



## **Eiger Announces First Patient Dosed in Phase 2 Multiple Ascending Dose Study of Subcutaneous Exendin (9-39) in Patients with Hypoglycemia Post-Gastric Bypass Surgery**

### **Novel first-in-class GLP-1 antagonist targeted for rare hypoglycemic condition**

PALO ALTO, Calif., May 10, 2016 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for rare diseases, announced today that the first patient has been dosed in a Phase 2 study to evaluate subcutaneously administered exendin (9-39) in patients who experience dangerously low blood glucose levels (hypoglycemia) after undergoing gastric bypass surgery. Exendin (9-39) is a 31-amino acid peptide, which selectively targets and blocks glucagon like peptide-1 (GLP-1) receptors, normalizing insulin secretion by the pancreas, and thereby reducing hypoglycemia.



Stanford researchers have already demonstrated in proof-of-concept exploratory clinical studies with exendin (9-39) that pharmacologic blockade of GLP-1 prevents hypoglycemia in post-bariatric surgical patients and may represent the first targeted medical treatment for patients with post-gastric bypass hypoglycemia.

"Increasing numbers of obese patients are turning to gastric bypass surgery as an effective means to rapidly and sustainably reduce weight and as a critical healthcare intervention," said David Cory, President and CEO of Eiger. "Unfortunately, some of these bypass surgery patients develop a chronic condition leading to severe hypoglycemia after meals which cannot be managed by dietary modification or resolved by existing pharmacologic agents. A significant unmet medical need exists and there is no approved therapy."

### **About Exendin (9-39) Phase 2 Multiple Ascending Dose Study Design**

This is a randomized, blinded, multiple ascending dose study designed to evaluate four different doses of subcutaneously administered exendin (9-39) during a three-day repeat dosing period in sixteen patients with documented hypoglycemia after gastric bypass surgery. The study will assess control of hypoglycemia and associated symptoms during the three-day dosing period through metabolic testing pre- and post-treatment. Safety and tolerability will be monitored throughout the study. In addition, serial blood samples will be collected for pharmacokinetic and pharmacodynamic assessments. Various markers of drug activity will be assessed, including changes in glucose, insulin, C-peptide, and glucagon.

### **About Insulin, GLP-1, and Exendin (9-39)**

Insulin is the major 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. Glucagon-like peptide – 1 (GLP-1) is a gastrointestinal hormone that is released postprandially (after meals) from the intestinal L-cells, which binds to GLP-1 receptors on the beta cells of the pancreas and causes insulin release. In patients with hypoglycemia after gastric bypass surgery, GLP-1-mediated insulin secretion is exaggerated.

Exendin (9-39) is a competitive GLP-1 antagonist which blocks GLP-1 from binding to the GLP-1 receptor and reduces insulin secretion. Exendin (9-39) is being investigated as a novel treatment for bariatric surgery-induced hypoglycemia. A therapy that safely and effectively mitigates insulin-induced hypoglycemia has the potential to address a significant unmet therapeutic need for certain rare medical conditions associated with hyperinsulinism. Exendin (9-39) has never been approved or commercialized for any indication. The long-term efficacy and safety of exendin (9-39) has not been established yet. More information on exendin (9-39) clinical trials may be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About Hypoglycemia Post Gastric Bypass Surgery**

Approximately 150,000-200,000 bariatric surgical procedures are performed each year in the United States, and another 120,000 are performed each year in Europe. The estimated prevalence of bariatric surgery-induced hyperinsulinemic hypoglycemia is less than 200,000 in the US and less than 5 in 10,000 in the EU, and potentially eligible for Orphan Designation in the US and Europe. As the number of gastric bypass surgeries to treat severe obesity has increased, so too has the number of individuals

who experience postprandial hypoglycemia (low blood glucose following a meal) with symptoms developing months or years following the gastric bypass procedure. Postprandial hypoglycemia occurs with a range of severity in post-gastric bypass patients. The mild end of the spectrum may be managed largely through dietary modification. The most severe forms result in postprandial hyperinsulinemic hypoglycemia with neuroglycopenic symptoms (altered mental status, loss of consciousness, seizures) that cannot be managed through dietary modification. There is no approved pharmacologic therapy.

#### **About Eiger**

Eiger is a clinical-stage biopharmaceutical company committed to bringing to market novel products for the treatment of rare diseases. The company has built a diverse portfolio of well-characterized product candidates with the potential to address diseases for which the unmet medical need is high, the biology for treatment is clear, and for which an effective therapy is urgently needed.

#### **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, included in this press release regarding our strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives, intentions, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "will" and other words and terms of similar meaning. Examples of such statements include, but are not limited to, whether or not pegylated interferon lambda-1a or lonafarnib or ubenimex or exendin (9-39) may be further developed and approved, statements relating to the availability of cash for Eiger's future operations, Eiger's ability to develop its drug candidates for potential commercialization, the timing of the commencement and number and completion of Phase 2 trials and whether the products can be successfully developed or commercialized. 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 period ended December 31, 2015 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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