PEARL-III Study Results in Patients with Chronic Hepatitis C Presented at the 21st Conference on Retroviruses and Opportunistic Infections (CROI)

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- High SVR_{12} rates of 99 percent achieved in patients with and without ribavirin in treatment-naïve genotype 1b patients
- High response rates also observed in patients across a range of gender, race and patient characteristics

WATERTOWN, Mass.--(BUSINESS WIRE)--Mar. 3, 2014-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA) today announced that detailed results from the PEARL-III study were presented today as part of the 21st Conference on Retroviruses and Opportunistic Infections (CROI) press conference and will also be presented as a late-breaker at the conference on March 4.

PEARL-III is one of the six phase 3 registrational studies conducted by AbbVie for the treatment of genotype 1 (GT1) hepatitis C virus (HCV) infection using a regimen containing Enanta's lead protease inhibitor ABT-450. ABT-450 is part of AbbVie's investigational three direct-acting antiviral regimen consisting of boosted protease inhibitor ABT-450/ritonavir, NS5A inhibitor ABT-267, and non-nucleoside polymerase inhibitor ABT-333.

The PEARL-III study met its primary and secondary endpoints. In the 419-patient study, sustained virologic response rates 12 weeks post-treatment (SVR_{12}) of 99.5 and 99.0 percent were achieved with the three-direct-acting antiviral regimen with and without RBV, respectively. There were no study drug discontinuations due to adverse events.

PEARL-III enrolled patients across different demographics and characteristics. Response rates in patients with certain characteristics (male gender, Black race and IL28B non-CC genotypes) were examined, as these patient populations have historically been associated with having a decreased response rate to treatment. High response rates were observed across all patients in the study, including those with these characteristics.

AbbVie expects to disclose detailed results of its other phase 3 registrational studies at future scientific congresses and in publications.

About Study M13-961 (PEARL-III)

PEARL-III is a global, multi-center, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of 12 weeks of treatment with AbbVie's regimen with and without RBV in non-cirrhotic, GT1b HCV-infected, treatment-naïve adult patients.

The study population consisted of 419 GT1b treatment-naïve patients with no evidence of liver cirrhosis: 209 patients randomized to the regimen without RBV for 12 weeks, and 210 patients randomized to the regimen with RBV for 12 weeks. Following 12 weeks of treatment, 99.0 percent receiving the regimen without RBV (n=207/209) and 99.5 percent receiving the regimen with RBV (n=209/210) achieved SVR_{12}. Patients in the treatment arm without RBV received placebo in substitution for RBV.

Patients with different demographics and characteristics were enrolled in the study, including gender, race (Black vs. non-Black), Hispanic/Latino ethnicity, age, geographic region, body mass index (BMI), liver fibrosis stage, IL28B genotype and viral load.

Across treatment arms in PEARL-III, there were no documented relapses within 12 weeks post-treatment. No on-treatment virologic failures occurred in the treatment arm without RBV and a single virologic failure occurred in the treatment arm with RBV. While all patients in the study completed therapy, two patients in the arm without RBV were lost to follow-up and therefore were considered treatment failures.

The most commonly reported adverse events (>10 percent for either arm) were headache, fatigue, pruritus, nausea and asthenia, with pruritus and nausea occurring at a statistically higher rate in the treatment arm with RBV compared to the arm without RBV. Anemia occurred more commonly among patients in the RBV-containing arm, with clinically significant anemia requiring RBV dose reductions occurring in 9 percent of these patients.

Additional information about AbbVie's phase 3 studies can be found on www.clinicaltrials.gov.

Protease Inhibitor Collaboration with AbbVie (formerly the research-based pharmaceutical business of Abbott Laboratories)

In December 2006, Enanta and Abbott announced a worldwide agreement to collaborate on the discovery, development and commercialization of HCV NS3 and NS3/4A protease inhibitors and HCV protease inhibitor-containing drug combinations. ABT-450 is a protease inhibitor identified as a lead compound through the collaboration. Under the agreement, AbbVie is responsible for all development and commercialization activities for ABT-450. Enanta received $57 million in connection with signing the collaboration agreement, has received $55 million in subsequent clinical milestone payments, and is eligible to receive an additional $195 million in payments for regulatory milestones, as well as double-digit royalties worldwide on any revenue allocable to the collaboration's protease inhibitors. Also, for any additional collaborative HCV protease inhibitor product candidate developed under the agreement, Enanta holds an option to modify the U.S. portion of it rights to receive milestone payments and worldwide royalties. With this option, Enanta can fund 40 percent of U.S. development costs and U.S. commercialization efforts (sales and promotion costs) for the additional protease inhibitor in exchange for 40 percent of any U.S. profits ultimately achieved after regulatory approval, instead of receiving payments for U.S. commercial regulatory approval milestones and royalties on U.S. sales of that protease inhibitor.

About Hepatitis C Virus (HCV)

Hepatitis C is a liver disease affecting over 170 million people worldwide. The virus is typically spread through direct contact with the blood of an infected person. Hepatitis C increases a person's risk of developing chronic liver disease, cirrhosis, liver cancer and death. Patients with compensated cirrhosis have a liver that is heavily scarred but that can still perform many important bodily functions with few or no symptoms. There is an acute need for new HCV therapies that are safer and more effective for many variants of the virus.

About Enanta

Enanta Pharmaceuticals is a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs in the infectious disease field. Enanta is discovering, and in some cases developing, novel inhibitors designed for use against the hepatitis C virus (HCV). These inhibitors include members of the direct acting antiviral (DAA) inhibitor classes – protease (partnered with AbbVie), NS5A (partnered with Novartis) and nucleotide polymerase – as well as a host-targeted antiviral (HTA) inhibitor class targeted against cyclophilin. Additionally, Enanta has created a new class of antibiotics, called Bicyclolides, for the treatment of multi-drug resistant bacteria, with a focus on developing an intravenous and oral treatment for hospital and community MRSA (methicillin-resistant *Staphylococcus aureus*) infections.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including with respect to the clinical data from AbbVie's phase 3 registrational studies of its HCV treatment regimen containing ABT-450 and the regimen's prospects for treatment of a range of gender, race and genetic types. Statements that are not historical facts are based on our management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management's beliefs and assumptions. The statements contained in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors that may affect actual results include detailed results of the other phase 3 registrational studies of the ABT-450-containing regimen, the development, regulatory and marketing efforts of AbbVie (our collaborator on ABT-450), the development, regulatory and marketing efforts of others with respect to any competitive regimen, regulatory actions affecting either the ABT-450-containing regimen, any competitive regimen or both. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this release, and Enanta undertakes no obligation to update or revise these statements, except as may be required by law.

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