Eiger BioPharmaceuticals Announces First Patient Enrolled in Phase 2 LIFT Study of Pegylated Interferon Lambda in Combination with Ritonavir-Boosted Lonafarnib at National Institutes of Health

PALO ALTO, Calif., Aug. 6, 2018 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for rare diseases, announced today first patient enrolled in the Phase 2 LIFT Study conducted within the National Institutes of Health (NIH) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). LIFT (Lambda InterFeron combo-Therapy) is an open-label, Phase 2 study designed to evaluate the efficacy and tolerability of pegylated interferon lambda (Lambda) in combination with ritonavir (RTV)-boosted lonafarnib (LNF) for a total of 24 weeks in approximately 26 patients with chronic hepatitis delta.

"We have previously demonstrated in multiple studies at NIDDK that lonafarnib and ritonavir-boosted lonafarnib can decrease HDV RNA viral load in patients infected with HDV," said Christopher Koh, MD, Principal Investigator at the NIDDK. "We have enrolled the first patient in LIFT, and now look forward to studying pegylated interferon lambda in combination with ritonavir-boosted lonafarnib."

"Eiger is developing lonafarnib-based regimens alone and in combination with pegylated interferon-alfa as the first potential therapies for the treatment of HDV, and this program is advancing into Phase 3 with the international, multi-center, D-LIVR study, planned to begin later this year," said David Apelian, MD, PhD, MBA, Chief Operating Officer and Executive Medical Officer. "Lambda represents a potentially better tolerated interferon for the treatment of HDV, and our goal is to expand future therapeutic options for patients with HDV infection."

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 completed dosing in 33 HDV-infected patients across international centers and is in Phase 2 development for HDV. Lambda has not been approved for any indication. Eiger has received Orphan Designation and Fast Track Designation by the U.S. Food and Drug Administration (FDA) for Lambda in HDV.

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 advancing into Phase 3 with a single, pivotal trial (D-LIVR Study) planned to initiate by the end of 2018. Lonafarnib has been granted Orphan Drug Designation by the U.S. 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 LIFT Study
LIFT (Lambda InterFeron combo-Therapy) 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 3Q 2018).

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 late stage biopharmaceutical company focused on the development and commercialization of targeted therapies for rare diseases. We innovate by developing well-characterized drugs in newly identified or novel targets in rare diseases. Our mission is to systematically reduce the time and cost of the drug development process to more rapidly deliver important medicines to patients. Our lead program in Hepatitis Delta Virus (HDV) infection is advancing into Phase 3 with a single, pivotal trial (D-LIVR Study) planned to initiate by the end of 2018. For additional information about Eiger and its clinical programs, please visit www.eigerbio.com.

The content of this news release is solely the responsibility of the authors and does not necessarily represent the official views or imply endorsement of the National Institutes of Health.

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 the timing of and our ability to initiate or enroll clinical trials; whether the LIFT study will be successful; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 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.

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