



Enanta Announces CHMP Grants Positive Opinions of AbbVie's VIEKIRAX™ (ombitasvir/paritaprevir(ABT-450)/ritonavir) + EXVIERA™ (dasabuvir) for the Treatment of Chronic Hepatitis C in Europe

November 21, 2014

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- ***Final decision from the European Commission expected in the first quarter of 2015***

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 21, 2014-- Enanta Pharmaceuticals, Inc., (NASDAQ: ENTA) a research and development-focused biotechnology company dedicated to creating small molecule drugs primarily in the infectious disease field, today announced that the European Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted positive opinions for AbbVie's investigational, all-oral, interferon-free treatment of VIEKIRAX™ (a combination of ombitasvir, paritaprevir (ABT-450) and ritonavir) plus EXVIERA™ (dasabuvir), with or without ribavirin (RBV), for patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection, and VIEKIRAX™ only, with RBV, for patients with genotype 4 (GT4) HCV infection. AbbVie anticipates that the European Commission will review the opinions and make a final decision sometime in the first quarter of 2015.

Paritaprevir is the generic name for ABT-450, an NS3/4A protease inhibitor that is Enanta's lead HCV candidate discovered during the ongoing collaboration between AbbVie and Enanta for HCV protease inhibitors and regimens that include protease inhibitors.

The combination of three direct-acting antivirals (3-DAA) consisting of VIEKIRAX™ + EXVIERA™ is being investigated for the treatment of genotype 1 chronic HCV infection, including patients with compensated cirrhosis. VIEKIRAX™ consists of the fixed-dose combination of paritaprevir 150mg and ritonavir 100mg with ombitasvir 25mg (NS5A inhibitor), dosed once daily. EXVIERA consists of dasabuvir 250mg (non-nucleoside NS5B polymerase inhibitor), dosed twice daily with or without ribavirin.

For genotype 4 chronic HCV patients, AbbVie's treatment is a combination of two direct-acting antivirals (2-DAA) consisting of VIEKIRAX™, dosed once daily, plus ribavirin, dosed twice daily.

"These positive opinions are an important step in bringing to market a potential new cure for patients living with hepatitis C virus," stated Jay R. Luly, Ph.D, President and CEO. "We are thrilled that our protease inhibitor paritaprevir is part of such an important regimen and look forward to the European Commission's final decision anticipated in the first quarter of 2015."

The marketing authorization applications (MAAs) for these regimens were submitted to the EMA on May 6, 2014 under an accelerated assessment, designated to new medicines of major public health interest. Review of the MAAs is being conducted under the centralized licensing procedure, which if approved will result in marketing authorizations valid in all 28 member states of the European Union, as well as Iceland, Liechtenstein and Norway.

The positive CHMP opinions are supported by a robust clinical development program consisting of six pivotal Phase 3 studies – SAPPHIRE-I, SAPPHIRE-II, PEARL-II, PEARL-III, PEARL-IV, and TURQUOISE-II.^{1,2,3,4,5} AbbVie's treatment regimen was evaluated in more than 2,300 GT1 patients in over 25 countries. In addition, the positive opinions were supported by a Phase 2 study, PEARL-I, in GT4 patients without cirrhosis⁶, as well as preliminary data from the TURQUOISE-I study in GT1 HCV and HIV-1 co-infected patients⁷ and from the CORAL-I study in liver transplant recipients with recurrent GT1 HCV infection patients new to treatment after transplantation.⁸

AbbVie estimates that approximately nine million people in Europe are infected with HCV, which over time may lead to cirrhosis and liver failure in about 10-20 percent of people with chronic HCV.^{9,10} GT1 is the most common type of HCV genotype⁹, accounting for 60 percent of cases worldwide. In Europe, the most prevalent genotype is 1b (47 percent).¹¹ GT4, most common in the Middle East, sub-Saharan Africa and Egypt, is becoming increasingly prevalent in several European countries including Italy, France, Greece and Spain.¹²

The U.S. Food and Drug Administration (FDA) granted priority review for AbbVie's investigational 3-DAA treatment regimen for patients with GT1 chronic HCV infection on June 13, 2014. The regimen was also granted Breakthrough Therapy designation by the FDA, a status given to investigational treatments for serious or life-threatening conditions with preliminary clinical evidence demonstrating substantial improvement on at least one clinically significant endpoint compared to available therapy.

