Eiger BioPharmaceuticals Announces Completion of Enrollment of Phase 2 LOWR HDV – 3 (LOnafarnib With Ritonavir in Hepatitis Delta Virus – 3) Study at National Institutes of Health (NIH)

PALO ALTO, Calif., January 19, 2016 /PRNewswire/ — Eiger BioPharmaceuticals, Inc. today announced the completion of enrollment of LOWR HDV – 3 (Lonafarnib With Ritonavir in Hepatitis Delta Virus – 3) at the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland. LOWR HDV – 3 is a double-blinded, randomized, placebo-controlled study designed to evaluate the efficacy and tolerability of three doses of lonafarnib – 50 mg, 75 mg and 100 mg – once daily, each combined with ritonavir 100 mg once daily. Twenty-one people with chronic hepatitis delta will be placed in one of six treatment groups. Each group will receive different doses of the study drugs for 12 or 24 weeks. Enrollment was completed in less than 4 months.

“The NIH Clinical Center previously completed the first Phase 2 study involving lonafarnib in hepatitis delta infected patients, with significant implications for treatment of chronic hepatitis delta, and these results were published in The Lancet Infectious Diseases in 2015,” said Christopher Koh, MD, the Lead Associate Investigator at the National Institute of Diabetes and Digestive and Kidney Diseases at the NIH. “Now that we have completed enrollment in a second study with lonafarnib in people with hepatitis delta, we look forward to reporting results upon study completion.”

“Hepatitis delta causes the most aggressive form of human viral hepatitis, with fast progression to cirrhosis and other life-threatening complications, and is a major health burden all over the world,” said Eduardo Martins, MD, DPhil, Senior Vice President of Liver and Infectious Diseases Drug Development at Eiger BioPharmaceuticals. “LOWR HDV – 3 is designed to help elucidate the antiviral potential of lonafarnib in combination with ritonavir in a longer duration study and we eagerly await results.”

About Sarasar® (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. Since prenylation is carried out by a host enzyme, this compound may present a higher barrier to development of viral
resistance mutations to therapy. Lonafarnib has been dosed in over 50 HDV-infected patients across international academic centers and is in Phase 2 development for HDV. Lonafarnib has been granted Orphan Drug Designation by the US FDA and European Medicines Agency (EMA), and Fast Track Designation by US 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 Hepatitis Delta Virus (HDV)

Hepatitis Delta (or Hepatitis D) is caused by infection with HDV and is considered to be one of the most severe forms of viral hepatitis in humans. Hepatitis D occurs only as a co-infection in individuals harboring Hepatitis B Virus (HBV). Hepatitis D leads to more severe liver disease than HBV alone and is associated with accelerated liver fibrosis, liver cancer, and liver failure. Hepatitis D is a disease with a significant impact on global health, which may affect up to approximately 15 million people worldwide. The prevalence of HDV varies among different parts of the world. Globally, HDV infection is reported to be present in approximately 5-6% 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, 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 committed to bringing to market novel products for the treatment of Orphan diseases. The company has built a diverse portfolio of well-characterized product candidates with the potential to address diseases for which the unmet medical need is high, the biology for treatment is clear, and for which an effective therapy is urgently needed.

Safe Harbor Statements

Additional Information about the Proposed Merger between Celladon Corporation and Eiger BioPharmaceuticals, Inc. and Where to Find It

In connection with the proposed merger between Celladon Corporation and Eiger BioPharmaceuticals, Inc., Celladon has filed a registration statement on Form S-4 with the Securities and Exchange Commission, or the SEC, including a proxy statement/prospectus/information statement, but the registration statement has not yet become effective. The proxy statement/prospectus/information statement and any other
relevant documents filed by Celladon with the SEC may be obtained free of charge at the SEC web site at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by Celladon by directing a written request to: Celladon Corporation, 12707 High Bluff Dr #200, San Diego, CA 92130, Attention: Investor Relations. Investors and security holders are urged to read the proxy statement/prospectus/information statement and the other relevant materials before making any voting or investment decision with respect to the proposed merger.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities in connection with the proposed merger shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Celladon and its directors and executive officers and Eiger and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Celladon in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the merger is included in the proxy statement/prospectus/information statement referred to above. Additional information regarding the directors and executive officers of Celladon is also included in Celladon Annual Report on Form 10-K for the year ended December 31, 2014 and the proxy statement for Celladon’s 2015 Annual Meeting of Stockholders. These documents are available free of charge at the SEC web site (www.sec.gov) and from Investor Relations at Celladon at the address described above.

SOURCE Eiger Bio, Inc.
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