



Enanta Pharmaceuticals Announces Submission of EU Marketing Authorization Applications to the European Medicines Agency for All-Oral, Interferon-Free Hepatitis C Regimen Containing ABT-450

May 8, 2014

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Submission Triggers \$20 million Payment to Enanta

WATERTOWN, Mass.--(BUSINESS WIRE)--May 8, 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 Marketing Authorization Applications (MAA) to the European Medicines Agency (EMA) seeking approval for its investigational, all-oral, interferon-free regimen for the treatment of adult patients infected with chronic genotype 1 (GT1) hepatitis C virus (HCV).

The three direct-acting antiviral investigational regimen consists of the fixed-dose combination of ABT-450/ritonavir (150/100mg) co-formulated with ombitasvir (ABT-267) 25mg, dosed once daily, and dasabuvir (ABT-333) 250mg with or without ribavirin (weight-based), dosed twice daily. ABT-450 is Enanta's lead protease inhibitor developed through Enanta's collaboration with AbbVie.

The MAAs are supported by AbbVie's data from the largest all-oral, interferon-free clinical program conducted to date in GT1 patients.¹ It includes data from six phase 3 studies involving more than 2,300 patients in over 25 countries.

The European MAA submissions trigger a \$20 million milestone payment to Enanta from AbbVie.

"There are a significant number of patients infected in the EU with chronic GT1 HCV for which this therapy could be beneficial," said Jay R. Luly, Ph.D., Enanta's President and Chief Executive Officer. "We look forward to the potential approval of this therapy in the EU."

Accelerated Assessment Granted

The EMA has granted AbbVie's request for accelerated assessment for ABT-450/ritonavir, ombitasvir (ABT-267), and dasabuvir (ABT-333), a designation that is granted to new medicines of major public health interest. Review of AbbVie's MAAs will be conducted under the centralized licensing procedure which, when finalized, provides one marketing authorization in all 28 member states of the European Union (EU). If approved, AbbVie has indicated that the ABT-450/ritonavir, ombitasvir (ABT-267) and dasabuvir (ABT-333) regimen could be available for marketing in the EU in the first quarter of 2015.

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 \$40 million in connection with the MAA filings in the European Union described above and AbbVie's recent FDA filing for the same regimen, and is eligible to receive up to an additional \$155 million in payments for regulatory and reimbursement approval 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 its 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 and royalties to Enanta resulting from such filings and any subsequent regulatory and reimbursement 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 HCV treatment regimens, regulatory and reimbursement 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.

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