

Eiger Updates Progress in Clinical Development Program for Exendin 9-39 to Treat Post-Bariatric Hypoglycemia (PBH)

- Exendin 9-39 investigational new drug (IND) application filed
- PBH Analyst / Key Opinion Leader Event planned December 9th
- Multiple-ascending dose (MAD) study interim data to be presented

PALO ALTO, Calif., Nov. 29, 2016 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq: EIGR), focused on the development and commercialization of therapies for rare diseases, today announced an update on the Company's development program for exendin 9-39 as a potential treatment for post-bariatric hypoglycemia (PBH), a rare, debilitating and chronic disorder with no approved treatment. Eiger is developing a novel subcutaneously-administered form of exendin 9-39 for patients who experience dangerously low post-prandial (post-meal) blood glucose levels due to PBH.



Eiger has now filed an investigational new drug (IND) application for exendin 9-39 with the FDA. Eiger is the exclusive licensee of exendin 9-39 from Stanford University, which, under the Stanford IND, has generated and presented promising proof of concept data in multiple studies in patients with PBH, including an intravenous (IV) infusion study of exendin 9-39 and a subcutaneous injection (SC) study involving single-ascending doses (SAD) of exendin 9-39. Eiger is currently sponsoring a multiple-ascending dose (MAD) study involving SC exendin 9-39 in patients with PBH at Stanford, with interim data to be presented at a Company-hosted Analyst / Key Opinion Leader (KOL) event on December 9th.

"We are pleased to achieve the milestone of filing of our own IND application for exendin 9-39, accelerating our pathway toward conducting a chronic dosing study to elucidate longer duration treatment of exendin 9-39 in patients with PBH, which should enable us to design a registration program," said David Cory, President and CEO of Eiger. "PBH represents a serious and large unmet medical need for patients who experience dangerous and debilitating effects of hypoglycemia due to this disorder, and for whom dietary modification alone is ineffective. There are currently no approved therapies for PBH, representing a therapeutically and commercially valuable market opportunity for SC exendin 9-39 that aligns well with our strategic focus on rare diseases."

Analyst / KOL Event Planned for December 9, 2016

Eiger will host an Analyst / KOL event on December 9th at the Lotte New York Palace Hotel in New York City from 8:00 AM to 9:30 AM (EST). This webcasted event will feature keynote presentations by endocrinology specialists, Mary-Elizabeth Patti, MD, Marzieh Salehi, MD, and Colleen Craig, MD, who will discuss new approaches to treating PBH. In addition, an overview of Eiger's PBH program, including a discussion of interim data from the MAD study with exendin 9-39, will be presented. The Company anticipates that data from the completed MAD study will inform the Phase 2b trial, planned for initiation in 2017.

To date, approximately 30 patients with PBH have been treated with exendin 9-39 at Stanford University. In an oral presentation at the June 2016 American Diabetes Association's 76th Scientific Sessions, Stanford investigators presented positive data from an 8-patient SAD study aimed at evaluating the pharmacokinetics, pharmacodynamics and tolerability of SC exendin 9-39 in patients with PBH. These data complemented results from a previous trial involving IV infusion of exendin 9-39, and demonstrated that pharmacologic blockade of GLP-1 receptors with SC exendin 9-39 could also prevent post-prandial hypoglycemia and improve associated symptoms in patients with PBH during an oral glucose tolerance test. No adverse reactions to exendin 9-39 were reported in the SAD study.

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 post-prandially 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 post-prandial 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 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.

The European Medicines Agency (EMA) has granted orphan designation to exendin 9-39 for the treatment of non-insulinoma pancreatogenous hypoglycemia syndrome (NIPHS). NIPHS describes a spectrum of acquired metabolic disorders characterized by inappropriately high insulin levels (hyperinsulinemia) and low blood glucose levels (hypoglycemia), which includes PBH.

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 lonafarnib 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 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-updates-progress-in-clinical-development-program-for-exendin-9-39-to-treat-post-bariatric-hypoglycemia-pbh-300369536.html

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