Eiger Announces Completion of Enrollment of Phase 2 LOWR HDV – 4 (LOnafarnib With Ritonavir in Hepatitis Delta Virus – 4) Study at Hannover Medical School

PALO ALTO, Calif., March 14, 2016 /PRNewswire/ — Eiger BioPharmaceuticals, Inc. today announced the completion of enrollment of LOWR HDV – 4 (LOnafarnib With Ritonavir in Hepatitis Delta Virus – 4) at Hannover Medical School in Hannover, Germany. LOWR HDV – 4 is an open-label study designed to evaluate the efficacy and tolerability of lonafarnib combined with ritonavir twice daily with the option of dose escalation at the discretion of the investigator. Fifteen people with chronic hepatitis delta will receive study drugs for 24 weeks. Enrollment was completed in less than 4 months.

“We are very pleased to conduct our first study with lonafarnib combined with ritonavir in HDV infected patients,” said Heiner Wedemeyer, MD, Research Group Leader in the Department of Gastroenterology, Hepatology and Endocrinology at Hannover Medical School. "Many drugs are dose escalated or titrated to allow patients to acclimate to therapy and optimize treatment. The LOWR HDV - 4 protocol design enables us to investigate the efficacy and tolerability of lonafarnib in combination with ritonavir in HDV infected patients with an option to dose escalate or titrate at pre-specified times during the 24 week dosing period."

“Hepatitis delta causes the most aggressive form of human viral hepatitis, with fast progression to cirrhosis and other life-threatening complications,” said Eduardo Martins, MD, DPhil, Senior Vice President of Liver and Infectious Diseases Drug Development at Eiger BioPharmaceuticals. “LOWR HDV – 4 is designed to help elucidate the antiviral potential of lonafarnib in combination with ritonavir in a longer duration study with the optionality of dose escalation, 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 60 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 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 15-20 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, 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

In connection with the proposed merger of Celladon Corporation (NASDAQ: CLDN) and Eiger, Celladon has filed a registration statement on Form S-4 (File No. 333-208521) with the Securities and Exchange Commission, or the SEC, including a proxy statement/prospectus/information statement. The registration statement was declared effective by the SEC on February 12, 2016. 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 at www.sec.gov and from Investor Relations at Celladon at the address described above.

**Note Regarding Forward-Looking Statements**

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements regarding the structure, timing and completion of Eiger’s proposed merger with Celladon and the development and potential benefits of Eiger’s product candidates. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon Celladon’s and Eiger’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those
anticipated in such forward-looking statements as a result of various factors, include the risks described in the “Risk Factors” section of the proxy statement/prospectus/information statement referred to above. All forward-looking statements contained in this press release speak only as of the date on which they were made. Eiger undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

SOURCE Eiger Bio, Inc.
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