Enanta Announces High SVR Rates with AbbVie's VIEKIRAX® + EXVIERA® Regardless of the Presence of Resistance-Associated Variants Prior to Treatment in Genotype 1 Chronic Hepatitis C Patients

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- *100 percent of genotype 1b (GT1b) patients who received VIEKIRAX + EXVIERA without ribavirin for 12 weeks, achieved* SVR_{12} *in a post-hoc analysis, regardless of whether baseline NS5A RAVs were present*[1]
- *97 percent of genotype 1a (GT1a) patients, with or without baseline NS5A RAVs, who received the regimen with ribavirin achieved* SVR_{12}[1]

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 14, 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, announced today data showing that patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection who received the recommended regimen of AbbVie's VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets), with or without ribavirin (RBV), achieved high sustained virologic response rates at 12 weeks post-treatment (SVR_{12}), regardless of the presence of baseline resistance-associated variants (RAVs).[1] These late-breaking data from a post-hoc analysis of five completed Phase 3 clinical trials will be presented today at The International Liver Congress™ (ILC) 2016, in Barcelona, Spain.

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).

The study found that no matter whether certain NS5A RAVs were present, 100 percent (n=148/148) of patients with GT1b chronic HCV infection who received VIEKIRAX + EXVIERA without RBV for 12 weeks, achieved SVR_{12}.[1] Results also showed 97 percent of patients with GT1a chronic HCV infection with or without baseline NS5A RAVs (n=57/59 and n=351/361respectively) achieved SVR_{12} when receiving the recommended regimen of VIEKIRAX + EXVIERA with RBV.[1] These findings included patients new to therapy and patients previously treated with pegylated interferon/ribavirin (pegIFN/RBV) (treatment-experienced), as well as GT1 patients with compensated cirrhosis.[1]

As the hepatitis C virus replicates, variants of the viral NS5A protein are produced.[2] The impact of these variants on treatment response, including the possibility of becoming resistant to therapy or achieving SVR, has yet to be fully determined.[3]

To understand more about the impact of variants on treatment response, next-generation sequencing was used to assess baseline samples for variants in NS5A, which were detected in 11 percent of GT1a patients and 19 percent of GT1b patients, with a detection threshold of 15 percent, consistent with the limits of detection for variants by population sequencing.[1] The post-hoc analysis was performed on data from five completed Phase 3 studies:[1] PEARL-IV (GT1a treatment-naïve, n=90), SAPPHIRE-II (GT1a pegIFN/RBV treatment-experienced, n=214), TURQUOISE-II (GT1a compensated cirrhosis – 24 week treatment arm, n=118), PEARL-II (GT1b pegIFN/RBV treatment-experienced, n=89) and TURQUOISE-III (GT1b compensated cirrhosis, n=59). Patients who did not achieve SVR for reasons other than virologic failure (such as early treatment discontinuations or SVR_{12} data unavailable) were excluded from the analysis.

About 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 and GT4 patients with compensated cirrhosis, 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 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 discovered novel protease inhibitors and NS5A inhibitors that are members of the direct-acting-antiviral (DAA) inhibitor classes designed for use against the hepatitis C virus (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. Please visit www.enanta.com for more information on Enanta's programs and pipeline.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including statements with respect to the prospects for AbbVie's HCV treatment regimens containing paritaprevir and Enanta's other research and development programs. 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 marketing VIEKIRAX) to market and sell VIEKIRAX-containing regimens; the development, regulatory and marketing efforts of others with respect to competitive HCV treatment regimens; regulatory and reimbursement actions affecting VIEKIRAX, 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]Sarrazin C, et al. Effect of Baseline Resistance-Associated Variants on SVR with the 3D Regimen plus RBV. Late Breaker Poster #LBP503; presented at the International Liver Congress™ (ILC) The Annual Meeting of the European Association for the Study of the Liver (EASL) in Barcelona, April 13-17, 2016.

[2] Schneider MD, et al. Antiviral therapy of hepatitis C in 2014: do we need resistance testing? Antiviral Res. 2014 May;105:64-71.

[3] American Association for the Study of Liver Diseases. Monitoring patients who are starting hepatitis C treatment, are on treatment, or have completed therapy, February 24, 2016, http://www.hcvguidelines.org/full-report/monitoring-patients-who-are-starting-hepatitis-c-treatment are-treatment-or-have. Accessed March 15, 2016.

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