Eiger BioPharmaceuticals Announces Complete Enrollment of *D-LIVR*, the Largest Phase 3 Study in Hepatitis Delta Virus (HDV), Investigating Lonafarnib, the Only Oral Agent in Development for HDV

- *Potential for Approval of Two Lonafarnib-based Regimens*
- *Over 400 Patients Enrolled in D-LIVR*
- *Topline Data Release Planned by End of 2022*

Palo Alto, Calif., November 1, 2021 / PRNewswire / -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases, today announced completion of enrollment in the Phase 3 *D-LIVR* study evaluating two different treatment regimens containing Lonafarnib, the Company's first-in-class oral prenylation inhibitor, for the treatment of chronic hepatitis delta virus (HDV) infection. The two regimens include all-oral Lonafarnib boosted with ritonavir and in combination with peginterferon alfa.

The *D-LIVR* study spans 116 clinical sites across 22 countries and is the largest Phase 3 study ever conducted in HDV. Over 400 patients have now been enrolled in *D-LIVR.* Eiger is planning for topline data release by the end of 2022.

"Completing enrollment of *D-LIVR* is a major milestone for both Eiger and patients with chronic HDV infection," said David Cory, President and CEO. "This trial is expected to generate pivotal results that will support approval of two Lonafarnib-based regimens for HDV in the U.S., Europe, and rest of world. In addition, *D-LIVR* is generating the single, largest source of HDV patient data from a well-controlled, global Phase 3 study to better characterize and understand this devastating disease. We look forward to reporting data from this landmark study and bringing potential new treatment options to patients."

About *D-LIVR*

D-LIVR (**D**elta **L**iver **I**mprovement and **V**irologic **R**esponse in HDV) is a global, multi-center, Phase 3 study to evaluate two Lonafarnib-based regimens: an all-oral arm of Lonafarnib boosted with ritonavir and a combination arm of Lonafarnib boosted with ritonavir combined with peginterferon alfa, with each arm to be compared to a placebo arm, in HDV-infected patients. The study also includes a peginterferon alfa monotherapy arm which will be used to demonstrate contribution of effect only. The

Lonafarnib containing arms will not be required to demonstrate superiority over peginterferon alfa. The primary endpoint is a composite of ≥ 2 log decline in HDV RNA and ALT normalization at end of 48 weeks of treatment. Key secondary endpoints include histologic improvement and improvement in fibrosis after 48 weeks of treatment, based on biopsies conducted at the start and end of treatment for all patients.

About Hepatitis Delta Virus (HDV)

HDV is the most severe form of human viral hepatitis. HDV occurs only as a co-infection in individuals infected with hepatitis B virus (HBV). HDV leads to more severe liver disease than HBV alone and is associated with accelerated liver fibrosis, liver cancer, and liver failure. It is estimated that 60% of HDV infected patients die within ten years. Approved nucleos(t)ide treatments for HBV only suppress HBV DNA, do not affect HBsAg and have no impact on HDV.

HDV is a disease with a significant impact on global health, which may affect up to 15-20 million people worldwide. Globally, HDV infection is reported to be present in approximately 4% to 6% of patients with chronic HBV.

About Lonafarnib

Lonafarnib is a well-characterized, first-in-class, oral prenylation inhibitor which blocks the final step in HDV viral assembly. Lonafarnib has been dosed in over 450 HDV-infected patients across global clinical sites, including the fully enrolled Phase 3 *D-LIVR* study. Lonafarnib has been granted Orphan Drug designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), Fast Track designation and Breakthrough designation by FDA and PRIME designation by EMA. Eiger licensed exclusive worldwide rights to lonafarnib from Merck, known as MSD outside of the United States and Canada.

About Eiger

Eiger is a commercial-stage biopharmaceutical company focused on the development and commercialization of targeted therapies for serious rare and ultra-rare diseases.

Eiger's lead clinical programs are focused on the development of foundational therapies for HDV infection, the most serious form of viral hepatitis, with two complementary HDV treatments. Lonafarnib is a first-in-class, oral prenylation inhibitor and Peginterferon Lambda is a first-in-class, type III, well-tolerated interferon. Both Lonafarnib and Peginterferon Lambda are in global Phase 3 studies.

For additional information about Eiger and its clinical programs, please visit www.eigerbio.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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 words such as "will," "may," "continue," "plan," "expect," "could," "potentially," other words of similar meaning and 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, the potential of a Lonafarnib-based regimen to be an effective therapy for HDV, the timely generation of clinical trial data to support a New Drug Application and its submission for approval to the FDA and a Marketing Authorization Application and its submission for approval to the EMA. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including additional applicable risks and uncertainties described in the "Risk Factors" sections in the Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and Eiger's subsequent filings with the SEC. The forward-looking statements contained in this press release are based on information currently available to Eiger and speak only as of the date on which they are made. Eiger does not undertake and specifically disclaims any obligation to update any forward-looking statements, whether as a result of any new information, future events, changed circumstances or otherwise.

SOURCE Eiger BioPharmaceuticals, Inc.

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