About Paritaprevir (ABT-450) Development

Paritaprevir, Enanta's lead HCV candidate formerly known as ABT-450, was discovered during the ongoing collaboration between AbbVie and Enanta for HCV protease inhibitors and regimens that include protease inhibitors. Paritaprevir is being developed by AbbVie in a two-direct-acting-antiviral (2-DAA) treatment regimen and a 3-DAA treatment regimen for HCV. The investigational, all-oral, 2-DAA regimen consists of a fixed-dose combination of paritaprevir/ritonavir (150/100mg) co-formulated with ombitasvir (25mg), dosed once daily, co-administered with or without weight-based ribavirin (1000mg or 1200mg in divided doses twice daily). The investigational, all-oral, 3-DAA regimen consists of the fixed-dose combination of paritaprevir/ritonavir (150/100mg) co-formulated with ombitasvir (25mg), dosed once daily, plus dasabuvir (250mg) with or without ribavirin, dosed twice daily. Applications for approval of paritaprevir as part of a multi-drug regimen were accepted for review in the United States and the European Union in the second quarter of 2014.

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 and ABT-493 are protease inhibitors identified through the collaboration. Under the agreement, AbbVie is now responsible for all development and commercialization activities for the collaboration's lead compound, paritaprevir, as well as ABT-493. Enanta has received \$152 million in connection with the collaboration agreement to date, (excluding research funding) and is eligible to receive payments for commercial regulatory approval milestones up to \$155 million and \$80 million for paritaprevir and ABT-493, respectively, as well as annually tiered, double-digit royalties per product on AbbVie's worldwide net sales allocable to any of the collaboration's protease inhibitors.

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 primarily 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 and nucleotide polymerase – as well as a host-targeted antiviral (HTA) inhibitor class targeted against cyclophilin. Additionally, Enanta has a Bicyclolide antibiotic in early clinical development with the National Institute of Allergy and Infectious Diseases (NIAID) for the potential treatment of multi-drug resistant bacterial infections.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including statements with respect to the timing and prospects for approval of AbbVie's HCV treatment regimens containing paritaprevir for use in Europe. Statements that are not historical facts are based on Enanta's 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 actions of AbbVie (our collaborator on paritaprevir) regulatory and reimbursement actions affecting any paritaprevir-containing regimen, and other risk factors described or referred to in "Risk Factors" in Enanta's most recent Annual Report on Form 10-K for the fiscal year ended September 30, 2013 and in other periodic reports filed with the Securities and Exchange Commission. 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 Feld JJ, Kowdley KV, Coakley E et al. Treatment of HCV with ABT-450/r–Ombitasvir and Dasabuvir with Ribavirin. N Engl J Med. 2014; 370: 1594-1603

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³ Andreone P, Colombo MG, Enejosa JV et al. ABT-450, Ritonavir, Ombitasvir, and Dasabuvir Achieves 97% and 100% Sustained Virologic Response With or Without Ribavirin in Treatment-Experienced Patients With HCV Genotype 1b Infection. Gastroenterology. 2014 Aug;147(2):359-365

⁴ Ferenci P, Bernstein D, Lalezari J et al. ABT-450/r–Ombitasvir and Dasabuvir with or without Ribavirin for HCV. N Engl J Med. 2014; 370:1983-1992

⁵ Poordad F, Hezode C, Trinh R et al. ABT-450/r–Ombitasvir and Dasabuvir with Ribavirin for Hepatitis C with Cirrhosis. N Engl J Med. 2014; 370: 1973-1982

⁶ Pol S, et al. Interferon-Free Regimens of Ombitasvir and ABT-450/r With or Without Ribavirin in Patients With HCV Genotype 4 Infection: PEARL-I Study Results. Hepatology. 2014; vol. 60, no. 4 supplement:1129A

⁷ Wyles D, Sulkowski M, Eron J, et al. TURQUOISE-I: 94% SVR12 in HCV/HIV-1 co-infected patients treated with ABT-450/r/ombitasvir and dasabuvir and ribavirin. Presented at the 65th Annual Meeting of the American Association for the Study of Liver Diseases (The Liver Meeting 2014), November 7–11, 2014, Boston, MA. Poster #1939

⁸ Kwo P, Mantry P, Coakley E, et al. An interferon-free antiviral regimen for HCV after liver transplantation. N Engl J Med. 2014; 1-8. doi: 10.1056/NEJMoa1408921

⁹European Association for the Study of the Liver. Clinical Practice Guidelines: Management of hepatitis C virus infection. J Hepatol. 2014; 60: 392-420

¹⁰ Global Alert and Response (GAR): Hepatitis C. World Health Organization Web site. <http://www.who.int/csr/disease/hepatitis/whocdscsrlyo2003/en/index2.html#HCV>. Published 2003. Accessed December 2014

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¹² Khattab MA, et al. Management of hepatitis C virus genotype 4: Recommendations of an International Expert Panel. J Hepatol. 2011; 54: 1250–1262



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