension, CV disease, lung disease, kidney disease, obesity, etc. The study enrolled patients regardless of vaccination status or variant strain of SARS-CoV-2. The primary endpoint was a clinical outcome comparing hospitalizations or emergency room visits greater than six hours after a single subcutaneous injection of peginterferon lambda versus placebo. The Data Safety Monitoring Board provided independent oversight for the trial and had previously discontinued other therapeutics due to observed futility. The *TOGETHER* study recruited from 12 sites in Brazil and 5 sites in Canada.

For more information, please visit www.clinicaltrials.gov (NCT04727424) and www.togethertrial.com.

About Eiger
Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies for hepatitis delta virus (HDV) and other serious 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: lonafarnib and peginterferon lambda for HDV, Zokinvy for progeria, and avexitide for both congenital hyperinsulinism and post-bariatric hypoglycemia.

For additional information about Eiger and its clinical programs, please visit www.eigerbio.com.

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 planned request for emergency use authorization of peginterferon lambda for the treatment of COVID-19, further development of peginterferon lambda, future interactions with FDA, our future financial condition, timing for and outcomes of clinical results, prospective products, preclinical and clinical pipelines, regulatory objectives, 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, the timing of our ongoing and planned clinical development; the sufficiency of our cash, cash equivalents and investments to fund our operations; the likelihood of obtaining an emergency use authorization from FDA for peginterferon lambda for COVID-19; our capability to provide sufficient quantities of any of our product candidates, including peginterferon lambda, to meet anticipated full-scale commercial demands; our ability to finance the continued advancement of our development pipeline; and the potential for success of any of our products or product candidates. 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, 2022 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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