



Eiger Announces Additional Phase 2 Clinical Trial Results for Lonafarnib at The International Liver Congress™ 2017

PALO ALTO, Calif., April 21, 2017 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc., (NASDAQ: EIGR) today announced additional supportive and encouraging lonafarnib (LNF) data from the LOWR HDV (Lonafarnib With Ritonavir in Hepatitis Delta Virus) Program presented at The International Liver Congress™ 2017, in Amsterdam, Netherlands. After 24 weeks of treatment, all-oral lonafarnib-based regimens (LNF 25 mg or 50 mg BID + Ritonavir, or RTV) suppressed HDV-RNA below the limit of quantitation in 36% of patients, and 60% achieved ALT normalization. The addition of PEG IFN to LNF 25 mg BID + RTV (triple therapy) suppressed HDV-RNA below the limit of quantitation in 80% of patients, and 78% achieved ALT normalization. In patients treated for 48 weeks with triple therapy of PEG IFN + LNF 25 mg BID + RTV, PCR-negativity was achieved in 67% of patients at the end of treatment.

"The LOWR HDV program was designed to identify optimal lonafarnib-based regimens to advance in development for the treatment of HDV, and we're continuing to successfully progress towards our goal," said David Cory, President and CEO of Eiger. "Data presented this week demonstrate multiple encouraging outcomes with lonafarnib-based regimens including viral load decline greater than 2 logs, viral load below the limit of quantitation, PCR-negativity, and ALT normalization. In addition, the finding that anti-HDV activity is enhanced with the addition of pegylated interferon alpha to lonafarnib-based regimens is particularly encouraging. We plan to advance all-oral lonafarnib-based regimens as well as triple therapy to include pegylated interferon lambda as potential treatments for HDV."

Key Results from LOWR Program Presentations:

End of Treatment Results at Week 24 (24 weeks dosing)

All-Oral LNF 25 mg or 50 mg BID + RTV suppresses HDV-RNA at end of treatment (Week 24)

- 5 of 14 (36%) HDV-RNA < LOQ (Limit of Quantitation by qPCR)
- 1 of 14 (9%) PCR-negative
- 4 of 8 (50%) > 2 log decline in patients with high baseline viral load (HDV RNA > 5 log)

Addition of PEG IFN to LNF 25 mg BID + RTV results in the highest response rates (Week 24)

- 4 of 5 (80%) HDV-RNA < LOQ
- 3 of 5 (60%) PCR-negative
- 3 of 4 (75%) > 2 log decline in patients with high baseline viral load (HDV RNA > 5 log)

ALT normalization achieved in LNF 25 mg or 50 mg BID + RTV regimens

- 60% (all-oral)
- 78% (with PEG IFN)

Adverse events (AEs) predominantly mild / moderate GI events with LNF treatment

Post-Treatment Follow-Up at Week 48 (24 weeks dosing + 24 weeks post-dosing)

Addition of PEG IFN to LNF 25 mg BID + RTV led to low-level viremia off therapy, with PCR negativity in patients at 24 weeks post-treatment

- 2 of 2 PCR-negative at 24 weeks post-treatment

End of Treatment Results at Week 48 (48 weeks dosing)

Addition of PEG IFN to LNF 25 mg BID + RTV

- 2 of 3 (67%) PCR-negative

Additional dosing regimens were also explored in the LOWR program, including QD dosing of LNF + RTV and dose titration with BID dosing of LNF + RTV. Anti-HDV activity was observed in all regimens (LNF 50 mg QD + RTV up to LNF 100 mg BID + RTV)

through Week 24 on treatment. HDV viral load returned to baseline in a majority of these patients by Week 24 of post-treatment, suggesting longer-term treatment of all-oral LNF + RTV or triple combination of LNF + RTV + PEG IFN may be necessary to achieve sustained antiviral suppression.

"Hepatitis Delta is the most aggressive form of viral hepatitis, and due to the absence of an approved therapy, HDV infection remains a significant unmet medical need and a public health challenge," said Eduardo Martins, MD, DPhil, Senior Vice President of Liver and Infectious Diseases Development at Eisai. "Each of the lonafarnib presentations given at The International Liver Congress™ 2017 highlight the activity of lonafarnib-based regimens in the treatment of patients with HDV infection. We look forward to discussing next steps with regulatory agencies later this year."

