



## **Eiger BioPharmaceuticals Announces Patent Protection for Lonafarnib Boosted with Ritonavir for Treatment of Hepatitis Delta Virus Infection in Europe and Japan**

### **Expanded Patent Portfolio Now Includes U.S., Europe and Japan**

PALO ALTO, Calif., Feb. 6, 2019 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq: EIGR), focused on the development and commercialization of targeted therapies for rare and ultra-rare diseases, announced today that the European Patent Office and the Japan Patent Office have both issued decisions to grant patents with claims covering a broad range of lonafarnib boosted with ritonavir dosing regimens for the treatment of hepatitis delta virus (HDV) infection. A similar patent issued in the U.S. in 2018. With the grant of these new European and Japanese patents, lonafarnib boosted with ritonavir has now obtained patent protection with claims covering treatment with lonafarnib boosted with ritonavir in key major pharmaceutical markets including the U.S., Europe, and Japan. The patents, when granted, will expire in 2035. Similar patent applications are currently pending in China and Korea. Lonafarnib is a first-in-class, oral farnesyl transferase inhibitor in Phase 3 development for the treatment of hepatitis delta virus (HDV) infection.

"This method of use patent covers lonafarnib boosted with ritonavir for the treatment of hepatitis delta virus infection, including specific doses and durations that we anticipate will appear on the first approved label," said David Cory, President and CEO of Eiger. "We now have patent protection in the most important pharmaceutical markets in the world, which is an important milestone as we begin enrolling D-LIVR, our single, pivotal, international registration study in HDV."

#### **About Lonafarnib**

Lonafarnib is a well-characterized, first-in-class, 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 3 development for HDV with a single, pivotal, international trial. Lonafarnib has been granted Orphan Drug designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), Fast Track designation and Breakthrough designation by U.S. FDA and PRIME designation by the EMA. 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 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. 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 accelerated development and commercialization of a pipeline of targeted therapies for rare and ultra-rare diseases. The company's lead program is in Phase 3, developing lonafarnib, a first-in-class, oral prenylation inhibitor for the treatment of Hepatitis Delta Virus (HDV) infection. The company is also preparing an NDA with plans to file in 2019 for lonafarnib in the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS or Progeria) and Progeroid Laminopathies. For additional information about Eiger, 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 whether the scope of patent protection for lonafarnib boosted with ritonavir dosing regimens for the treatment of hepatitis delta virus infection will provide commercial protection for Eiger products; whether Eiger would be permitted to file an NDA based on PRF data and the timing and outcome of any FDA meeting with respect to lonafarnib and Progeria, 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, including our ability to protect our planned use of ritonavir-boosted lonafarnib; 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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