Eiger Announces Publication of Phase 2 PREVENT Study Results of Avexitide in Post-Bariatric Hypoglycemia in Journal of Clinical Endocrinology & Metabolism

- Primary and Secondary Endpoints Achieved with Statistical Significance
- FDA and EMA Concurrence on Single Pivotal Trial Toward Registration

PALO ALTO, Calif., Feb. 23, 2021 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc (Nasdaq: EIGR), a commercial-stage biopharmaceutical company focused on the development and commercialization of foundational therapies for Hepatitis Delta Virus (HDV) infection, today announced that positive results from the Phase 2 **PREVENT** study of Avexitide in patients with severe Post-Bariatric Hypoglycemia (PBH) were published in *Journal of Clinical Endocrinology & Metabolism* (Craig, C.M. et al, 2021).

PREVENT is the first randomized placebo-controlled study to evaluate the efficacy of a pharmacologic agent for patients with PBH in the outpatient setting. PREVENT investigated the safety and efficacy of Avexitide administered as 30 mg twice daily (BID) or 60 mg once daily (QD) subcutaneous (SC) injections in post-bariatric surgical patients who experience chronic, dangerously low, postprandial blood glucose levels, known as post-bariatric hypoglycemia or PBH.

Patients with severe PBH experience frequent postprandial episodes of hypoglycemia accompanied by neuroglycopenic signs and symptoms, including altered mental status, visual changes, motor incoordination, loss of consciousness, and seizures, putting patients at risk for injury or death from falls, motor vehicle accidents, or prolonged hypoglycemia and rendering many unable to drive, work, live alone, or care for dependents. Avexitide is a targeted, first-in-class, GLP-1 antagonist in development for the treatment of hyperinsulinemic hypoglycemia conditions, including PBH and congenital hyperinsulinism (CHI), disorders for which there are no approved treatments.

Primary endpoint was met with statistical significance by both dosing regimens. During hypoglycemia provocation in the clinical setting, the mean plasma glucose nadir was increased by 21% (p=0.001) and 26% (p=0.0002) following Avexitide 30 mg and 60 mg dosing, respectively, compared to placebo, corresponding to 50% and 75% fewer participants requiring rescue. Consistent with Avexitide's mechanism of action, peak insulin was reduced by 23% (p=0.029) and 21% (p=0.042) following Avexitide 30 mg and 60 mg dosing, respectively.

Metabolic and clinical parameters were also monitored during each patient's daily routine in the outpatient setting as assessed by self-blood glucose monitoring (SBGM), electronic diary, and blinded continuous glucose monitoring (CGM). Patients experienced significantly fewer Levels 1-3 hypoglycemia events during Avexitide treatment, defined, respectively as SBGM <70 mg/dL, SMBG <54 mg/dL, and a severe event characterized by altered mental and/or physical functioning requiring assistance. Patients also demonstrated reductions in percent time in hypoglycemia during diurnal periods (8 am to midnight) and number of hypoglycemia events as measured by CGM.

Avexitide was well-tolerated in this study. The most common adverse events were injection site bruising, nausea, and headache, all of which occurred with lower frequency during Avexitide vs. placebo treatment.

Eiger previously reported topline data from this study on March 25, 2019.

"Avexitide treatment demonstrated significant and consistent improvements across multiple clinical and metabolic parameters, as measured both in the clinical setting during hypoglycemia provocation and in the patient home setting under 'real world' conditions. Significant improvements in primary and secondary endpoints were observed, with reductions in postprandial hyperinsulinemic hypoglycemia during mixed meal provocation," said Colleen Craig, MD, Avexitide Program Lead at Eiger. "Significant improvements were also observed in the home setting, with fewer hypoglycemia events and less time spent with dangerously low glucose levels. Avexitide may represent a first promising treatment for patients with severe PBH."

Eiger has received concurrence from FDA and EMA on a single Phase 3, registration-enabling study of Avexitide in PBH, including overall study design, study size and endpoints.

