



Enanta Pharmaceuticals Announces Preliminary Data from AbbVie's Phase 3b RUBY-I Study in Chronic Hepatitis C Patients with Renal Impairment Presented at The International Liver Congress™ 2015

April 25, 2015

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- ***In preliminary data from RUBY-I, patients receiving VIEKIRAX + EXVIERA with or without ribavirin who reached post-treatment week four (n=10 of 20 enrolled) achieved 100 percent sustained virologic response at four weeks post-treatment (SVR4)¹***
- ***Treatment regimen evaluating VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) with or without ribavirin (RBV) contains Enanta's lead protease inhibitor, paritaprevir***

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 25, 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, announced today new preliminary safety and efficacy data from the first cohort of AbbVie's ongoing, Phase 3b RUBY-I study. RUBY-I is evaluating the regimen of VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) with or without ribavirin (RBV) in treatment-naïve, non-cirrhotic, genotype 1 (GT1) chronic hepatitis C patients with severe renal impairment (stage 4 or 5), including those on hemodialysis. The primary endpoint of the study is the percentage of patients achieving sustained virologic response at 12 weeks post-treatment (SVR₁₂). The first ten patients, or 100 percent, who have reached post-treatment week four to date (n=10 of 20 enrolled) achieved SVR₄ (n=10/10).¹ The RUBY-I study was presented as a late-breaker today at The International Liver Congress™ (ILC) 2015, the 50th annual meeting of the European Association for the Study of the Liver (EASL) in Vienna, Austria.

"We are encouraged by this promising data in this difficult-to-treat patient population," stated Jay R. Luly, Ph.D., President and Chief Executive officer. "We look forward to the final data from this and other studies that AbbVie is conducting in special populations."

RUBY-I data showed no virologic failures to date.¹ Preliminary safety analyses reported that patients experienced mainly mild or moderate adverse events when receiving VIEKIRAX + EXVIERA with or without RBV, most commonly (> 20 percent) anemia, fatigue, diarrhea, nausea, dizziness and headache.¹ To date, eight of 13 GT1a patients had a RBV dose interruption.¹

Paritaprevir, Enanta's lead protease inhibitor, is one of the three direct-acting antivirals (DAAs) included in AbbVie's HCV treatment regimens approved in the U.S. for genotype 1 chronic hepatitis C virus as VIKIERA PAK®, in the E.U. as VIEKIRAX® + EXVIERA®, and in Canada as HOLKIRA PAK®. AbbVie is responsible for all development and commercialization activities for regimens that contain paritaprevir.

Additional Phase 3b studies from AbbVie presented at ILC 2015 included MALACHITE-I and MALACHITE-II data, and TOPAZ-I and TOPAZ-II study design. The MALACHITE studies evaluate adult patients with GT1 chronic HCV infection without cirrhosis receiving VIEKIRAX + EXVIERA with or without RBV compared to treatment with telaprevir with pegylated-interferon and RBV, which remains the standard of care in many regions of the world.^{2,3} The TOPAZ studies will evaluate the effect of SVR₁₂ on long-term outcomes five years following treatment with VIEKIRAX + EXVIERA with or without RBV in adults with GT1 chronic HCV infection.⁴

About RUBY-I Study

RUBY-I is an ongoing multi-center, open-label, Phase 3b study with two cohorts to evaluate the safety and efficacy of 12 or 24 weeks of treatment with VIEKIRAX® + EXVIERA® with or without ribavirin, based on sub-genotype in treatment-naïve, adult patients with genotype 1 (GT1) chronic hepatitis C virus infection who have severe renal impairment (pre-dialysis; stage 4 chronic kidney disease) or end-stage renal disease (on hemodialysis; stage 5 chronic kidney disease) with or without compensated cirrhosis.¹ Cohort 1 consists of 20 patients without cirrhosis and cohort 2 will evaluate approximately 20 patients with or without compensated cirrhosis. Ribavirin was started at 200mg once daily for all GT1a-infected patients and dosed four hours prior to the start of GT1a patients on hemodialysis. Additional study results, including cohort 2, will be disclosed at future scientific congresses.

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. Enanta's lead protease inhibitor, paritaprevir, is part of AbbVie's recently approved HCV treatment regimens. 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 Statement Disclaimer

This press release contains forward-looking statements, including statements with respect to the prospects for clinical study results with treatment

regimens containing paritaprevir for HCV. 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) to develop and obtain additional regulatory approvals for treatment regimens containing paritaprevir; the development, regulatory and marketing efforts of others with respect to competitive HCV treatment regimens; regulatory and reimbursement actions affecting any paritaprevir-containing regimens, any competitive regimens, 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, 2014 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.

¹ Pockros P, et al. Safety Of Ombitasvir/Paritaprevir/Ritonavir Plus Dasabuvir For Treating HCV GT1 Infection In Patients With Severe Renal Impairment Or End-stage Renal Disease: The RUBY-I Study. Presented at the 50th International Liver Congress (ILC); April 22-26; Vienna, Austria

² Conway B, et al. MALACHITE-I: Phase 3b Trial Of Ombitasvir/Paritaprevir/R And Dasabuvir +/-Ribavirin Or Telaprevir + Peginterferon/Ribavirin In Treatment-naïve Adults With HCV Genotype 1. Abstract presented at the 50th International Liver Congress (ILC); April 22-26; Vienna, Austria

³ Dore G, et al. MALACHITE-II: Phase 3b Trial Of Ombitasvir/Paritaprevir/R And Dasabuvir + Ribavirin Or Telaprevir + Peginterferon/Ribavirin In Peginterferon/Ribavirin Treatment-experienced Adults With HCV Genotype 1. Abstract presented at the 50th International Liver Congress (ILC); April 22-26; Vienna, Austria

⁴ Dumas E, et al. Phase 3b Studies To Assess Long-term Clinical Outcomes In HCV GT1-infected Patients Treated With Ombitasvir/Paritaprevir /Ritonavir And Dasabuvir With Or Without Ribavirin. Abstract presented at the 50th International Liver Congress (ILC); April 22-26; Vienna, Austria.



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