Eiger BioPharmaceuticals Announces New Data Supporting Broader Potential of Avexitide in Patients with Post-Bariatric Hypoglycemia and Hyperinsulinemic Hypoglycemia After Gastrointestinal Surgeries

- *Data presented in oral presentation at ENDO 2022 on June 11*
- *Avexitide significantly reduced the number of hypoglycemia events and the amount of time spent in hypoglycemia*
- *Study included patients who had undergone gastric bypass, vertical sleeve, total gastrectomy, or Nissen fundoplication procedures*

Palo Alto, Calif., June 13, 2022 -- Eiger BioPharmaceuticals, Inc. (Nasdaq: EIGR), a commercial-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure hepatitis delta virus (HDV) and other serious diseases, today announced Phase 2b results of avexitide in patients with post-bariatric hypoglycemia (PBH) and hyperinsulinemic hypoglycemia (HH) after other gastrointestinal surgeries, demonstrating statistically significant reductions in hypoglycemia and meeting the primary and secondary endpoints of the study. The data were presented by Marilyn Tan, MD, Clinical Associate Professor of Medicine at Stanford University School of Medicine, in an oral presentation on June 11 at the Endocrine Society (ENDO) 2022 meeting in Atlanta, Georgia.

“Patients suffering from hypoglycemia after bariatric and other gastrointestinal surgeries often experience debilitating symptoms and worsening in quality of life. With no approved treatments, current approaches such as nutrition therapy or off-label use of pharmacotherapies have limited efficacy and are often poorly tolerated,” said Dr. Tan. “Avexitide led to a significant reduction in the occurrence and extent of hypoglycemia, confirming results previously observed in gastric bypass patients, and demonstrated comparable or greater responses among patients with severe hypoglycemia after sleeve gastrectomy, total gastrectomy or Nissen fundoplication. GLP-1 antagonism with avexitide represents a logical therapeutic approach, based on the role of GLP-1 in mediating hyperinsulinemic hypoglycemia, and I look forward to its continued development as a treatment option that could make a meaningful difference in the lives of patients.”

“These data further support the potential for avexitide as a targeted treatment to prevent hypoglycemia associated with gastrointestinal surgery, with consistent improvements observed across all surgical subtypes studied,” added Colleen Craig, MD, Vice President, Metabolic Diseases, Eiger. “Together with our promising results in patients with congenital hyperinsulinism, these new data build a solid foundation for the role of GLP-1 in mediating hyperinsulinemic hypoglycemia. We are pleased to be initiating our first pivotal Phase 3 clinical program for avexitide this year.”

In April, Eiger announced it is initiating the Phase 3 *AVANT* registrational program for avexitide in congenital hyperinsulinism (HI) this year. Avexitide has been granted Orphan Drug designation in the

U.S. by FDA for the treatment of hyperinsulinemic hypoglycemia (which includes HI) and has also been granted Rare Pediatric Disease designation making it eligible for a priority review voucher upon regulatory approval. Avexitide is the only investigational therapy for HI that has been granted Breakthrough Therapy designation by FDA.

Phase 2b Trial Results

This Phase 2b, open-label, investigator-initiated, cross-over study (NCT04652479) assessed the safety and efficacy of avexitide in hyperinsulinemic hypoglycemia after bariatric or other gastrointestinal surgeries. Sixteen patients with a history of recurrent hypoglycemia refractory to medical nutrition therapy (MNT) and exhibiting at least two severe hypoglycemia events while adhering to MNT over a 14-day period were included. Metabolic and symptomatic parameters were assessed by self-monitoring of blood glucose (SMBG), electronic diary (eDiary) and blinded continuous glucose monitoring (CGM) during 14 days of MNT as compared to 14 days of MNT + avexitide administered by subcutaneous injection at a dose of 45 mg twice daily or 90 mg once daily for a total of 28-days of treatment.

The primary and secondary endpoints, which measured frequency of hypoglycemia and amount of time in hypoglycemia, were met with statistical significance. Compared with MNT alone, avexitide 45 mg twice daily and 90 mg once daily reduced the rate of Level 1 hypoglycemia (SMBG <70 mg/dL) by 54% (p=0.003) and 68% (p=0.0005), respectively; Level 2 hypoglycemia (SMBG <54 mg/dL) by 57% (p=0.003) and 53% (p=0.004), respectively; and Level 3 hypoglycemia (severe event characterized by altered mental and/or physical function requiring assistance, as captured by eDiary) by 68% (p=0.0003) and 66% (p=0.0003), respectively.

Objective assessment by blinded CGM, substantiated SMBG, and eDiary results, with both dosing regimens (45 mg BID and 90 mg QD) demonstrating significant reductions in hypoglycemia events (up to 65%) and time spent in hypoglycemia (up to 64%). A greater magnitude of effect was consistently observed with once daily (90 mg QD) than twice daily (45 mg BID) dosing, as measured by blinded CGM.

Avexitide was well-tolerated, with no serious adverse events or participant withdrawals. The most common adverse events were diarrhea, headache, and injection site reaction/bruising.

About Post-Bariatric Hypoglycemia and Hyperinsulinemic Hypoglycemia after Gastrointestinal Surgeries

Post-bariatric hypoglycemia (PBH) and other forms of hyperinsulinemic hypoglycemia (HH) after gastrointestinal surgeries are characterized by exaggerated secretion of glucagon-like peptide-1 (GLP-1) after meals, dysregulated secretion of insulin, and a rapid drop in blood sugar. Hypoglycemia typically occurs one to three hours after meals and is often accompanied by symptoms of brain glucose starvation (neuroglycopenia), such as blurred vision, confusion, speech difficulty, and incoordination.

Severe hypoglycemia events can result in serious outcomes such as loss of consciousness, falls, seizures, and motor vehicle accidents, putting patients at risk for death and disability. Recurrent hypoglycemia events can have serious implications on quality of life, including heightened fear of hypoglycemia and reduced functionality, such as ability to work, drive, and independently perform activities of daily living.

About Avexitide

Avexitide is an investigational, first-in-class glucagon-like peptide-1 receptor (GLP-1r) antagonist in development for the treatment of congenital hyperinsulinism (HI) and post-bariatric hypoglycemia (PBH). Avexitide has been granted Breakthrough Therapy designation for both HI and PBH.

By binding to the GLP-1r on pancreatic beta cells and preventing GLP-1r signaling, avexitide works upstream of beta cell insulin secretion to reduce dysregulated insulin secretion and the occurrence of hypoglycemia. By addressing underlying disease mechanisms, avexitide may offer a targeted approach to treating hypoglycemia in patients with hyperinsulinemic hypoglycemia, including HI and PBH. Eiger has developed a novel formulation of avexitide for subcutaneous injection.

About Eiger

Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure 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. Eiger is also developing peginterferon lambda as a therapeutic for COVID-19 and reported positive results from *TOGETHER,* a Phase 3 investigator-initiated study.

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 HI and PBH.

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 U.S. 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, our anticipated significant milestones in 2022; the timing of our ongoing and planned clinical development across our pipeline; our expectations regarding the commencement of a Phase 3 study of avexitide in congenital hyperinsulinism; our ability to finance the continued advancement of our development pipeline products; and the potential for success of any of our 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 Annual Report on Form 10-Q for the quarter ended March 31, 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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