Enanta Announces CHMP Grants Positive Opinion for an Eight-Week Treatment Option with AbbVie's VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) for Patients with Genotype 1b Chronic Hepatitis C

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- *CHMP opinion is a step closer to the approval of an eight-week regimen of VIEKIRAX + EXVIERA for previously untreated genotype 1b (GT1b) chronic hepatitis C virus (HCV) patients with minimal to moderate fibrosis**
- *AbbVie's EMA label expansion is supported by 98 percent SVR12 rate in patients in the dedicated Phase 3b GARNET study1*
- *GT1b is the most common HCV subtype globally and accounts for approximately 47 percent of the estimated nine million people infected with chronic HCV in Europe 2,3,4*
- *Paritaprevir is Enanta's lead protease inhibitor and one of the three direct-acting antivirals in VIEKIRAX + EXVIERA*

WATERTOWN, Mass.--(BUSINESS WIRE)--Feb. 27, 2017-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted a positive opinion for an eight-week treatment regimen of AbbVie's VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) as an option for previously untreated adult patients with genotype 1b (GT1b) chronic HCV infection and minimal to moderate fibrosis.*

VIEKIRAX + EXVIERA is currently approved in the European Union for use as a 12-week treatment for GT1b chronic HCV-infected patients without cirrhosis or with compensated cirrhosis. Paritaprevir is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and one of the three direct-acting antivirals in VIEKIRAX + EXVIERA.

Approximately 160 million people worldwide are infected with HCV, with GT1b being the most common subtype globally.[2,5] In Europe, this subtype accounts for approximately 47 percent of the estimated nine million people infected with chronic HCV across the continent.[3,4]

The CHMP positive opinion is supported by data from the dedicated Phase 3b GARNET study. Results showed that with eight weeks of treatment with VIEKIRAX + EXVIERA, 98 percent (n= 160/163) of previously untreated GT1b chronic HCV infected patients without cirrhosis achieved sustained virologic response at 12 weeks post-treatment (SVR_{12}).[1] The most commonly reported adverse events, occurring at rates equal to or greater than 5 percent, were headache (21 percent), fatigue (17 percent), nasopharyngitis (8 percent), pruritus (8 percent), nausea (6 percent) and asthenia (5 percent).

**When assessing severity of liver disease using non-invasive methods, additional blood tests improve accuracy and should be undertaken prior to 8 week treatment in all patients with moderate fibrosis.*

About AbbVie's GARNET Study1

The Phase 3b GARNET study was a multicenter, open-label, single-arm study, investigating the safety and efficacy of eight weeks of treatment with VIEKIRAX + EXVIERA without ribavirin in treatment-naïve patients with GT1b chronic HCV infection without cirrhosis.[1] The study enrolled 166 patients across 20 sites around the world. Of the 166 patients enrolled, 163 patients had GT1b chronic HCV infection without cirrhosis and three patients with other HCV genotypes were excluded from the efficacy analysis. The primary endpoint was the percentage of patients who achieved SVR_{12}.

Two patients experienced post-treatment relapse and one discontinued due to noncompliance. Less than one percent of patients experienced serious adverse events or clinically significant (Grade ?3) laboratory abnormalities. One patient discontinued treatment on Day 45 due to an adverse event but achieved SVR_{12}.

Additional information about the GARNET study can be found on www.clinicaltrials.gov.

VIEKIRAX® + EXVIERA®

VIEKIRAX + EXVIERA is approved in the European Union for the treatment of genotype 1 (GT1) chronic hepatitis C virus (HCV) infection, including patients with compensated cirrhosis. VIEKIRAX is approved in the European Union for the treatment of genotype 4 (GT4) chronic HCV infection.

