Eiger Announces FDA Breakthrough Therapy Designation for Peginterferon Lambda for Treatment of Hepatitis Delta Virus Infection

-- Fourth Eiger Program Granted Breakthrough Therapy Designation

PALO ALTO, Calif., Aug. 20, 2019 /PRNewswire/ -- 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 peginterferon lambda (Lambda) for the treatment of hepatitis delta virus (HDV) infection.

Breakthrough Therapy Designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). Eiger's application was supported by data from the Phase 2 LIMT Lambda monotherapy study in 33 HDV-infected patients. Lambda is a first-in-class type III interferon for the treatment of HDV, the most severe form of human viral hepatitis for which there is no approved therapy.

"We look forward to continued collaboration with the FDA, now on four Breakthrough Therapy Designation programs including both Lonafarnib and Lambda for hepatitis delta virus (HDV) infection, Lonafarnib for Hutchinson-Gilford Progeria Syndrome (Progeria) and Progeroid Laminopathies, and Avexitide for post-bariatric hypoglycemia (PBH)," said David Cory, President and CEO of Eiger.

About Peginterferon Lambda (Lambda)
Lambda is a well-characterized, late-stage, first-in-class, type III interferon (IFN) that stimulates immune responses that are critical for the development of host protection during viral infections. Lambda targets type III IFN receptors which are distinct from the type I IFN receptors targeted by IFN alfa. These type III receptors are highly expressed on hepatocytes with limited expression on hematopoietic and central nervous system cells, which may reduce off-target effects and improve tolerability of Lambda. Although Lambda does not use the IFN alfa receptor, signaling through either the IFN Lambda or IFN alfa receptor complexes results in the activation of the same Jak-STAT signal transduction cascade.

Eiger licensed worldwide rights to Lambda from Bristol-Myers Squibb. Lambda has previously been administered to over 3,000 patients in Phase 1, 2, and 3 clinical trials. Eiger has investigated Lambda in over 50 HDV-infected patients across international academic centers, first in the Phase 2 LIMT Lambda monotherapy study, where a 36% durable virologic response was demonstrated at 24 weeks post-treatment, and second in the Phase 2 LIFT Lambda combination study with lonafarnib and ritonavir which is currently dosing. Lambda has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), and Breakthrough Therapy and Fast Track designation by U.S. FDA. Lambda is an investigational agent and not yet approved for any indication.

About Hepatitis Delta Virus (HDV)
Hepatitis Delta is caused by infection with the hepatitis delta virus and leads to the most severe form of viral hepatitis. Hepatitis delta occurs only as a co-infection in individuals harboring hepatitis B virus (HBV). Hepatitis delta leads to more severe liver disease than HBV alone and is associated with accelerated liver fibrosis, liver cancer, and liver failure. Approved nucleos(t)ide treatments for HBV only suppress HBV DNA, do not affect HBsAg and have no impact on HDV. Investigational agents in development for HBV target functional cure, are not expected to eliminate extra-hepatic reservoirs of HBsAg and are thus not expected to impact HDV infection.

Hepatitis delta is a disease with a significant impact on global health, which may affect up to 15-20 million people worldwide. The prevalence of HDV varies among different parts of the world. Globally, HDV infection is reported to be present in approximately 4.3% to 5.7% of chronic Hepatitis B carriers.

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 fourth quarter 2019. For additional information about Eiger and its clinical programs, please visit 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 submit an NDA and MAA for Progeria and progeroid laminopathies in fourth quarter 2019, present end-of-treatment data in our LIFT study, progress our Phase 3 D-LIVR study in HDV, receive FDA registration guidance for Avexitide in PBH and for peginterferon lambda in HDV; our ability to transition into a commercial stage biopharmaceutical company; our ability to finance the continued advancement of our development pipeline products; and the potential for success of any of our product candidates. 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 June 30, 2019 and Eiger's subsequent filings with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.

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