

## **Eiger Announces Breakthrough Therapy Designation Granted by FDA for Avexitide for Treatment of Post-Bariatric Hypoglycemia (PBH)**

### **- Third Eiger Pipeline Program Granted Breakthrough Therapy Designation**

**PALO ALTO, Calif., June 17, 2019** — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for rare and ultra-rare diseases, today announced that the Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for avexitide for the treatment of post-bariatric hypoglycemia (PBH). FDA Breakthrough Therapy Designation involves a fast track development and FDA review process with guidance designed to expedite the development and review of medicines intended to treat serious or life-threatening diseases. PBH is a chronic condition occurring in post-bariatric surgical patients leading to dangerously low, postprandial blood glucose levels. Severe PBH episodes can result in altered mental status, loss of consciousness, seizures, and coma. Due to increasing morbid obesity, the number of bariatric surgeries are increasing, leading to an increased number of patients suffering from PBH. Avexitide is a targeted, first-in-class, GLP-1 antagonist in development for the treatment of PBH, a chronic, debilitating disorder for which there is no approved treatment.

“Our avexitide PBH clinical program has dosed 54 patients across four Phase 2 studies, involving both inpatient and outpatient treatment, with promising results for patients suffering from post-bariatric hypoglycemia,” said David Cory, President and CEO of Eiger. “We look forward to continued collaboration with the FDA, now on three Breakthrough Therapy Designation programs including lonafarnib for hepatitis delta virus (HDV) infection, lonafarnib for Hutchinson-Gilford Progeria Syndrome (Progeria) and Progeroid Laminopathies, and avexitide for post-bariatric hypoglycemia (PBH).”

### **About Avexitide**

Avexitide is a well-characterized, first-in-class, 31-amino acid GLP-1 antagonist that selectively targets and blocks GLP-1 receptors, normalizing insulin secretion by the pancreas, and thereby reducing postprandial hypoglycemia. Avexitide has been dosed in 54 patients across four Phase 2 studies in patients suffering from PBH. Avexitide is well-tolerated with the most common treatment emergent adverse events including mild to moderate injection site bruising, nausea, and headache. Avexitide has been granted Breakthrough Therapy Designation by the FDA, as well as Orphan Drug Designation in the U.S. by the FDA for the treatment of hyperinsulinemic hypoglycemia and Orphan Drug Designation by the EMA for the treatment of non-insulinoma pancreatogenous hypoglycemia syndrome (NIPHS). Both of these broad orphan designations include PBH. Avexitide has never been approved or commercialized for any indication. More information on avexitide 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 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 one or more years following surgery. PBH can occur with a range of severity in post-bariatric surgical patients. Severe hypoglycemia can result in neuroglycopenic outcomes (altered mental status, loss of consciousness, seizures, coma). Recurrent episodes of severe hypoglycemia can be debilitating with a significant negative impact on quality of life. There is no approved treatment for PBH.

### **About Eiger**

Eiger is a late-stage biopharmaceutical company focused on the development and commercialization of a pipeline of first-in-class, well-characterized drugs for serious rare and ultra-rare diseases for patients with high unmet medical needs and for which no approved therapies exist.

The Company's lead program is in Phase 3, developing lonafarnib, a first-in-class prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. The company is also advancing peginterferon lambda, a first-in-class interferon, toward a Phase 3 study for the treatment of HDV. Eiger is preparing an NDA and MAA for lonafarnib to treat Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies with plans to file in 2019. For additional information about Eiger and its clinical programs, please visit [www.eigerbio.com](http://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, including statements regarding our future financial condition, timing for and outcomes of clinical results, business strategy and plans and objectives for future operations, are forward looking statements. These forward-looking statements include terminology such as "believe," "will," "may," "estimate," "continue," "anticipate," "contemplate," "intend," "target," "project," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms. Forward looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned clinical development, including plans to complete enrollment of our D-LIVR study by the end of 2019, submit an NDA and MAA for Progeria and progeroid laminopathies in 2019, complete end of Phase 2 meetings for peginterferon lambda in HDV and avexitide in post bariatric hypoglycemia; whether our Phase 2 study results will support further development of

avexitide; and the potential safety, efficacy, clinical and pharmaco-economic benefits of our product candidates as well as the commercial opportunities, including potential market sizes and segments. These statements concern product candidates that have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). No representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

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 quarter ended March 31, 2019 and Eiger’s subsequent filings with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required.



SOURCE: Eiger BioPharmaceuticals, Inc.

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