Breakthrough Therapy Designation from the U.S. Food and Drug Administration Granted to Investigational HCV Regimen Containing Protease Inhibitor ABT-450

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WATERTOWN, Mass.--(BUSINESS WIRE)--May. 6, 2013-- Enanta Pharmaceuticals, Inc., (NASDAQ: ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs in the infectious disease field, today announced that AbbVie's investigational direct-acting antiviral (DAA) combination regimen with and without ribavirin for the treatment of genotype 1 (GT1) hepatitis C virus (HCV) infection has been designated as a Breakthrough Therapy by the U.S. Food and Drug Administration (FDA). ABT-450, Enanta's lead HCV protease inhibitor identified in its ongoing collaboration with AbbVie, is one of three DAAs in the regimen.

The all-oral, triple-DAA combination regimen is currently being studied in Phase 3 clinical trials that are being conducted by AbbVie. The Phase 3 program includes more than 2,000 patients with genotype 1 HCV infection, with trial sites in 29 countries. The DAAs in the trials include ABT-450/r (protease inhibitor and ritonavir) combined with two of AbbVie's proprietary investigational DAAs, ABT-267 (NS5A inhibitor) and ABT-333 (non-nucleoside polymerase inhibitor), and are being dosed with and without ribavirin.

According to the FDA, Breakthrough Therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy designation include preliminary clinical evidence demonstrating a drug may have substantial improvement on at least one clinically significant endpoint compared to available therapy. A Breakthrough Therapy designation conveys all of the fast track program features, as well as more intensive FDA guidance on an efficient drug development program.[1]

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. There is an acute need for new HCV therapies that are safer and more effective for many variants of the virus.

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. Under the agreement, AbbVie (as the successor to Abbott) is responsible for all development and commercialization activities for ABT-450. Enanta received a $57 million upfront payment upon signing the collaboration agreement, has received all 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) 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.

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 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 class of host-targeted antiviral (HTA) inhibitors targeted against cyclophilin. Additionally, Enanta has created a new class of antibiotics, called Bicyclolides, for the treatment of multi-drug resistant bacteria, with a current focus on developing an intravenous and oral treatment for hospital and community MRSA (methicillin-resistant *Staphylococcus aureus*) infections.

Forward-Looking Statement Disclaimer

This press release contains forward-looking statements, including statements with respect to the Breakthrough Therapy designation that the FDA has given to AbbVie's regimen containing ABT-450 for treatment of genotype 1 HCV infection and milestones and royalties that Enanta is eligible to receive on ABT-450 and any additional collaboration protease inhibitor products. 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 the development and commercialization efforts of AbbVie for HCV treatment regimens containing ABT-450 or any additional collaboration protease inhibitor product, regulatory actions affecting clinical development or treatment regimens containing ABT-450 or any additional collaboration protease inhibitor product, and clinical development of competitive product candidates. 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.

[1]U.S. Food and Drug Administration. Frequently Asked Questions: Breakthrough Therapies. 2013. http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm341027.htm.

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