



## **Eiger BioPharmaceuticals Announces Completion of Enrollment in Phase 2 PREVENT Study of Avexitide (formerly Exendin 9-39) in Patients Suffering from Post-Bariatric Hypoglycemia**

PALO ALTO, Calif., Aug. 13, 2018 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for rare diseases, announced completion of enrollment of the Phase 2 PREVENT study. PREVENT is a multi-center, placebo-controlled study investigating the safety and durability of effect of subcutaneous (SC) avexitide (formerly exendin 9-39) in post-bariatric surgical patients who experience dangerously low, postprandial blood glucose levels (hypoglycemia) known as post-bariatric hypoglycemia (PBH). A total of 18 patients were enrolled across five study sites in the United States. There is currently no FDA approved pharmacologic therapy for PBH.

At Eiger's request, avexitide has recently been adopted by the United States Adopted Name (USAN) Council and will be the *International Nonproprietary Name (INN)*, which is used to identify pharmaceutical substances or active pharmaceutical ingredients. Each *INN* is a unique *name* that is globally recognized. A *nonproprietary name* is also known as a generic *name*. Eiger plans to seek approval for a proprietary name or brand name during Phase 3 development.

Avexitide 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 results from 3 separate proof of concept clinical studies involving 36 PBH patients treated with avexitide. Pharmacologic blockade of GLP-1 with avexitide has been shown to prevent hypoglycemia in post-bariatric surgical patients.

"Our previous clinical studies dosed PBH patients with avexitide for up to 3 days and demonstrated positive early proof of concept in the prevention of post-bariatric hypoglycemia during an oral glucose tolerance test (OGTT)," said Lisa Porter, MD, Chief Medical Officer, Metabolic Diseases at Eiger. "PREVENT is our first out-patient study evaluating multiple doses and durability of effect of avexitide for a treatment period of 28-days in patients suffering from PBH. We look forward to reporting top line results of the PREVENT study later this year."

### **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 28-day dosing of avexitide in patients with post-bariatric hypoglycemia. Participants were randomized and assigned in a 1:1 ratio to one of two treatment arms. All participants received 2 dosing regimens of avexitide and matching placebo, self-administered via subcutaneous (SC) injection in an out-patient setting. Participants underwent in-clinic mixed meal tolerance test (MMTT) provocations with concomitant blood draws and symptom assessments. Outcomes include improvement in plasma glucose nadir levels and patient reported symptom scores.

### **About Insulin, GLP-1, and Avexitide**

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.

**Avexitide (formerly 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. Avexitide is being investigated as a novel treatment for PBH. Avexitide 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. Avexitide has never been approved or commercialized for any indication. More information on avexitide clinical trials may be found at [www.clinicaltrials.gov](http://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 innovate by developing well characterized drugs acting on newly identified or novel targets in rare diseases. 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](http://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, including whether the D-LIVR study will be supported by the FDA as a single, pivotal study to support registration; the timing of and our ability to initiate or enroll clinical trials, including whether our D-LIVR study can be advanced by the end of this year; whether PREVENT Phase 2 study results will support further development of avexitide; our ability to make timely regulatory filings and obtain and maintain regulatory approvals for lonafarnib as a single agent or in combination, ubenimex, PEG IFN lambda, avexitide and our other product candidates; our intellectual property position; and the potential safety, efficacy, reimbursement, convenience clinical and pharmaco-economic benefits of our product candidates as well as the commercial opportunities, including potential market sizes and segments; our ability to finance the continued advancement of our development pipeline products, including our results of operations, cash available, financial condition, liquidity, prospects, growth and strategies; 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 the risks described in the "Risk Factors" sections in the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 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.

Investors: Ingrid Choong, PhD

Email: [ichoong@eigerbio.com](mailto:ichoong@eigerbio.com)

Phone: 1-650-619-6115

View original content with multimedia: <http://www.prnewswire.com/news-releases/eiger-biopharmaceuticals-announces-completion-of-enrollment-in-phase-2-prevent-study-of-avexitide-formerly-exendin-9-39-in-patients-suffering-from-post-bariatric-hypoglycemia-300695866.html>

SOURCE Eiger BioPharmaceuticals, Inc.