Presentations at The International Liver Congress™ 2017:

- *Wedemeyer, H. et al; "A Phase 2 Dose-Escalation Study of Lonafarnib Plus Ritonavir in Patients With Chronic Hepatitis D: Final Results from The Lonafarnib With Ritonavir in HDV-4 (LOWR HDV-4) Study"; Abstract #PS-039, Oral Presentation.*
- *Yurdaydin, C. et al; "A Phase 2 Dose-Optimization Study of Lonafarnib with Ritonavir for the Treatment of Chronic Delta Hepatitis—End of Treatment Results from the LOWR HDV-2 Study"; Abstract #GS-008, Oral Presentation.*
- *Koh, C. et al; "Phase 2 study exploring once daily dosing of ritonavir boosted lonafarnib for the treatment of chronic delta hepatitis – end of study results from the LOWR HDV-3 study"; Abstract #LBP-519, Poster Presentation.*
- *Yurdaydin, C. et al; "The Prenylation Inhibitor Lonafarnib (LNF) Can Induce Post-Treatment Viral Clearance in Patients with Chronic Delta Hepatitis (CDH) Resulting in ALT Normalization and Regression of Fibrosis"; Abstract #THU-161, Poster Presentation, Oral ePoster Presentation.*
- *Yurdaydin, C. et al; "Results from Retreatment with Lonafarnib of a Subset of HDV-Infected Patients"; 13th Hepatitis Delta International Network (HDIN) Meeting, Oral Presentation.*

LOWR HDV Studies:

The LOWR HDV program was designed to be a multi-center, international Phase 2 program, to identify dosing regimens and durations of lonafarnib (LNF) with ritonavir (RTV) ± pegylated interferon (PEG IFN) to move forward in development for the treatment of hepatitis delta infection (HDV).

- LOWR HDV – 2 is a dose-finding study to identify combination regimens of lonafarnib and ritonavir ± PEG IFN α , with efficacy and tolerability for longer term dosing to enable HDV RNA clearance. In this open-label study, 58 HDV-infected patients have been enrolled to date into 10 groups of different doses of lonafarnib in combination with ritonavir ± PEG IFN α for dosing durations of 12 to 48 weeks. Lonafarnib doses range from 25 mg BID to 100 mg BID. LOWR HDV – 2 is closing at Ankara University in Ankara, Turkey.
- LOWR HDV – 3 was a double-blinded, randomized, placebo-controlled study designed to evaluate the efficacy and tolerability of once-daily doses of lonafarnib – 50 mg, 75 mg and 100 mg – each combined with ritonavir 100 mg once daily for 12 or 24 weeks. Twenty-one patients with chronic hepatitis delta were randomized into one of six treatment groups. LOWR HDV – 3 was conducted at the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland, and the study has completed.
- LOWR HDV – 4 was an open-label study to evaluate the efficacy and tolerability of dose escalation of lonafarnib combined with ritonavir administered twice daily for dosing durations of 24 weeks. Fifteen patients were initiated at lonafarnib 50 mg and ritonavir 100 mg twice daily, and dose-escalated up to lonafarnib 100 mg twice daily as tolerated. LOWR HDV – 4 was conducted at Hannover Medical School in Hannover, Germany, and the study has completed.

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. Lonafarnib has been dosed in over 120 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 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 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 pegylated interferon lambda-1a or lonafarnib or ubenimex or exendin 9-39 may be further developed and approved, and whether promising earlier clinical study results will be repeated in larger, later clinical studies, 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 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, 2016 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.

Investors: Ingrid Choong, PhD, Eiger BioPharmaceuticals, 650-619-6115, ichoong@eigerbio.com

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/eiger-announces-additional-phase-2-clinical-trial-results-for-lonafarnib-at-the-international-liver-congress-2017-300443308.html>

SOURCE Eiger BioPharmaceuticals, Inc.

