



## **Eiger Announces Positive Clinical Results of Single Ascending Dose Study of Subcutaneous Exendin (9-39) in Patients with Post-Bariatric Hypoglycemia**

**Oral Presentation at American Diabetes Association Meeting in New Orleans, LA**

PALO ALTO, Calif., June 13, 2016 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of therapies for rare diseases, announced today the presentation of positive results of a study evaluating subcutaneously administered exendin (9-39) in post-bariatric surgical patients who experience dangerously low, postprandial blood glucose levels (hypoglycemia) known as post-bariatric hypoglycemia (PBH). Results were delivered by Stanford researchers as an oral presentation at the American Diabetes Association 2016 annual meeting in New Orleans.



The study used a single ascending dose (SAD) design to examine the pharmacokinetics, pharmacodynamics, and local tolerability of three escalating doses of subcutaneous exendin (9-39). Eight subjects suffering from PBH were enrolled and administered oral glucose tolerance tests (OGTT) with and without subcutaneous exendin (9-39). Hypoglycemia was defined as a plasma glucose level of 50 mg/dL or less during OGTT. Prevention of hypoglycemia and reduction in hypoglycemic symptoms was achieved in all eight subjects at all dose levels of subcutaneous exendin (9-39). Conversely, without subcutaneous exendin (9-39), all eight subjects became hypoglycemic and required rescue during baseline OGTT when plasma glucose reached 50 mg/dL. Exendin (9-39) was well tolerated and no adverse reactions were noted. The principal investigator was Tracey McLaughlin, M.D., Associate Professor of Medicine (Endocrinology) at the Stanford University School of Medicine.

"Stanford researchers have now demonstrated in two separate clinical proof-of-concept studies, first using an intravenous infusion of exendin (9-39) and now using a subcutaneous injection of exendin (9-39), that pharmacologic blockade of glucagon-like peptide-1 (GLP-1) receptors prevents hypoglycemia in post-bariatric surgical patients during OGTT," said David Cory, President and CEO of Eiger. "A significant unmet medical need exists and exendin (9-39) represents the first potential targeted therapy for patients suffering from PBH."

### **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. GLP-1 binds to GLP-1 receptors on the beta cells of the pancreas and causes insulin release. In patients with PBH, GLP-1-mediated insulin secretion is 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 hypoglycemia. Exendin (9-39) is being investigated as a novel treatment for PBH. 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 Post-Bariatric Hypoglycemia (PBH)**

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 PBH is less than 200,000 in the United States and less than 5 in 10,000 in the European Union, within the population prevalence for Orphan Designation in the United States and European Union, alone or as a subset of hyperinsulinemic hypoglycemic disorders. As the number of bariatric surgeries to treat severe obesity has increased, so too has the number of individuals who experience PBH with symptoms developing one to several 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) that are unresponsive to diet 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 our periodic reports filed with the Securities and Exchange Commission. We assume no obligation to update any forward-looking statements, except as required by law.

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