

Enanta Announces 95 percent SVR12 rate in AbbVie's Phase 3 Study of All-Oral Treatment for Hepatitis C Virus in Japanese Patients

- Regimen contains Enanta's lead protease inhibitor, paritaprevir (formerly ABT-450)
- 95 percent SVR12 rate achieved in Japanese patients new to therapy with genotype 1b chronic hepatitis C virus infection without cirrhosis and with a high viral load
- Regulatory filing in Japan planned by AbbVie for the first quarter of 2015

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WATERTOWN, Mass.--(BUSINESS WIRE)--Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, today announced topline Phase 3 results from the GIFT-1 study, AbbVie's investigational, all-oral, ribavirin-free, two direct-acting antiviral treatment with ombitasvir/paritaprevir/ritonavir (OBT/PTV/r) in patients with genotype 1b (GT1b) chronic hepatitis C virus (HCV) infection in Japan. The primary endpoint of the GIFT-I study was achieved, demonstrating a 95 percent (n= 106/112) sustained virologic response rate at 12 weeks post-treatment (SVR12) in the sub-group of previously untreated non-cirrhotic adult GT1b Japanese patients who were eligible for therapy with interferon (IFN) and had a high viral load. AbbVie's investigational, two direct-acting antiviral (2-DAA) treatment used in this study consists of the fixed-dosed combination of paritaprevir/ritonavir (150/100 mg) with ombitasvir (25 mg), dosed once daily. Paritaprevir (formerly known as ABT-450) is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and is one of the two direct-acting antivirals in the treatment regimen. AbbVie is responsible for all development and commercialization activities for the collaboration's lead compound, paritaprevir.

In Japan, it is estimated that up to 2 million people are living with HCV.¹ Genotype 1b is the most common sub-genotype in Japan affecting nearly half the people infected with HCV in that country.²

AbbVie has stated they will disclose detailed GIFT-I study results at future scientific congresses and in publications.

About GIFT-I Study

GIFT-I (M13-004) is a Phase 3, multi-center study designed to evaluate the efficacy and safety of 12 weeks of treatment with ombitasvir/paritaprevir/ritonavir (OBV/PTV/r tablet) in adult Japanese patients (n=363) with chronic genotype 1b (GT1b) hepatitis C virus (HCV) infection. Patients included were those without cirrhosis as well as some patients with compensated cirrhosis, of whom some were new to therapy (treatment-naïve) and others had failed previous treatment with interferon (IFN) with or without ribavirin (RBV) (treatment-experienced). The study consists of two sub-studies. Sub-study one included patients without cirrhosis randomized to OBV/PTV/r or placebo. Sub-study two included patients with compensated cirrhosis, who received open-label treatment with OBV/PTV/r.

The primary efficacy population comprised a sub-group of the treatment-naïve patient GT1b chronic HCV infected patient population. This sub-group consisted of treatment-naïve patients without cirrhosis who were eligible for therapy with IFN with or without RBV, had a high viral load ($\geq 100,000$ IU/mL) and received at least one dose of the double-blind active study drug. The primary endpoint was assessed at 12 weeks post treatment (SVR12).

In patients without cirrhosis, the most commonly reported adverse events in the treatment arm were nasopharyngitis (16.7 percent OBV/PTV/r vs. 13.2 percent placebo), headache (8.8 percent OBV/PTV/r vs. 9.4 percent placebo), and oedema peripheral (5.1 percent OBV/PTV/r vs. 0 percent placebo). Two patients without cirrhosis (0.9 percent) discontinued treatment due to adverse events. Within the primary efficacy patient population, there were no on-treatment virologic failures and 2.8 percent of patients (n=3/109) experienced relapse. Additional information about AbbVie's GIFT-1 study can be found on www.clinicaltrials.gov.

Protease Inhibitor Collaboration with AbbVie

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. Paritaprevir (ABT-450) and ABT-493 are protease inhibitors identified through the collaboration. AbbVie is Abbott's successor under the agreement and is responsible for all development and commercialization activities for the collaboration's lead compound, paritaprevir, as well as ABT-493, the collaboration's next-generation protease inhibitor.