Eiger Completes Enrollment in Phase 2 Multiple-Ascending Dose Study of Exendin 9-39 in Post-Bariatric Hypoglycemia Patients

PALO ALTO, Calif., June 6, 2017 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of therapies for rare diseases, today announced completion of enrollment of the 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 post-bariatric hypoglycemia (PBH). Results from 19 of 20 patients will be presented at the 2017 American Diabetes Association meeting in San Diego on June 11th.

"We have previously demonstrated positive proof of concept results in two separate single dose studies at Stanford, using an intravenous infusion and also a subcutaneous injection, that exendin 9-39 can prevent hypoglycemia in post-bariatric surgical patients during an oral glucose tolerance test (OGTT)," said Lisa Porter, MD, Senior Vice President, Metabolic Diseases at Eiger. "We are encouraged by previously presented interim results of the ongoing MAD study with SC exendin 9-39 dosing up to 3 days with desired activity and tolerability, and look forward to presentation of additional results at the ADA meeting, including data with Eiger's new proprietary liquid formulation. 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 of BID treatment to prevent hypoglycemia and the accompanying symptoms. Twenty patients suffering from PBH were administered a baseline OGTT followed by administration of SC exendin 9-39 in a range of doses for up to 3 days. Interim results for 11 of 20 patients who completed up to 3 days of dosing were recently reported.

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 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. 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 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, lonafarnib, ubenimex or exendin 9-39, including SC formulation, may be further developed and approved, whether Phase 1 and 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 new liquid formulation will be consistent with results seen with IV and SC formulations of 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 Quarterly Report on Form 10-Q for the three months ended March 31, 2017 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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