VIEKIRAX tablets consist of the fixed-dose combination of paritaprevir 150mg (NS3/4A protease inhibitor) and ritonavir 100mg with ombitasvir 25mg (NS5A inhibitor), dosed once daily. EXVIERA tablets consist of dasabuvir 250mg (non-nucleoside NS5B polymerase inhibitor) dosed twice daily. VIEKIRAX + EXVIERA is taken with or without ribavirin (RBV), dosed twice daily based on patient type. VIEKIRAX + EXVIERA is taken for 12 weeks with or without RBV, except in genotype 1a patients with compensated cirrhosis (Child-Pugh A), who should take it for 24 weeks with RBV.

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 CHC in adults.

Important EU Safety Information

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 inhibitors of CYP2C8.

Special warnings and precautions for use

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

Risk of Hepatic Decompensation and Hepatic Failure in Patients with Cirrhosis

VIEKIRAX and EXVIERA are not recommended in patients with moderate hepatic impairment (Child-Pugh B). Patients with cirrhosis should be monitored for signs and symptoms of hepatic decompensation, including hepatic laboratory testing at baseline and during treatment.

ALT elevations

Transient elevations of ALT to >5x ULN without concomitant elevations of bilirubin occurred in clinical trials with VIEKIRAX + EXVIERA and were more frequent in a subgroup who were using ethinyl estradiol-containing contraceptives.

Pregnancy and concomitant use with ribavirin

Extreme caution must be taken to avoid pregnancy in female patients and female partners of male patients when VIEKIRAX with or without EXVIERA is taken in combination with ribavirin, see section 4.6 and refer to the Summary of Product Characteristics for ribavirin for additional information.

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.

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's research and development efforts are currently focused on the following disease targets: non-alcoholic steatohepatitis (NASH)/ primary biliary cholangitis (PBC), respiratory syncytial virus (RSV) and hepatitis B virus (HBV).

Enanta has discovered novel protease inhibitors for use against the hepatitis C virus (HCV). These protease inhibitors, developed through Enanta's collaboration with AbbVie, include paritaprevir, currently marketed in AbbVie's HCV regimens, and glecaprevir (ABT-493), Enanta's second protease inhibitor product, which AbbVie is developing as part of its investigational HCV regimen of glecaprevir/pibrentasvir (G/P) now in registration in the U.S., the E.U. and Japan. Royalties and any further milestone payments from this collaboration will provide funding for Enanta's earlier development programs, including its Phase 1 FXR agonist program for NASH/PBC, and its preclinical programs for HBV and RSV. Please visit www.enanta.com for more information on Enanta's programs and pipeline.

Forward Looking Statements

This press release contains forward-looking statements, including statements with respect to the prospects for approval of the label expansion for AbbVie's VIEKIRAX + EXVIERA regimen as an eight-week treatment in the E. U. for GT1b HCV.. Statements that are not historical facts are based on management's current expectations, estimates, forecasts and projections about Enanta's business and the industry in which it operates and 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 and risks that may affect actual results include: the efforts of AbbVie (our collaborator on paritaprevir that is marketing VIEKIRAX + EXVIERA) to obtain regulatory approval of the label expansion for VIEKIRAX + EXVIERA in the E.U.; the development, regulatory and marketing efforts of others with respect to competitive HCV treatment regimens; and other risk factors described or referred to in "Risk Factors" in Enanta's most recent Form 10-K for the fiscal year ended September 30, 2016 and other periodic reports filed more recently 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.

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[1] Welzel, T. et al. GARNET: High SVR Rates Following Eight-Week Treatment with Ombitasvir/Paritaprevir/Ritonavir + Dasabuvir for Patients with HCV Genotype 1b Infection. Presented at the European Association for the Study of the Liver Special Conference: New Perspectives in Hepatitis C Virus Infection – The Roadmap for Cure, Paris, France on September 23-24, 2016.

[2] Gower E. et al. Global epidemiology and genotype distribution of the hepatitis C virus infection. Journal of Hepatology Update: Hepatitis C, 2014; 61: S45-S57.

[3] 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.

[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] Lavanchy D. Evolving epidemiology of hepatitis C virus. Clin Microbiol Infect. 2011; 17(2):107-15.

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