



## **Eiger BioPharmaceuticals Announces Oral Presentation of Phase 2 PREVENT Study Results of Avexitide in Post-Bariatric Hypoglycemia at Endocrine Society Meeting (ENDO) 2019**

- **Statistically Significant Reduction in Hyperinsulinemic Hypoglycemia**
- **Reduced Rates of Hypoglycemia and Rescue in Outpatient Setting**

PALO ALTO, Calif., March 25, 2019 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today announced Phase 2 PREVENT study results in an oral presentation at ENDO 2019 in New Orleans. PREVENT is a multi-center, placebo-controlled, outpatient study investigating the safety and durability of 28-day dosing of avexitide subcutaneous (SC) injections in post-bariatric surgical patients who experience chronic, dangerously low, postprandial blood glucose levels, known as post-bariatric hypoglycemia or PBH.

Severe PBH can result in altered mental status, loss of consciousness, seizures, and coma. Avexitide is a targeted, first-in-class, GLP-1 antagonist in development for the treatment of PBH, a disorder for which there is no approved treatment.

"Targeted blockade of GLP-1, which is known to be elevated in patients suffering from PBH, significantly reduced postprandial insulin peaks and increased postprandial glucose nadir levels in both once daily and twice daily dosing regimens of avexitide," said Dr. Clare Lee, Assistant Professor of Medicine in Division of Endocrinology, Diabetes and Metabolism at Johns Hopkins University. "The PREVENT results are promising for patients suffering from post-bariatric hypoglycemia, a debilitating complication of bariatric surgery for which an effective treatment is urgently needed."

The primary efficacy endpoint of improved postprandial glucose nadir during mixed meal tolerance testing (MMTT) was achieved with statistical significance with avexitide 30 mg BID (57.1 vs 47.1 mg/dL;  $p = 0.001$ ) and 60 mg QD (59.2 vs 47.1 mg/dL;  $p = 0.0002$ ), with fewer participants requiring glycemic rescue during each of the active dosing regimens than during placebo dosing. The secondary endpoint of reduced postprandial insulin peak during MMTT was also statistically significant with avexitide 30 mg BID (349.5 vs 454.5  $\mu$ U/mL;  $p < 0.03$ ) and 60 mg QD (357.2 vs 454.5  $\mu$ U/mL;  $p = 0.04$ ).

Improvements in metabolic and clinical parameters were also monitored during each patients' daily routine in the outpatient setting and assessed by self-blood glucose monitoring (SBGM), electronic diary, and continuous glucose monitoring (CGM). Patients experienced fewer episodes of hypoglycemia (hypoglycemia symptoms confirmed by SBGM concentrations of  $<70$  mg/dL), severe hypoglycemia (neuroglycopenic symptoms confirmed by SBGM concentrations  $<55$  mg/dL) and a reduced rate of rescue during both dosing regimens of avexitide as compared to placebo. Rescue is defined as self- or third-party administration of oral or g-tube intake to prevent or treat hypoglycemia. Patients also demonstrated reductions in percent time in hypoglycemia during diurnal periods (8 am to midnight) and number of episodes of hypoglycemia as measured by CGM.

Avexitide was well-tolerated in this study. There were no treatment-related serious adverse events and no participant withdrawals. Adverse events were typically mild to moderate in severity. The most common adverse events were injection site bruising, nausea, and headache, all of which occurred with lower frequency during avexitide dosing periods than during the placebo dosing period.

"Avexitide treatment led to statistically significant improvements on both the primary and secondary endpoints in this 28-day outpatient study, reducing postprandial hyperinsulinemic hypoglycemia and associated signs and symptoms," said Lisa Porter, MD, Chief Medical Officer of Metabolic Diseases at Eiger. "We now look forward to meeting with regulatory authorities to discuss next steps to advance this much-needed therapy."

### **About Avexitide**

Avexitide 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 Drug designation in the European Union by the EMA for the treatment of non-insulinoma pancreatogenous hypoglycemia syndrome (NIPHS) and Orphan Drug designation in the U.S. 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 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 subcutaneous (SC) injections for 14 days in a single-blinded manner followed by avexitide SC 30 mg twice daily (BID) injections for 14 days and 60 mg once daily (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 late stage biopharmaceutical company focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases. We innovate by developing well-characterized drugs in 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.

The company's lead program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. Eiger is also preparing an NDA and MAA for lonafarnib to treat Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies with plans to file in 2019. 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 plans to complete enrollment of our D-LIVR study by the end of 2019, submit an NDA and MAA for Progeria and progeroid laminopathies in 2019, timing of end of treatment data in our LIFT study and progress our Phase 3 study in HDV; 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 the risks described in the "Risk Factors" sections in the Annual Report on Form 10-K for the year ended December 31, 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.

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