About Avexitide

Avexitide is a well-characterized, first-in-class, 31-amino acid GLP-1 antagonist that selectively targets and blocks GLP-1 receptors, normalizing insulin secretion by the pancreas, and thereby reducing postprandial hypoglycemia. Avexitide is Phase 3 ready and has received concurrence from FDA and EMA on a single Phase 3, registration-enabling study of Avexitide in severe

PBH. Avexitide has been granted Breakthrough Therapy Designation by the FDA, as well as Orphan Drug Designation in the U.S. by the FDA for the treatment of hyperinsulinemic hypoglycemia and Orphan Drug Designation by the EMA for the treatment of non-insulinoma pancreatogenous hypoglycemia syndrome (NIPHS). Both of these orphan designations include PBH. Avexitide has never been approved or commercialized for any indication. More information on Avexitide clinical trials may be found at www.clinicaltrials.gov.

About PREVENT

Eighteen patients with refractory, severe PBH were enrolled across five U.S. academic centers and dosed as outpatients in the PREVENT study. All patients received placebo SC injections for 14 days in a single-blinded manner followed by Avexitide SC 30 mg BID injections for 14 days and 60 mg QD injections for 14 days, for a total of 28 days active dosing, in a double-blinded to dose, cross-over design.

About Post-Bariatric Hypoglycemia (PBH)

Approximately 150,000-200,000 bariatric surgical procedures are performed each year in the United States, and another 100,000 are performed each year in Europe. The estimated prevalence of PBH is approximately 30,000 in the United States and approximately 25,000 in the European Union. As the number of bariatric surgeries to treat obesity and related comorbidities has increased, so too has the number of individuals who experience PBH, with symptoms typically developing one or more years following surgery. PBH can occur with a range of severity in post-bariatric surgery patients. Severe hypoglycemia results in neuroglycopenic outcomes (altered mental status, loss of consciousness, seizures, coma) which are unresponsive to diet modification. Severe PBH can be debilitating with a significant negative impact on quality of life. There is no approved treatment for PBH.

About Eiger

Eiger is a commercial-stage biopharmaceutical company focused on the development and commercialization of foundational therapies for Hepatitis Delta Virus (HDV) infection, the most serious form of human viral hepatitis.

Eiger is developing two complementary treatments for HDV. 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 approval. A Marketing Authorization Application (MAA) is under review by the European Medicines Agency (EMA). Outside the U.S., Eiger's established global Managed Access Program, expected to span greater than 40 countries, ensures all children and young adults with Progeria and Progeroid Laminopathies have access to treatment.

For additional information about Eiger, 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 "believe," "will," "may," "estimate," "continue," "anticipate," "contemplate," "intend," "target," "project," "should," "plan," "expect," "predict," "could," "potentially" 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, our anticipating significant milestones in 2021, the timing of our ongoing and planned clinical development, including our ability to support the launch of a new product and ship to specialty pharmacies; the sufficiency of our cash, cash equivalents and investments to fund our operations through at least Q4 2023;our development programs for Zokinvy generally; and the potential approval of Zokinvy in jurisdictions outside of the U.S., including the EU; the risks related to the commercialization of Zokinvy, our ability to manufacture sufficient quantities of Zokinvy, and the commercial launch of Zokinvy in the U.S., the market potential for Zokinvy as a treatment for Progeria and processing-deficient Progeroid Laminopathies; our progression and enrollment of our Phase 3 D-LIVR study in HDV; our ability to maintain supply of our commercial and clinical trial materials; our plans to advance Lambda in HDV in the U.S. and EU; our ability to transition into a commercial stage biopharmaceutical company; our ability to finance the continued advancement of our development pipeline products; 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 September 30, 2020 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.

Investors and Media:

Ingrid Choong, PhD
Sr VP, Clinical Development
Email: ichoong@eigerbio.com
Phone : 1-650-619-6115

Sri Ryali
CFO
Email: sryali@eigerbio.com
Phone: 1-650-272-6138

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