Enanta Pharmaceuticals Announces New Drug Application Submission to the U.S. FDA for All-Oral, Interferon-Free Hepatitis C Regimen

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Filing Triggers Milestone Payment to Enanta

- *AbbVie's submission to FDA triggers $20 million milestone payment to Enanta*
- *Regimen includes Enanta's and AbbVie's protease inhibitor ABT-450*

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 22, 2014-- 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, Enanta's collaboration partner for ABT-450, has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for an investigational, all-oral, interferon-free regimen for the treatment of adult patients with chronic genotype 1 (GT1) hepatitis C virus (HCV) infection.

The three direct-acting antiviral regimen consists of boosted protease inhibitor ABT-450/ritonavir, NS5A inhibitor ABT-267, and non-nucleoside polymerase inhibitor ABT-333. ABT-450 is the lead protease inhibitor developed through Enanta's collaboration with AbbVie.

The U.S. NDA filing triggers a $20 million milestone payment to Enanta from AbbVie. AbbVie also plans to submit applications for regulatory approval of its regimen in the European Union in early May. Enanta is entitled to receive an additional $20 million upon the first regulatory filing in the European Union for a regimen containing a collaboration compound.

The NDA is supported by AbbVie's data from the largest all-oral, interferon-free clinical program in GT1 patients conducted to date,[1] with six phase 3 studies that included more than 2,300 patients in over 25 countries.

"This submission marks a very significant step toward Enanta being part of the first wave of all-oral therapies that may be approved to treat patients with genotype 1 hepatitis C virus," stated Jay R. Luly, Ph.D., Enanta's President and Chief Executive Officer. "No all-oral therapy has yet been approved to treat GT1 HCV infection, which is estimated to affect approximately 70% of the 3.2 million people of the U.S. population infected with HCV."[2]

In May of 2013, AbbVie's investigational direct-acting antiviral (DAA) regimen with and without ribavirin for HCV genotype 1 was designated as a Breakthrough Therapy by the U.S. FDA. This designation is intended to help expedite the development of drugs for serious or life-threatening conditions and is based in part on preliminary clinical evidence demonstrating a drug or regimen may have substantial improvement on at least one clinically significant endpoint compared to available therapy.

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. 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, is entitled to receive $20 million in connection with the NDA filing in the U.S. described above, and is eligible to receive up to an additional $175 million in payments for regulatory and commercialization 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 ABT-450

ABT-450 is an NS3 protease inhibitor discovered through Enanta's ongoing collaboration with AbbVie. AbbVie and Enanta have an agreement to collaborate on the discovery, development and commercialization of HCV NS3 and NS3/4A protease inhibitors. Protease inhibitors play an essential role in the viral life cycle of the hepatitis C virus (HCV). Inhibition of the protease prevents non-structural (NS) proteins from forming and thereby prevents replication and survival of the HCV virus. ABT-450 is part of AbbVie's investigational regimen for HCV that consists of boosted protease inhibitor ABT-450/ritonavir (referred to as ABT-450/r), NS5A inhibitor ABT-267 and non-nucleoside polymerase inhibitor ABT-333.

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 statements with respect to the prospects for regulatory filings for AbbVie's HCV treatment regimen containing ABT-450 and the prospects for milestone payments to Enanta resulting from such filings and any subsequent regulatory approvals. 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 efforts of AbbVie (our collaborator on ABT-450) to obtain regulatory approvals and commercialize treatment regimens containing ABT-450, the development, regulatory and marketing efforts of others with respect to competitive treatment regimens, regulatory actions affecting any ABT-450-containing regimen, any competitive regimen, or both, and the level of market acceptance and the rate of reimbursement for any ABT-450-containing regimen. 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] Comparison based on review of data from www.clinicaltrials.gov for phase 3a programs of Gilead, BMS and BI as of November 15, 2013.

[2] http://www.cdc.gov/hepatitis/HCV/PDFs/HepCGeneralFactSheet.pdf; www.cdc.gov.

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