Enanta Pharmaceuticals Announces Data on Eight-Week Treatment of AbbVie's VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) in Patients with Genotype 1b Chronic Hepatitis C

September 23, 2016

- *AbbVie reports 98 percent of previously untreated genotype 1b (GT1b) chronic hepatitis C virus (HCV) infected patients without cirrhosis achieved SVR_{12} in Phase 3b GARNET study[1]*
- *First study evaluating 8 weeks of VIEKIRAX (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA (dasabuvir tablets)[1]*
- *GT1b is the most common HCV subtype globally[2], accounting for approximately 47 percent of the estimated nine million people infected with chronic HCV in Europe alone[3,4]*

WATERTOWN, Mass.--(BUSINESS WIRE)--Sep. 23, 2016-- 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 new data showing high response rates with just eight weeks of VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) treatment. VIEKIRAX + EXVIERA is currently approved in the European Union for GT1b patients without cirrhosis or with compensated cirrhosis for 12 weeks.

In AbbVie's Phase 3b GARNET study, 98 percent (n=160/163) of previously untreated patients with genotype 1b (GT1b) chronic hepatitis C virus (HCV) infection without cirrhosis achieved sustained virologic response rates at 12 weeks post-treatment (SVR_{12}).[1] These data were presented today at the 2016 EASL Special Conference: New Perspectives in Hepatitis C Virus Infection – The Roadmap for Cure, in Paris, France and included in the newly published 'EASL Recommendations on Treatment of Hepatitis C.'

Paritaprevir is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and is one of the direct-acting antivirals in AbbVie's VIEKIRAX + EXVIERA treatment regimen for chronic hepatitis C virus (HCV).

In 2016, the World Health Organization has estimated that 130-150 million people worldwide are infected with HCV.[5] In Europe, GT1b is the predominant genotype, accounting for approximately 47 percent of the estimated nine million Europeans infected with chronic HCV.[3,4,6]

In the GARNET study, the most commonly reported adverse events (?5 percent) were headache (21 percent), fatigue (17 percent), nasopharyngitis (8 percent), pruritus (8 percent), nausea (6 percent) and asthenia (5 percent). These adverse events were mostly mild, with one patient discontinuing treatment due to adverse events.[1]

About the GARNET Study1
The Phase 3b GARNET study is 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 is the percentage of patients who achieved a sustained virologic response 12 weeks after treatment (SVR_{12}).

Two patients experienced post-treatment relapse and one subject 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 are 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.

Protease Inhibitor Collaboration with AbbVie (formerly the research-based pharmaceutical business of Abbott Laboratories)
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 responsible for all development and commercialization activities for the collaboration's lead compound, paritaprevir, as well as ABT-493, the collaboration's second protease inhibitor. Enanta is eligible to receive annually tiered, double-digit royalties per product on AbbVie's worldwide net sales allocable to the collaboration's protease inhibitor products and is eligible to receive up to $80 million in commercial regulatory approval milestones for ABT-493.

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 is currently focused on four disease targets: Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), Non-alcoholic Steatohepatitis (NASH) and Respiratory Syncytial Virus (RSV).

Enanta has developed direct-acting-antiviral (DAA) inhibitors designed for use against HCV. Enanta's protease inhibitors, developed through its collaboration with AbbVie, include paritaprevir, which is contained in AbbVie's marketed DAA regimens for HCV, and ABT-493, Enanta's second protease inhibitor, which AbbVie is developing in phase 3 studies in combination with ABT-530, AbbVie's NS5A inhibitor. Enanta has also discovered a cyclophilin inhibitor, EDP-494, a novel, host-targeting mechanism for HCV, which is now in phase 1 clinical development, and EDP-305, an FXR agonist, which Enanta plans to advance into clinical development for NASH later in 2016. In addition, Enanta has early lead candidates for HBV and RSV in preclinical testing. 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 eight-week treatment with VIEKIRAX + EXVIERA without ribavirin in treatment-naïve patients with GT1b chronic HCV infection without cirrhosis. 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 commercialize the regimen; the development, regulatory and marketing efforts of others with respect to competitive HCV treatment regimens; regulatory and reimbursement actions affecting VIEKIRAX + EXVIERA, any competitive regimen, or both; 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, 2015 and any 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,

[5] World Health Organization. Draft global health sector strategies: Viral hepatitis, 2016–2021. A69/32, 22 April 2016

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

[7] Messina, et al. Global distribution and prevalence of hepatitis C virus genotypes. Hepatology 2015; 61: 77-87

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