



Enanta Announces JAMA Publication of Results from AbbVie's Study of VIEKIRA PAK™ (ombitasvir, paritaprevir, ritonavir tablets; dasabuvir tablets) in Chronic Hepatitis C Patients with HIV-1 Co-Infection (TURQUOISE-I)

February 23, 2015

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- *In adult patients co-infected with genotype 1 (GT1) hepatitis C virus (HCV) and human immunodeficiency virus type 1 (HIV-1), using VIEKIRA PAK with ribavirin (RBV), (TURQUOISE-I Study) demonstrated sustained virologic response rates 12 weeks post-treatment (SVR₁₂) of 94 percent with 12 weeks of treatment and 91 percent with 24 weeks of treatment, respectively*
- *Regimen contains Enanta's lead protease inhibitor, paritaprevir*
- *Additional sub-analyses of TURQUOISE-I data to be presented this week at the Annual Conference on Retroviruses and Opportunistic Infections (CROI)*

WATERTOWN, Mass.--(BUSINESS WIRE)--Feb. 23, 2015-- 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 results from part one of the Phase 2 portion of AbbVie's Phase2/3 open-label study, TURQUOISE-I, in genotype 1 chronic hepatitis C patients with human immunodeficiency virus type 1 (HIV-1) co-infection were published online in *The Journal of the American Medical Association (JAMA)*. Additional sub-analyses also will be presented in both oral and poster presentations on Feb. 26, at the Annual Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle, Washington.

As published today in *JAMA*, and originally presented at The Liver Meeting®2014, the TURQUOISE-I study showed patients co-infected with genotype 1 (GT1) hepatitis C virus (HCV) and HIV-1 receiving VIEKIRA PAK™ (ombitasvir, paritaprevir, ritonavir tablets; dasabuvir tablets) and ribavirin (RBV) for 12 weeks or 24 weeks achieved sustained virologic response rates 12 weeks post-treatment (SVR₁₂) of 94 percent (n=29/31) and 91 percent (n=29/32), respectively. The SVR₁₂ rates were 91 percent (n=51/56) for subjects with HCV GT1a infection and 100 percent (n=7/7) for those with HCV GT1b infection.

Paritaprevir is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and is one of the three direct-acting antivirals in the TURQUOISE-I treatment regimen. AbbVie is responsible for all development and commercialization activities for regimens that contain paritaprevir.

VIEKIRA PAK is contraindicated with efavirenz (Sustiva) because co-administration is poorly tolerated and results in liver enzyme elevations. The ritonavir component of VIEKIRA PAK is an HIV-1 protease inhibitor and can select for HIV-1 protease inhibitor resistance. To reduce this risk, HCV/HIV-1 co-infected patients should also be on a suppressive antiretroviral (ART) drug regimen. The most common adverse events occurring in at least 10 percent of patients in TURQUOISE-I were fatigue (48%), insomnia (19%), nausea (17%), headache (16%), itching (13%), cough (11%), irritability (10%), and yellowing of the eyes (10%).

Sub-analyses of these data will be presented later this week at CROI in oral and poster presentations:

- **High SVR Regardless of Time to Suppression with Paritaprevir/r/Ombitasvir & Dasabuvir + RBV**
Oral Presentation #147
February 26, 2015, 10:30-10:45 p.m. PST, Room 6AB
Analysis of time to HCV suppression in HCV/HIV co-infected patients in TURQUOISE-I
- **Hematologic Analysis of Paritaprevir/r/Ombitasvir and Dasabuvir + RBV in TURQUOISE-I**
Poster #691
February 26, 2015, 2:30-4:00 p.m. PST, Poster Hall
In this analysis of the TURQUOISE-I study, certain laboratory values in patients taking paritaprevir/r/ombitasvir and dasabuvir with RBV were examined, including hemoglobin, CD4+ T cells, and lymphocyte count

About TURQUOISE-I

TURQUOISE-I is an ongoing Phase 2/3, multi-center, randomized, open-label study evaluating the efficacy and safety of VIEKIRA PAK (ombitasvir, paritaprevir, ritonavir (25/150/100 mg once daily) and dasabuvir (250 mg twice daily) with RBV (weight based dosing of 1000 mg or 1200 mg per day divided twice daily) for 12 or 24 weeks in adult patients with chronic GT1 HCV infection with or without compensated liver cirrhosis who are also infected with HIV-1.

Study patients were either new to therapy (treatment-naïve) or had failed previous treatment with pegylated interferon and RBV (treatment-experienced), had a stable immune status (CD4+ counts of ≥ 200 cells/mm³ or CD4+ % $\geq 14\%$). Patients were on a stable HIV-1 ART regimen that

included tenofovir disoproxil fumarate plus emtricitabine or lamivudine, administered with ritonavir-boosted atazanavir or raltegravir. Patients on atazanavir stopped the ritonavir component of their HIV-1 ART regimen upon initiating treatment with VIEKIRA PAK + RBV. Atazanavir was taken with the morning dose of VIEKIRA PAK. The ritonavir component of the HIV-1 ART regimen was restarted after completion of treatment with VIEKIRA PAK and RBV. Of the five patients who were non-responders, one experienced virologic failure, one discontinued treatment, one experienced relapse and two patients had evidence of HCV reinfection post-treatment. Based on the results of this study, prescribers should follow the same dosing recommendations for mono-infected patients as outlined in the VIEKIRA PAK prescribing information.

Elevations in total bilirubin were the most common laboratory abnormality, were mainly composed of indirect bilirubin, and were not associated with elevations in commonly measured liver enzymes. Reductions in RBV dose because of anemia or reduced hemoglobin occurred in 10 percent of patients (n=6/63); all six patients achieved SVR₁₂.

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. AbbVie is Abbott's successor under the agreement and is responsible for all development and commercialization activities for 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 AbbVie's paritaprevir-containing, VIEKIRA PAK + ribavirin in patients co-infected with GT1 HCV and HIV-1. 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 efforts of AbbVie (our collaborator on paritaprevir) regarding commercialization of regimens containing paritaprevir, market acceptance of VIEKIRA PAK in the U.S. and other markets, 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 in jurisdictions beyond the U.S. and Europe. 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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