



Eiger BioPharmaceuticals Announces Presentation of Positive Phase 2 Results of Avexitide in Congenital Hyperinsulinism at the American Diabetes Association Virtual 81st Scientific Session

- Primary Endpoint of Glucose Infusion Rate Achieved with Significance

Palo Alto, Calif., June 28, 2021 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq: EIGR), a commercial-stage biopharmaceutical company focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today announced an oral poster presentation of Phase 2 study results of Avexitide in congenital hyperinsulinism (HI) at the American Diabetes Association (ADA) 81st Scientific Session. Avexitide is a targeted, first-in-class, GLP-1 antagonist in development for the treatment of HI, an ultra-rare, life-threatening, pediatric disorder of persistent hypoglycemia that results in irreversible brain damage in up to 50% of children.

This Phase 2 study measured the effect of avexitide infusion on glucose requirements in 13 neonates and infants with HI. Patients were randomized to single ascending doses of avexitide or placebo by continuous IV infusion in a crossover study design. Primary endpoint was glucose infusion rate (GIR). Avexitide significantly reduced GIR when evaluated across dose levels ($p=0.0087$) with dose-dependent improvements observed. Avexitide 100, 200 and 1,000 pmol/kg/min ascending doses demonstrated 1.3 (15%), 2.9 (24%), and 4.3 (56%) mg/kg/min reductions in GIR relative to placebo, respectively, and entirely abolished the glucose requirement in 50% of patients at the top dose. Avexitide was well-tolerated in this study. Adverse events were typically mild in severity and transient, and there were no serious adverse events.

This study was led by Diva De León, MD, Professor of Pediatrics and Chief of the Division of Endocrinology and Diabetes at Children's Hospital of Philadelphia (CHOP).

"Avexitide infusion demonstrated significant reductions in glucose infusion requirements to maintain euglycemia or normal glucose levels in neonates and infants," said Colleen Craig, MD, Vice President of Metabolic Diseases at Eiger. "Avexitide represents a promising, targeted approach for the treatment of congenital hyperinsulinism, an urgent, unmet medical need with no approved therapy."

“We are focused on completing all registration enabling activities to advance avexitide in congenital hyperinsulinism this year including regulatory concurrence, manufacturing, and device development,” said David Cory, President and CEO at Eiger. “Our goal is to be Phase 3 ready as early as 2022.”

About Phase 2 Study NCT00835328

In this Phase 2 trial, 13 neonates and infants, ages 11 days to 5 months with diazoxide-unresponsive HI, were randomized to single ascending doses of avexitide or placebo by continuous IV infusion for up to 12 hours in a crossover study design. Plasma glucose was monitored every 30 minutes with GIR adjusted hourly to maintain euglycemia. The primary endpoint was GIR. Relationships between avexitide exposure and absolute difference in GIR during avexitide vs. placebo were evaluated.

About Avexitide

Avexitide is a 31-amino acid peptide that selectively targets and blocks GLP-1 receptors, reducing dysregulated insulin secretion by the pancreas, and thereby reducing fasting and postprandial hypoglycemia. Proof of concept has been demonstrated in 39 patients across three Phase 2 studies in neonates, children and adolescents with congenital hyperinsulinism. Avexitide has been granted Orphan Drug designation by the FDA for the treatment of hyperinsulinemic hypoglycemia (which includes HI), Orphan Drug designation by the EMA for the treatment of congenital hyperinsulinism and Rare Pediatric Disease designation by the FDA.

Avexitide is also in development for post-bariatric hypoglycemia (PBH). Four clinical studies have been completed in 54 patients with PBH. Eiger has received concurrence from FDA and EMA on a single Phase 3 study for patients with 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 broad orphan designations include PBH.

Avexitide is not approved or commercialized for any indication. More information on avexitide clinical trials may be found at www.clinicaltrials.gov.

About Congenital Hyperinsulinism (HI)

Congenital hyperinsulinism (HI) is a rare, genetic, pediatric metabolic disorder characterized by severe fasting and protein-induced hypoglycemia due to dysregulated secretion of insulin by the pancreas. Repeat episodes and/or dangerously low blood sugars increase the risk of neurological and developmental complications, including persistent feeding problems, learning disabilities, recurrent seizures, brain damage, or

even death. Existing medical options are often ineffective or are associated with substantial side effects that discourage compliance and lead to suboptimal treatment outcomes. Subtotal pancreatectomy is an option, but this approach can be associated with life-threatening complications, does not immediately fully resolve hypoglycemia in most patients, and ultimately leads to the development of lifelong insulin-dependent diabetes.

About Eiger

Eiger is a commercial-stage biopharmaceutical company focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases.

Eiger's lead clinical programs are focused on the development of foundational therapies for Hepatitis Delta Virus (HDV) infection, the most serious form of viral hepatitis, with two complementary HDV treatments. Lonafarnib is a first-in-class, oral prenylation inhibitor in a global Phase 3 trial. Peginterferon lambda is a first-in-class, type III, well-tolerated 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 approved product. A Marketing Authorization Application (MAA) is under review by the European Medicines Agency (EMA).

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

Note Regarding Forward-Looking Statements

This press release contains "forward-looking" statements that involve substantial risks and uncertainties. Words such as "will," "may," "continue," "plan," "expect," "could," "potential" and similar expressions are intended to identify forward-looking statements. These statements include those regarding the potential for Avexitide to be a first-in-class GLP-1 antagonist for the treatment of HI, as well as its ability to achieve adequate steady-state plasma concentrations to lower GIR requirements and be a well-tolerated approach to treatment of HI; our future development plans for Avexitide in HI and PBH; and the potential for success of any of our product candidates. These forward-looking statements are subject to risks and uncertainties, including, without limitation, risks and uncertainties associated with the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success, including risks related to failure or delays in successfully initiating, enrolling or completing clinical studies; the risks that results obtained in clinical trials to date may not be inductive of results obtained in ongoing or future trials; the time-consuming and uncertain regulatory approval process; the sufficiency of Eiger's cash resources; and other risks and

uncertainties described in the "Risk Factors" sections in the Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 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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