New England Journal of Medicine Publishes Positive Phase 3 *TOGETHER* Results with Peginterferon Lambda in COVID-19

- *Phase 3 TOGETHER data showed early treatment with a single dose of peginterferon lambda (Lambda) in patients with mild-to-moderate COVID-19 infections resulted in significantly decreased clinical events*
- *Lambda reduced risk of hospitalization or emergency room visits by 51% (primary endpoint)*
- *Lambda reduced risk of hospitalization by 42% and COVID-19 related death by 50%*
- *Effects consistent across multiple dominant SARS-CoV-2 variants in a largely vaccinated population*

PALO ALTO, Calif., February 8, 2023 -- 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 announced the publication of data from the investigator-sponsored Phase 3 *TOGETHER* study in patients with COVID-19 in the *New England Journal of Medicine (NEJM).* The study, which evaluated newly diagnosed outpatients with mild-to-moderate COVID-19, found that among predominantly vaccinated participants with COVID-19, a single-dose treatment with Eiger's investigational agent, peginterferon lambda, resulted in significantly decreased clinical events. The manuscript titled "Effect of Early Treatment with Pegylated Interferon Lambda among COVID-19 Patients" will be published in the February 9, 2023 issue of *NEJM* and follows the topline safety and efficacy data announced March 17 2022.

"We are pleased to see the positive results from the *TOGETHER* study published in the *New England Journal of Medicine*, emphasizing the importance of the trial which showed that a single dose of peginterferon lambda resulted in a significant reduction of risk in COVID-19-related hospitalizations or deaths in a predominantly vaccinated population," said Gilmar Reis, MD, PhD, co-Lead Investigator for *TOGETHER* and Associate Professor of Medicine McMaster University, Hamilton, Canada and Pontifical Catholic University of Minas Gerais, Brazil.

"Peginterferon lambda has tremendous therapeutic potential, and we continue to see the emergence of aggressive variants of the virus spreading around the globe which are less sensitive to both vaccines and treatment with antibodies," said Jordan Feld, MD, MPH, Associate Professor of Medicine at University of Toronto and Senior Scientist at Toronto Centre for Liver Disease and Toronto General Hospital Research Institute and co-Lead Investigator for *TOGETHER*. "Resistance due to variants or new strains of the virus could be an issue with some therapies, but this may not be a concern with peginterferon lambda due to its mechanism of action that involves activation of multiple virus-killing pathways."

The primary endpoint was a composite endpoint of COVID-19-related hospitalization or emergency room visits greater than six hours. Secondary endpoints included SARS-CoV-2 viral clearance, all-cause hospitalization, mortality due to COVID-19, days in hospital and on ventilator, and adverse events. In the study, 931 patients received peginterferon lambda and 1018 received placebo. This was among the first trials to include a predominantly vaccinated population with 84% of the population having received vaccination prior to study entry. The study period included emergence of multiple COVID-19 variants of concern.

The publication detailed results, highlighting a 51% reduction in COVID-19-related hospitalizations or emergency room visits greater than six hours (the primary outcome) for participants receiving peginterferon lambda vs. placebo, with 2.7% (25 of 931) of participants randomized to peginterferon lambda experiencing a primary outcome event, compared with 5.6% (57 of 1018) (relative risk 0.49, 95% Bayesian credible interval 0.30-0.76, posterior probability >99.9%) among patients randomized to placebo. This effect was maintained in subgroup analyses including COVID-19-related hospitalization alone (relative risk 0.57, 95% Bayesian credible intervals 0.33-0.95) and COVID-19-related hospitalization or death (hazard ratio 0.59, 95% Bayesian credible interval 0.35-0.97). The effects were consistent across dominant variants and vaccination status. Among individuals with a high viral level at baseline, peginterferon lambda resulted in lower viral loads and a higher percentage of patients clearing SARS-COV-2 RNA by Day 7, compared to placebo. The incidence of adverse events was similar in the two groups. Primary events in the study happened a median of 5 days (interquartile range 3 to 7 days) after randomization. The treatment effect for peginterferon lambda was more pronounced in patients who were treated within 3 days of symptom onset.

Peginterferon lambda was consistent in the direction of effect on all secondary outcomes. Risk of COVID-19 hospitalization or all-cause death was reduced by 47% (hazard ratio, 0.53, 95% Bayesian credible interval 0.31 to 0.91) in participants receiving peginterferon lambda. In patients receiving treatment within 3 days of symptom onset, greater treatment effects were observed in the peginterferon lambda group, including 65% reduction of COVID-19 related hospitalization (hazard ratio 0.35, 95% Bayesian credible interval 0.15 -0.75), 81% risk reduction in all-cause death (relative risk 0.19 [0/567 vs 3/590], 95% Bayesian credible interval 0.01-1.57) and 89% risk reduction among unvaccinated patients (hazard ratio, 0.11; 95% Bayesian credible interval, 0.01 to 0.83). There was one COVID-19-related death in the peginterferon lambda group and four in the placebo group. Incidence of any treatment emergent adverse events was similar between peginterferon lambda and placebo groups, which were primarily injection site reactions.

“These data demonstrate the potential of peginterferon lambda to confer a meaningful benefit for patients with COVID-19 and suggests potential for other respiratory viral infections,” said David Apelian MD, PhD, Interim CEO, Eiger. “We have over 100,000 peginterferon lambda syringes readily available with additional manufacturing intermediates to support a capacity of >10 million units if needed. We are grateful to the clinical trial participants and investigators for which none of this would be possible. In the context of our ongoing portfolio prioritization process, we continue to explore opportunities for ex-US emergency use of peginterferon lambda for COVID-19.”

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 Drug 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, NCT04967430) 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 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 identifying registration pathways for peginterferon lambda for COVID-19 and other respiratory viral infections; our capability to provide sufficient quantities of any of our product candidates to meet anticipated full-scale commercial demands; our ability to finance, independently or through collaborations, the continued advancement of our development pipeline and product launch; 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 September 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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