



Eiger Announces Multiple Advances in Exendin 9-39 Program for the Treatment of Post-Bariatric Hypoglycemia (PBH)

- Positive Interim Data from Phase 2 Multiple-Ascending Dose Study**
- Novel Liquid Formulation of Exendin 9-39**
- US Orphan Designation for Hyperinsulinemic Hypoglycemia**

PALO ALTO, Calif., Dec. 12, 2016 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq: EIGR), focused on the development and commercialization of therapies for rare diseases, today announced clinical and regulatory advances in the development of exendin 9-39 for the treatment of post-bariatric hypoglycemia (PBH). Advances in the program included interim results of an ongoing Phase 2 multiple-ascending dose (MAD) study evaluating subcutaneous (SC) exendin 9-39 in post-bariatric surgical patients who experience dangerously low, postprandial blood glucose levels (hypoglycemia) known as PBH, plans to advance a newly developed novel liquid formulation of exendin 9-39, and granting of US orphan designation for exendin 9-39 in hyperinsulinemic hypoglycemia, a broad category of syndromes which includes PBH.

"We have previously demonstrated positive proof of concept results in two separate single-day dosing studies at Stanford, first using an intravenous infusion and more recently using a subcutaneous injection, that exendin 9-39 can prevent hypoglycemia in post-bariatric surgical patients during an oral glucose tolerance test (OGTT)," said Marilyn Tan, MD, Principal Investigator and Clinical Assistant Professor of Medicine at Stanford University School of Medicine. "We are encouraged by interim results of the ongoing MAD study with SC exendin 9-39, dosing up to 3 days with desired activity and tolerability in the dosing range. Exendin 9-39 represents the first potential targeted therapy for patients suffering from PBH, a significant unmet medical need."

The MAD study is a dose-ranging trial designed to examine efficacy, safety, and PK of multiple-ascending doses of SC exendin 9-39 after up to 3 days to prevent hypoglycemia and reduce hypoglycemic symptoms. Patients suffering from PBH are administered a baseline OGTT followed by administration of SC exendin 9-39 in a range of doses (0.05 to 0.4 mg/kg) for up to 3 days. Interim results for eleven patients who have completed up to 3 days of dosing were reported. All doses of exendin 9-39 led to an increase in glucose nadir (reduced magnitude of hypoglycemia) during OGTT on the last day of treatment. Patients administered SC exendin 9-39 doses ≥ 0.2 mg/kg demonstrated a mean 51% decrease in peak postprandial insulin levels, experienced desired therapeutic increases in glucose nadir, did not require rescue with IV dextrose, and experienced reduced neuroglycopenic (caused by a shortage of glucose in the brain) symptom scores. All doses administered were well-tolerated with headache or nausea as the only reported adverse events.

Eiger also reported the development of a proprietary, novel liquid formulation of exendin 9-39 which in dog studies has demonstrated a greater than two-fold increase in peak plasma concentrations compared to the original lyophilized powder of exendin 9-39. Development of a liquid formulation of exendin 9-39 represents an opportunity for lower dosing and once on the market, would eliminate the need for patients to dissolve powder in saline, a more convenient product presentation for patients. Eiger plans to evaluate the new exendin 9-39 liquid formulation in patients in the ongoing MAD study and also in a Phase 1 PK study scheduled for Q1 2017, both of which will inform the next, larger Phase 2 study planned for 2017.

In addition, Eiger announced today that exendin 9-39 has received Orphan Drug Designation from the US Food and Drug Administration (FDA) for the treatment of hyperinsulinemic hypoglycemia, a spectrum of congenital and acquired metabolic disorders characterized by inappropriately high insulin levels (hyperinsulinemia) and low blood glucose levels (hypoglycemia), which includes post-bariatric hypoglycemia (PBH).

These results and updates were presented and webcasted during a Key Opinion Leader event hosted by Eiger on December 9, 2016 entitled, "Post-Bariatric Hypoglycemia (PBH): Developing a Treatment." Playback is available on the Company website.

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 EU orphan designation by the EMA for the treatment of non-insulinoma pancreatogenous hypoglycemia syndrome (NIPHS) and US orphan designation by the FDA for the treatment of hyperinsulinemic hypoglycemia, and both of these broad designations include 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 SC injected exendin 9-39 have not yet been established. 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 12 to 18 months 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 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 identified, and for which an effective therapy is urgently needed. For more information, please visit the Company's website at 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, 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 lonafermin or ubenimex or exendin 9-39, including SC formulation, may be further developed and approved, whether Phase 2 studies of exendin 9-39 will show safety and activity consistent with early clinical results, including the interim results of the MAD study, or that the SC formulation will be consistent with results seen with IV exendin 9-39, 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. Eiger assumes no obligation to update any forward-looking statements, except as required by law.

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/eiger-announces-multiple-advances-in-exendin-9-39-program-for-the-treatment-of-post-bariatric-hypoglycemia-pbh-300376412.html>

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