



Eiger Announces First Patient Dosed in Phase 2 PREVENT Study of Exendin 9-39 in Patients Suffering from Post-Bariatric Hypoglycemia

PALO ALTO, Calif., March 26, 2018 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq: EIGR), focused on the development and commercialization of therapies for rare diseases, today announced the first patient dosed in PREVENT, a Phase 2, multi-center study of subcutaneous (SC) exendin 9-39 in post-bariatric surgical patients who experience dangerously low, postprandial blood glucose levels (hypoglycemia) known as post-bariatric hypoglycemia (PBH). PREVENT will target enrollment of 20 PBH patients across U.S. sites.

Exendin 9-39 is a first in class, GLP-1 antagonist in development as a convenient, novel liquid formulation for SC administration for PBH. Eiger has previously announced positive clinical results with exendin 9-39 in PBH patients across 3 proof-of-concept clinical studies involving 36 patients demonstrating that pharmacologic blockade of GLP-1 prevents hypoglycemia in post-bariatric surgical patients.

"We are pleased to begin the first multi-center study of exendin 9-39 and dose our first PBH patient in the PREVENT study," said Lisa Porter, MD, Senior Vice President, Metabolic Diseases. "The PREVENT study will test multiple doses and evaluate durability of effect of exendin 9-39 for longer treatment periods in patients suffering from PBH. Exendin 9-39 is the first potential targeted therapy for PBH, a significant unmet medical need."

About the PREVENT Study

The PREVENT study is a Phase 2, multicenter, randomized, single-blind, placebo-controlled cross-over study to assess the efficacy and safety of exendin 9-39 in patients with post-bariatric hypoglycemia. Participants will be randomized and assigned in a 1:1 ratio to one of two treatment arms. All participants will receive 2 dosing regimens of exendin 9-39 and matching placebo, self-administered via subcutaneous (SC) injection. Participants will undergo in-clinic mixed meal tolerance test (MMTT) provocations with concomitant blood draws and symptom assessments.

About Insulin, GLP-1, and Exendin 9-39

Insulin is the principal physiologic hormone secreted to control high blood glucose levels. Abnormal increases in insulin secretion can lead to profound hypoglycemia (low blood sugar), a state that can result in significant morbidities, including seizures, brain damage, and coma. GLP-1 is a gastrointestinal hormone that is released postprandially from the intestinal L-cells. GLP-1 binds to GLP-1 receptors on the beta cells of the pancreas and increases the release of insulin. In patients with PBH, GLP-1-mediated insulin secretion is dysfunctionally exaggerated.

Exendin 9-39 is a 31-amino acid peptide that selectively targets and blocks GLP-1 receptors, normalizing insulin secretion by the pancreas, and thereby reducing postprandial hypoglycemia. Exendin 9-39 is being investigated as a novel treatment for PBH. Exendin 9-39 has been granted orphan designation in the European Union by the EMA for the treatment of non-insulinoma pancreatogenous hypoglycemia syndrome (NIPHS) and orphan designation in the United States by the FDA for the treatment of hyperinsulinemic hypoglycemia. Both of these broad designations include PBH. Exendin 9-39 has never been approved or commercialized for any indication. More information on exendin 9-39 clinical trials may be found at www.clinicaltrials.gov.

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. Mild to moderate hypoglycemia may be managed largely through dietary carbohydrate restriction, whereas 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 pharmacologic therapy.

About Eiger

Eiger is a clinical-stage biopharmaceutical company focused on the development and commercialization of targeted therapies for rare diseases. We are committed to translational innovation and the development of well-characterized drugs acting on newly identified or novel targets. Our mission is to systematically reduce the time and cost of the drug development process to more rapidly deliver important medicines to patients with rare diseases. Our lead program in Hepatitis Delta Virus (HDV) infection, is

moving into Phase 3 with a single, pivotal trial planned to initiate by the end of the year. 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. 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 ongoing and planned clinical development, the timing of and our ability to initiate or enroll clinical trials, and our ability to make regulatory filings and obtain and maintain regulatory approvals for lonafarnib, ubenimex, PEG IFN lambda, exendin 9-39 and our other product candidates, our intellectual property position, the potential safety, efficacy, reimbursement, convenience clinical and pharmaco-economic benefits of our product candidates, commercial opportunities, including potential market sizes and segments, our ability to commercialize, expectations regarding clinical trial data and FDA outcomes, including whether we will be able to reach agreement on a single pivotal study for lonafarnib and the nature and scope of any such study to support approval, our results of operations, cash needs, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including the risks described in the "Risk Factors" sections in the Annual Report on Form 10-K for the year ended December 31, 2017 and Eiger's periodic reports filed with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.

SOURCE Eiger BioPharmaceuticals, Inc.

Investors: Ingrid Choong, PhD

Email: ichoong@eigerbio.com

Phone: 1-650-619-6115

 View original content with multimedia: <http://www.prnewswire.com/news-releases/eiger-announces-first-patient-dosed-in-phase-2-prevent-study-of-exendin-9-39-in-patients-suffering-from-post-bariatric-hypoglycemia-300619053.html>

SOURCE Eiger BioPharmaceuticals, Inc.

