Eiger BioPharmaceuticals Provides Update on Plans for Emergency Use Authorization Application Following FDA Feedback

PALO ALTO, Calif., October 5, 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 announced that, following feedback from the U.S. Food and Drug Administration (FDA), the company will not submit an emergency use authorization (EUA) application of peginterferon lambda for the treatment of patients with mild-to-moderate COVID-19.

Following Eiger's press release on September 6, 2022, the company submitted a pre-EUA meeting request to FDA, as well as additional morbidity and mortality outcomes data and analyses from the investigator-sponsored *TOGETHER* study. This included further statistical modeling and efficacy analyses of the study's primary and secondary endpoints and long-term follow-up data that the company believes continue to support the initial positive topline outcomes reported in March. In response, FDA denied the request for a pre-EUA meeting. Citing its concerns about the conduct of the *TOGETHER* study, FDA concluded that any authorization request based on these data is unlikely to meet the statutory criteria for issuance of an EUA in the current context of the pandemic.

FDA suggested that, given peginterferon lambda's mechanism of action and the ongoing need for improved COVID-19 therapeutics, Eiger consider requesting an end-of-Phase 2 meeting to discuss a company-sponsored pivotal trial that could support an eventual Biologics License Application (BLA). Eiger is evaluating next steps for this program in the U.S., as well as ex-U.S. emergency use authorization pathways, and strategic options for continued development of peginterferon lambda for COVID-19 and other respiratory viral infections.

"While we are disappointed that FDA will not consider an EUA application based on results generated from the *TOGETHER* study, we continue to have strong conviction in the potential of peginterferon lambda to confer a meaningful benefit for patients with COVID-19 and other respiratory viral infections," said David Cory, President and CEO, Eiger. "COVID-19 related deaths remain alarmingly high around the globe, including in the U.S. where, according to recent data from the Centers for Disease Control and Prevention, approximately 400 people die every day from this disease."

Eiger is advancing a late-stage pipeline of multiple FDA Breakthrough Therapy designated programs in Phase 3, including lonafarnib and peginterferon lambda for hepatitis delta virus (HDV) infection, and avexitide for congenital hyperinsulinism. The company expects to report topline data from *D-LIVR,* Eiger's landmark Phase 3 study of lonafarnib-based regimens for HDV, by year end.

About *TOGETHER* Study

TOGETHER is an independent multi-center, investigator-sponsored, randomized, placebo-controlled adaptive platform Phase 3 study evaluating therapeutics in newly diagnosed, high-risk, non-hospitalized patients with mild-to-moderate 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. The study was ongoing at the time the peginterferon lambda arm was added. The evaluation of peginterferon lambda versus placebo was the second largest study to date of a COVID-19 therapeutic of > 1,900 patients. Eligibility criteria required that all patients had laboratory-confirmed mild or moderate COVID-19 and were randomized within seven days of symptom onset. The study enrolled patients regardless of vaccination status or variant strain of SARS-CoV-2. The primary endpoint was a reduction in risk of clinical outcome comparing hospitalizations or emergency room visits greater than six hours after a single subcutaneous injection of peginterferon lambda versus placebo through Day 28. A key secondary endpoint was reduction in risk of hospitalizations or death in patients when dosed within three days of symptom onset. 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 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.

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 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 obtaining alignment on a registration-enabling study from the FDA for peginterferon lambda for COVID-19; the potential actions of FDA and ex-U.S. regulatory authorities regarding the continued development of peginterferon lambda for COVID-19 and other respiratory viral infections; 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 independently or through collaborations the continued advancement of our development pipeline, including the peginterferon lambda; expectations regarding the timing and availability of topline data from our Phase 3 *D-LIVR* study in HDV; 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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