Enanta Announces European Commission Grants Marketing Authorizations for AbbVie's VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets)...

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WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 16, 2015--

Enanta Announces European Commission Grants Marketing Authorizations for AbbVie's VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) for the Treatment of Genotypes 1 and 4 Chronic Hepatitis C Virus

- *VIEKIRAX® contains Enanta's lead protease inhibitor, paritaprevir (formerly ABT-450)*
- *All-oral, interferon-free regimen also approved for HCV/HIV-1 co-infection, patients on opioid substitution therapy and patients who have undergone a liver transplant*[1,2]
- *VIEKIRAX + EXVIERA are the first products to be approved as a combination treatment of three direct-acting antivirals with distinct mechanisms of action targeting HCV at multiple steps in the viral lifecycle*[1,2]
- *In phase 3 clinical trials, VIEKIRX + EXVIERA cured 95-100 percent of hepatitis C patients, with less than 2 percent of patients experiencing virologic failure*[1,2]
- *Tolerability profile shows more than 98 percent of patients completed a full course of therapy*[3]

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 that the European Commission has granted marketing authorizations for AbbVie's VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets)[1,2] with or without ribavirin (RBV) for the treatment of patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection, including those with compensated liver cirrhosis, HIV-1 co-infection, patients on opioid substitution therapy and liver transplant recipients.[1,2]The European Commission has also approved VIEKIRAX for use with RBV for the treatment of patients with genotype 4 (GT4) chronic HCV infection.[1]

Paritaprevir (formerly known as ABT-450) is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and is one of two direct-acting antivirals (DAAs) in the VIEKIRAX tablet. AbbVie is responsible for all worldwide development and commercialization of VIEKIRAX-containing regimens and other regimens containing paritaprevir. Enanta is entitled to a $50 million milestone payment from AbbVie upon commercial regulatory approval of VIEKIRAX in Europe.

"We are pleased that paritaprevir will now be available in Europe as well as in the U.S. as part of AbbVie's HCV treatment regimen to help patients suffering from HCV," stated Jay R. Luly, Ph.D. President and CEO. "With these approvals, in addition to a treatment for genotype 1 HCV patients, there is now a treatment for genotype 4 HCV patients in Europe as well."

The approvals follow a review under accelerated assessment by the European Medicines Agency designated to new medicines of major public health interest. AbbVie's HCV treatment regimens are now licensed for use in all 28 member countries of the European Union, as well as in the U.S., Canada, Switzerland, Iceland, Liechtenstein and Norway. Approximately nine million people in Europe are infected with chronic HCV, a major cause of liver cancer and liver transplantation.[4] Genotype 1 is the most prevalent form of HCV in Europe, and it accounts for 60 percent of cases worldwide.[5] In Europe, the most prevalent sub-genotype is 1b (47 percent).[6] Genotype 4, 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.[7]

Clinical Development Program for VIEKIRAX® + EXVIERA®

The approval of VIEKIRAX + EXVIERA is supported by a robust clinical development program designed to study the safety and efficacy of the regimen in more than 2,300 enrolled patients across 25 countries.[1,2] The program consisted of six pivotal Phase 3 studies, which demonstrated that VIEKIRAX + EXVIERA cured 95-100 percent of hepatitis C patients with GT1 HCV infection who received the recommended regimen, with less than 2 percent of patients experiencing virologic failure.[1,2] Additionally, more than 98 percent (n=2,011/2,053) of patients in clinical trials completed a full course of therapy.[3] Most common (>20 percent) adverse reactions for VIEKIRAX + EXVIERA with RBV were fatigue and nausea.[1,2]

The approval of VIEKIRAX + EXVIERA is also based on the results from Phase 2 clinical trials in GT1 chronic HCV infected patients, which showed that VIEKIRAX + EXVIERA cured 97 percent (n=33/34) of liver transplant recipients, 92 percent (n=58/63) of patients co-infected with HIV-1 and 97 percent (n=37/38) of patients on opioid substitution therapy.[1,2] Patients who achieve a sustained virologic response (SVR_{12}) are considered cured of hepatitis C.

Approval of VIEKIRAX in GT4 chronic hepatitis C was based on a Phase 2 study in which patients treated with VIEKIRAX with RBV achieved 100

percent SVR_{12}.[1]

About VIEKIRAX® + EXVIERA®

VIEKIRAX + EXVIERA is approved for the treatment of genotype 1 chronic hepatitis C virus (HCV) infection, including patients with compensated cirrhosis. VIEKIRAX consists of the fixed-dose combination of paritaprevir 150mg (NS3/4A protease inhibitor) and ritonavir 100mg with ombitasvir 25mg (NS5A inhibitor), dosed once daily, and EXVIERA consists of dasabuvir 250mg (non-nucleoside NS5B polymerase inhibitor) dosed twice daily taken with or without ribavirin, dosed twice daily. VIEKIRAX + EXVIERA is taken for 12 weeks with or without RBV, except in GT1a patients with cirrhosis, who should take it for 24 weeks.

