Eiger BioPharmaceuticals Announces Positive Guidance Following FDA Meeting on Hepatitis Delta Virus Registration Program

- Phase 3 D-LIVR Trial Planned to Initiate in Second Half 2018

PALO ALTO, Calif., March 21, 2018 — Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for rare diseases, announced today positive FDA guidance from a face to face discussion on the Hepatitis Delta Virus (HDV) program in February, including agreement that a single, registration trial in HDV can support an NDA filing.

D-LIVR (**D**elta **L**iver **I**mprovement and **V**irologic **R**esponse in HDV) is expected to be an international, multi-center, Phase 3 study of approximately 300 patients to evaluate an all-oral arm of lonafarnib (LNF) + ritonavir (RTV) and a combination arm of LNF + RTV + pegylated interferon-alfa (PEG IFN-α), with each arm to be compared to a placebo arm (background HBV nucleos(t)ide only), in HDV-infected patients. A PEG IFN-α alone arm will be dosed to demonstrate contribution of effect only. The LNF containing arms will not be required to demonstrate superiority over PEG IFN-α alone. The company is currently defining primary and secondary endpoints with the FDA.

“We are very pleased by the collaborative discussion with FDA and look forward to our planned advancement of the Phase 3 program for chronic HDV later this year,” said David Apelian, MD, PhD, MBA, Chief Operating Officer and Executive Medical Officer.

The Agency discussion also supported the development of pegylated interferon lambda (Lambda) in HDV infection and based on that discussion Eiger plans a Phase 2 study of Lambda in combination with LNF and RTV. **LIFT** (**L**ambda **I**nter**F**eron combo-**T**herapy) is an open-label, Phase 2 study evaluating Lambda + LNF + RTV in approximately 26 HDV-infected patients. Patients will be dosed for 24 weeks + undergo follow up for 24 weeks. Primary endpoint will be ≥ 2 log decline in HDV RNA at end of treatment. Secondary endpoints will include histology (>2 point improvement in histological activity index and no progression in fibrosis) at end of treatment. LIFT will be conducted within the National Institutes of Health (NIH) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and enrollment is planned for 2Q 2018.

“We look forward to advancing a single pivotal trial in HDV using a lonafarnib-based regimen,” said David Cory, President and Chief Executive Officer. “We are executing on our goal to develop the first approved therapy for HDV patients, with opportunities for label expansion and increased therapeutic options in the future. We expect to share additional information on the planned registration program in 2Q 2018.”

About Lonafarnib
Lonafarnib is a well-characterized, late-stage, orally active inhibitor of farnesyl transferase, an enzyme involved in modification of proteins through a process called prenylation. HDV uses this host cell process inside liver cells to complete a key step in its life cycle. Lonafarnib inhibits the prenylation step of HDV replication inside liver cells and blocks the virus life cycle at the stage of assembly. Lonafarnib has been dosed in over 120 HDV-infected patients across international academic centers and is in Phase 2 development for HDV. Lonafarnib has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), and Fast Track Designation by U.S. FDA. Lonafarnib is not approved for any indication, and is licensed from Merck Sharp & Dohme Corp. (known as MSD outside of the United States and Canada).

About Pegylated Interferon 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 in April 2016. Lambda has been administered in HBV / HCV clinical trials involving over 3,000 subjects. Lambda has not been approved for any indication. Eiger has received Orphan Designation and Fast Track Designation for Lambda in HDV.

About Hepatitis Delta Virus (HDV)
Hepatitis Delta is caused by infection with HDV and is considered to be one of the most severe forms of viral hepatitis in humans. 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. Hepatitis delta is a disease with a significant impact on global health, which may affect up to approximately 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. The prevalence of HDV in patients infected with chronic HBV is even higher in certain regions, including certain parts of Mongolia, China, Russia, Central Asia, Pakistan, Turkey, Africa, Middle East and South America, with an HDV prevalence as high as 60% being reported in HBV-infected patients in Mongolia and Pakistan.

About Eiger

Eiger is a clinical-stage biopharmaceutical company focused on the development and commercialization of targeted therapies for rare diseases. We are committed to translational innovation and the development of well-characterized drugs acting on newly identified or novel targets. Our mission is to systematically reduce the time and cost of the drug development process to more rapidly deliver important medicines to patients with rare diseases. Our lead program in Hepatitis Delta Virus (HDV) infection, is moving into Phase 3 with a single, pivotal trial planned to initiate by the end of the year. 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 whether the D-LIVR study will be supported by the FDA as a single, pivotal study to support registration; the timing of and our ability to initiate or enroll clinical trials, including whether our D-LIVR study can be advanced by the end of this year; our ability to make timely regulatory filings and obtain and maintain regulatory approvals for lonafarnib as a single agent or in combination, ubenimex, PEG IFN lambda, exendin 9-39 and our other product candidates; our intellectual property position; and the potential safety, efficacy, reimbursement, convenience clinical and pharmaco-economic benefits of our product candidates as well as the commercial opportunities, including potential market sizes and segments; our ability to finance the continued advancement of our development pipeline products, including our results of operations, cash available, financial condition, liquidity, prospects, growth and strategies; and the potential for success of any of our product candidates.

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 year ended December 31, 2017 and Eiger's periodic reports filed with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.

SOURCE: Eiger BioPharmaceuticals, Inc.

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