



Eiger Announces Additional LOWR HDV Program Data, Clinical and Regulatory Plans at the American Association for the Study of Liver Diseases (AASLD) Meeting

- Update on Data Presented and Analyst Meeting through Monday Evening

PALO ALTO, Calif., Nov. 14, 2016 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (NASDAQ: EIGR) today announced presentation of additional data from the LOWR HDV (L^onafarnib Wⁱth Rⁱtonavir in H^epatitis D^elta Vⁱrus) Program presented today at the American Association for the Study of Liver Diseases (AASLD) meeting in Boston, Massachusetts. The Company hosted a review of key findings from the LOWR HDV Program with HDV key opinion leaders and principal investigators and discussed regulatory plans. LOWR HDV is a multi-center, international Phase 2 program designed to identify optimal dosing of lonafarnib (LNF) with ritonavir (RTV) ± pegylated interferon (PEG IFN) for development in the treatment of hepatitis delta infection (HDV).



Summary:

- LNF + RTV (all-oral) regimens achieve HDV-RNA PCR-negativity on treatment
- Low dose LNF + RTV + PEG IFN achieves the most rapid and profound viral load decline, with the highest rate of HDV-RNA PCR-negativity on treatment
- LNF + RTV based regimens lead to normal ALT
- Gastrointestinal adverse events were predominantly mild or moderate
- LNF based regimens can induce a reactivation of the immune response to HDV leading to post-treatment viral clearance of HDV-RNA and reversal of fibrosis
- Company is currently enrolling LIMT HDV, a dose-ranging proof-of-concept study of PEG IFN lambda (LMD) in HDV
- Company described CLIRIT-I, a planned triple-combination study of LNF + RTV + LMD vs LMD alone for discussions with regulatory authorities for the purpose of registration
- Company described LOWR HDV – 5, a planned all-oral study of LNF and LNF + RTV, with endpoints including HDV-RNA PCR-negativity and histology improvement
- Company plans to develop a clinical data package and discuss regulatory plans with agency in 2017

Lonafarnib Presentations at AASLD: Today (November 14):

LOWR HDV – 4 Dose-Escalation Study

Wedemeyer, H. et al; "A Phase 2 Study of Titrating-Dose Lonafarnib Plus Ritonavir in Patients With Chronic Hepatitis D: Interim Results From The Lonafarnib With Ritonavir In HDV – 4 (LOWR HDV – 4) Study." Abstract #230, Oral Presentation, Parallel 35: Hepatitis B: Novel Therapies, November 14, 5:00 – 5:15 pm, Sheraton: Back Bay ABC

LOWR HDV – 4 is an open-label study to evaluate the efficacy and tolerability of dose-escalation of LNF combined with RTV administered twice daily for dosing durations of 24 weeks. Fifteen patients were initiated at LNF 50 mg and RTV 100 mg twice daily, and dose-escalated up to LNF 100 mg twice daily at the discretion of the investigator and patient tolerability. LOWR HDV – 4 is being conducted at Hannover Medical School in Hannover, Germany, and dosing has been completed.

Results from LOWR HDV – 4:

- Rapid LNF dose-escalation from 50 mg BID to 100 mg BID (+ RTV):
 - 5/15 (33%) achieved and maintained LNF 100 mg BID + RTV through week 24
 - 1/5 (20%) achieved HDV-RNA PCR-negativity at week 24
 - 1/5 (20%) reduced HDV-RNA to 32 IU/mL (assay lower limit of detection is 14 IU/mL) at week 24
- Gastrointestinal AEs mostly grade 1-2
 - 8/15 (53%) required dose reduction and 2/15 (13%) were discontinued

- Dose-escalation may benefit some patients

"We are pleased to participate in the LOWR HDV Program to determine optimal dosing of LNF in HDV-infected patients," said Heiner Wedemeyer, MD, Principal Investigator at Hannover Medical School. "The LOWR HDV – 4 study enabled us to investigate rapid dose-escalation of LNF in combination with RTV for 24 weeks. While we did see variability in tolerability, for those patients who were able to tolerate this rapid dose-escalation well, we saw good responses in viral load declines with 2/5 (40%) of those who tolerated rapid dose escalation achieving HDV-RNA PCR-negativity or approaching the limit of detection at just 24 weeks. In addition, 53% of all patients in this study normalized ALT. Slower dose-escalation, based on individual patient tolerability, may enable more patients to have the desired response. This study highlights one of several potentially promising paths towards an all-oral therapy for HDV."

Developing a Treatment for HDV: LOWR HDV Program Review

A review of key findings from the Phase 2 LOWR HDV Program, including LOWR HDV – 2, – 3, – 4 studies. November 14, 6:30 – 8:00 pm, Hilton Boston Back Bay, Mariner Room.

Renowned key opinion leaders and principal investigators Cihan Yurdaydin, MD (Ankara University), Heiner Wedemeyer, MD (Hannover Medical School), and Jeffrey Glenn, MD, PhD (Stanford School of Medicine) reviewed presentations and discussed results of the Phase 2 LOWR HDV Program presented during AASLD 2016. Members of the Eiger executive team provided an overview of the Company's regulatory plans and next steps for its HDV program, which include both LNF and PEG IFN Lambda (LMD).