For the treatment of genotype 4 chronic HCV patients, AbbVie's treatment consists of VIEKIRAX dosed once daily taken with RBV, dosed twice daily.

EU Indication

VIEKIRAX is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults. EXVIERA is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults.

IMPORTANT EU SAFETY INFORMATION FROM ABBVIE

Contraindications:

VIEKIRAX + EXVIERA are contraindicated in patients with severe hepatic impairment (Child-Pugh C). Patients taking ethinyl estradiol-containing medicinal products must discontinue them and switch to an alternative method of contraception prior to initiating VIEKIRAX + EXVIERA. Do not give VIEKIRAX with certain drugs that are sensitive CYP3A substrates or strong inhibitors of CYP3A. Do not give VIEKIRAX and EXVIERA with strong or moderate enzyme inducers. Do not give EXVIERA with certain drugs that are strong or moderate inducers of CYP2C8.

Special warnings and precautions for use:

VIEKIRAX + EXVIERA are not recommended as monotherapy and should be used in combination with other medicinal products for the treatment of hepatitis C infection.

Pregnancy and concomitant use with ribavirin

When VIEKIRAX + EXVIERA are used in combination with ribavirin, women of childbearing potential or their male partners must use an effective form of contraception during the treatment and 6 months after the treatment. Refer to the Summary of Product Characteristics for ribavirin for additional information.

ALT elevations

Transient elevations of ALT to >x5 ULN without concomitant elevations of bilirubin occurred in clinical trials with VIEKIRAX + EXVIERA and more frequent in a subgroup who were using ethinylestradiol-containing contraceptives.

Use with concomitant medicinal products

Use caution when administering VIEKIRAX with fluticasone or other glucocorticoids that are metabolized by CYP3A4. A reduction in colchicine dosage or interruption in colchicine is recommended in patients with normal renal or hepatic function. VIEKIRAX with or without EXVIERA is expected to increase exposure of statins so certain statins need to be discontinued or dosages reduced. Low dose ritonavir, which is part of VIEKIRAX, may select for PI resistance in HIV co-infected patients without ongoing antiretroviral therapy. HIV co-infected patients without suppressive antiretroviral therapy should not be treated with VIEKIRAX.

Adverse Reactions

Most common (>20 percent) adverse reactions for VIEKIRAX + EXVIERA with RBV were fatigue and nausea.

Full summary of product characteristics is available at www.ema.europa.eu.

Globally, prescribing information varies; refer to the individual country product label for complete information.

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. Under the agreement, AbbVie 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.

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 for viral infections and liver diseases. 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. In addition, Enanta has a preclinical program in non-alcoholic steatohepatitis, or NASH, which is a condition that results in liver inflammation and damage caused by a buildup of fat in the liver.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including with respect to the prospects for milestone and royalty payments to Enanta related to the European Commission approval of AbbVie's paritaprevir-containing VIEKIRAX and Enanta's prospects for its continued pursuit of other potential

drugs. 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 commercialization efforts of AbbVie (our collaborator on paritaprevir) regarding treatment regimens containing paritaprevir, market acceptance of those regimens, the impact of competitive products on the use and sales of those regimens, and regulatory actions affecting clinical development of paritaprevir 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.

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[1] VIEKIRAX™ tablets (ombitasvir/paritaprevir/ritonavir) Summary of product characteristicsMaidenhead, UK. AbbVie, Ltd.

[2] EXVIERA™ tablets (dasabuvir) Summary of product characteristicsMaidenhead, UK. AbbVie, Ltd.

[3]AbbVie data on file

[4] Hatzakis A. et al. The state of hepatitis B and C in Europe: report from the hepatitis B and C summit conference. Journal of Viral Hepatitis, 2011; 18 (Suppl. 1): 1–16

[5] Global Alert and Response (GAR): Hepatitis C. World Health Organisation Web site. http://www.who.int/csr/disease/hepatitis/whocdscsrlyo2003/en/index2.html#HCV. Published 2003. Accessed November, 2013

[6] O'Leary JG, Davis GL. Hepatitis C. In: Feldman M, Friedman LS, Brandt LJ, eds. Sleisenger and Fordtran's Gastrointestinal and Liver Disease: Pathophysiology/Diagnosis/Management. 9th ed, Vol 1. Philadelphia, PA: Saunders Elsevier. 2010:1313-1335

[7] 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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