

Eiger BioPharmaceuticals Announces Abstracts and Presentations of Lonafarnib Data in Hepatitis Delta at the European Association for the Study of the Liver (EASL) Meeting

PALO ALTO, Calif., March 30, 2016 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc, (NASDAQ: EIGR) today announced that abstracts from its Hepatitis Delta Virus (HDV) development program will be presented at the European Association for the Study of the Liver (EASL) meeting in Barcelona, Spain, April 13 to 17, 2016. In addition, interim data from the LOWR HDV – 2 (LOnafarnib With Ritonavir in Hepatitis Delta Virus – 2) Phase 2 study in patients infected with HDV will be presented for the first time at the Hepatitis Delta International Network meeting (HDIN) at EASL.



LOWR HDV -2 is a dose finding study to identify optimal combination regimens of lonafarnib (LNF) and ritonavir (RTV) \pm PEG-IFN- α , with efficacy and tolerability for longer term dosing to enable HDV RNA clearance. In this study, approximately 40 HDV infected patients have been enrolled to date into 9 groups of different doses of LNF in combination with RTV for dosing durations of 12 or 24 weeks. LNF doses range from 150 mg qd to 25 mg bid. Quantitative serum HDV RNA viral loads, biochemical parameters, and lonafarnib drug levels were measured. As of March 2016, over 30 patients have received at least 12 weeks of treatment in LOWR HDV-2.

The HDIN invited talk and the accepted EASL abstracts are listed below:

- Yurdaydin, C. et al; "Exploring optimal dosing of lonafarnib with ritonavir for the treatment of chronic delta hepatitis results from the on-going LOWR HDV 2 study." Oral Presentation, Hepatitis Delta International Network (HDIN) April 13, 2016; 4:15-4:30 pm. Fira Barcelona Gran Via, Room E1, Hall 8.
- Dahari, H. et al; "Hepatitis delta virus (HDV) kinetics under the prenylation inhibitor lonafarnib suggest HDV-mediated suppression of the HBV replication." Poster Presentation FRI-111 April 15, 2016.
- Dahari, H. et al; "Pharmacokinetics and pharmacodynamics modeling of lonafarnib in patients with chronic hepatitis delta virus infection." Poster Presentation FRI-115 April 15, 2016.

About Sarasar® (Ionafarnib)

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 100 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 rare 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.

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, included in this press release regarding our strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives, intentions, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "will" and other words and terms of similar meaning. Examples of such statements include, but are not limited to, whether or not lonafarnib may be further developed and approved, statements relating to the availability of cash for Eiger's future operations, Eiger's ability to develop its drug candidates for potential commercialization, the timing of the commencement and completion of Phase 2 trials. Eiger may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements and one should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including the risks that Eiger's planned clinical trials may be prolonged or delayed requiring Eiger to incur additional costs; that Eiger's planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities; that Eiger's product candidates may have undesirable side effects which may delay or prevent marketing approval; that, even if approved by the FDA or non-U.S. regulatory authorities, Eiger's product candidates may not achieve broad market acceptance; and the risks described in the "Risk Factors" sections the Registration Statement on Form S-4 (file no. 333-208521) and of 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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