Highlights and Discussion:

- LonaFarnib Phase 2 Program includes 111 patients dosed to date, across 3 international sites, exploring greater than one-dozen regimens in HDV-infected patients
- LOWR HDV Program data suggest LNF doses and combinations for future studies
 - LNF 25 mg BID + RTV + PEG IFN
 - Leads to best anti-HDV response rate to date
 - 3 of 5 (60%) become HDV-RNA PCR-negative at week 24
 - 5 of 5 (100%) below limit of HDV-RNA quantification at week 24
 - Dosing > 6 months may improve outcomes (HDV-RNA PCR-negativity)
 - 60% of patients normalized ALT at week 24
 - LNF 50 mg BID + RTV leads to 2 of 11 (18%) HDV-RNA PCR-negativity
 - Further studies of all-oral therapy are warranted
 - LNF 25 mg and 50 mg BID based regimens are generally well tolerated
 - Mostly grade 1 GI AEs observed in LNF 25 and 50 mg BID based regimens
 - Longer dosing now possible
- LIMT HDV Study - Lambda Interferon MonoTherapy in HDV Study
 - Enrolling and dosing
 - 48-week, international, dose finding, proof of concept study
 - LMD 120 mcg QW
 - LMD 180 mcg QW
 - Data to guide next study: LMD mono vs LNF + LMD combo
- CLIRIT-I HDV Study - Combined LonaFarnib with RITonavir and Lambda HDV Study
 - Planned
 - 48-week study with multiple arms to include:
 - LMD
 - LNF 25 mg BID + RTV + LMD
 - Multiple HDV treatment options for registration in a single study
- LOWR HDV – 5 Study
 - Planned
 - 48-week, single site, all-oral, Phase 2 study
 - Endpoints are HDV-RNA response and liver histology improvement

"We are pleased to announce results from multiple studies in the ongoing Phase 2 LOWR HDV Program at AASLD 2016, which provide additional evidence of the antiviral activity of LNF in various regimens in HDV-infected patients," said Eduardo B. Martins, MD, DPhil, Senior VP of Liver and Infectious Diseases Drug Development. "Perhaps the most exciting outcome is the 24 week data from triple combination of LNF 25 mg BID + RTV + PEG IFN, where the most promising results were obtained. The ongoing LIMT HDV Study is designed to assess the anti-HDV activity of two different doses of LMD monotherapy, and we believe should serve as a bridge to CLIRIT-I HDV, a planned triple combination study of LNF + RTV + LMD versus LMD alone, both of which

represent potential HDV treatment pathways. Also leveraging the data obtained from LOWR HDV – 2, we are planning LOWR HDV – 5, a 48-week study of all-oral LNF based regimens, with the goal of cure and improvement in liver histology."

About the LIMT HDV Phase 2 Study

LIMT HDV is a 1:1 randomized, open-label study of LMD 120 or 180 microgram subcutaneous injections administered weekly for 48 weeks in approximately 30 patients with chronic HDV. End of treatment will be followed by a treatment-free 24-week observation period. The primary objective of the phase 2 study is to evaluate the safety, tolerability, and efficacy of treatment with two dose levels of LMD monotherapy in patients with chronic HDV infection. All patients will also be administered an anti-HBV nucleos(t)ide analog throughout the study. The trial will be conducted at international sites including New Zealand, Israel and Pakistan.

About Pegylated Interferon Lambda

Pegylated interferon lambda (LMD) is a well-characterized, late-stage, first in class, type III interferon (IFN) that stimulates immune responses that are critical for the development of host protection during viral infections. LMD targets type III IFN receptors which are distinct from the type I IFN receptors targeted by IFN alfa. These type III receptors are highly expressed on hepatocytes with limited expression on hematopoietic and central nervous system cells, which may reduce the off-target effects associated with other IFNs and improve the tolerability of LMD. Although LMD does not use the IFN alfa receptor, signaling through either the IFN LMD or IFN alfa receptor complexes results in the activation of the same Jak-STAT signal transduction cascade.

About Sarasar™ (lonafarnib)

Lonafarnib (LNF) 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. LNF 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, treatment with LNF may present a higher barrier to development of viral resistance mutations. LNF has been dosed in over 100 HDV-infected patients across international academic centers and is in Phase 2 development for HDV. LNF 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. LNF 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 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. Hepatitis delta 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 identified, 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 pegylated interferon lambda-1a or lonafarnib or ubenimex or exendin 9-39 may be further developed and the timing of potential additional clinical trials and potential for approval, statements relating to the availability of cash for Eiger's future operations and drug development portfolio, Eiger's ability to develop its drug candidates for potential commercialization, the timing of the commencement and number and completion of Phase 2 trials and whether the products can be successfully developed or commercialized. 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 Annual Report on Form 10-K for the period ended December 31, 2015 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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