Enanta Announces that AbbVie's Investigational, Pan-Genotypic Regimen of ABT-493 and ABT-530 Shows High SVR Rates in Genotype 1 Hepatitis C Patients Who Failed Previous Therapy with Direct-Acting Antivirals

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- *95 percent of patients achieved SVR_{12} with 12 weeks of ABT-493 and ABT-530 with and without RBV in GT1 chronic HCV infected patients without cirrhosis who failed previous therapy with DAAs in a modified intent-to-treat analysis*
- *91 percent achieved SVR_{12} with RBV in the primary intent-to-treat analysis; 86 percent achieved SVR_{12} without RBV*
- *ABT-493 is Enanta's second protease inhibitor being developed in combination with ABT-530, AbbVie's NS5A inhibitor*

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 15, 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 that in AbbVie's MAGELLAN-1 study of genotype 1 (GT1) chronic hepatitis C virus (HCV) infected patients who failed previous therapy with direct-acting antivirals (DAAs), 91 percent (n=20/22) achieved sustained virologic response at 12 weeks post-treatment (SVR_{12}) after 12 weeks of treatment with ABT-493 and ABT-530 with ribavirin (RBV) in the primary intent-to-treat analysis. Additionally, 86 percent (n=19/22) of GT1 patients who received ABT-493 and ABT-530 without RBV, achieved SVR_{12}.[1] In a modified intent-to-treat analysis of these patients, excluding those who did not achieve SVR for reasons other than virologic failure, 95 percent of patients who received the regimen, with or without RBV (n=20/21, n=19/20; respectively) achieved SVR_{12}.

The results were evaluated in the ongoing MAGELLAN-1 study of AbbVie's once-daily, investigational, pan-genotypic regimen of co-formulated ABT-493 (300mg) and ABT-530 (120mg) for the retreatment of non-cirrhotic patients with GT1 chronic HCV who have failed previous therapy with DAAs. These data will be presented today at The International Liver Congress™ (ILC) 2016 in Barcelona, Spain.

ABT-493 is Enanta's second protease inhibitor being developed through its collaboration with AbbVie and is one of the two new direct-acting antivirals in the combination treatment being investigated in the ongoing MAGELLAN-1 study.

"With limited treatment options for this difficult-to-treat patient population, these high SVR rates are very encouraging and show potential in treating patients who have failed DAA therapy previously," stated Jay R. Luly, Ph.D., President and Chief Executive Officer.

No patients discontinued treatment due to adverse events, and two patients experienced virologic failure, one from each arm.[1] The most common adverse events (≥10 percent of patients overall) were headache (30 percent), fatigue (27 percent) and nausea (20 percent).[1]

About MAGELLEN-1[1]
MAGELLAN-1 is an ongoing Phase 2, randomized, open-label multicenter study to evaluate the efficacy, safety and pharmacokinetics of ABT-493 and ABT-530, with or without RBV, in adults with genotype 1, 4, 5 or 6 chronic HCV infection who failed a prior DAA-containing therapy.

In Part 1 of the study, 50 GT1 patients without cirrhosis who previously failed therapy containing a protease inhibitor and/or NS5A inhibitor, with or without a NS5B polymerase inhibitor, were randomized to receive once-daily ABT-493 and ABT-530 at doses of 200/80mg (Arm A), 300/120mg with 800mg RBV (Arm B), or 300/120mg without RBV (Arm C), for 12 weeks. The primary efficacy endpoint was SVR_{12}. Patients who failed previous treatment for reasons other than breakthrough or relapse were excluded. Deep sequencing (Illumina MiSeq) revealed pre-existing resistance-associated variants (RAVs) in 41 patients (82 percent), 15 in NS3, 10 in NS5A, and 16 with RAVs in both targets. Data presented at ILC 2016 were based on an analysis of the intent-to-treat population.

Data from the first six patients enrolled in Arm A (once-daily ABT-493 and ABT-530 at doses of 200/80mg) showed 100 percent achieved SVR_{12}. Additional patients were enrolled and received study drug at the higher doses of the combination that will be used in Phase 3 clinical trials, 300/120mg ABT-493/ABT-530 with or without 800mg RBV. There were no grade 3 or 4 laboratory abnormalities.

Part 2 of the study is underway to examine once-daily ABT-493 (300mg) and ABT-530 (120mg) without RBV in a larger group of DAA treatment-experienced patients, including those with compensated cirrhosis and in genotypes 4, 5 or 6.

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 investigational HCV treatment regimen containing ABT-493 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 developing ABT-493) to develop and obtain regulatory approval of any regimens containing ABT-493 and successfully commercialize them; the development, regulatory and marketing efforts of others with respect to competitive HCV treatment regimens; regulatory and reimbursement actions affecting any ABT-493-containing HCV regimen, 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] Poordad, F et al. High Efficacy of ABT-493 and ABT-530 in HCV Genotype 1 Infected Patients Who Have Failed Direct-Acting Antiviral- Containing Regimens: The MAGELLAN-I Study. Oral presentation #GS11 presented at The International Liver Congress™ (ILC), the Annual Meeting of the European Association for the Study of the Liver (EASL) in Barcelona, Spain, April 13-17, 2016.

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