Enanta Announces New Data from AbbVie's SURVEYOR-1 and SURVEYOR-2 Studies Showing High Sustained Virologic Response Rates after 8 or 12 Weeks of Treatment in Patients with any of Genotypes 1 through 6 of Hepatitis C Virus

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- *97-98 percent SVR_{12} achieved with eight weeks of ABT-493 and ABT-530 treatment in genotypes 1, 2 or 3 HCV patients without cirrhosis in SURVEYOR 1 and 2 studies[1,2]*
- *100 percent SVR_{12} achieved with 12 weeks of treatment in difficult-to-treat genotype 3 patients with compensated cirrhosis (Child-Pugh A) new to therapy [3]*
- *100 percent SVR_{12} achieved with 12 weeks of treatment in genotypes 4, 5 or 6 patients without cirrhosiss; eight-week treatment duration being investigated in this ongoing study[4]*
- *ABT-493 is Enanta's second protease inhibitor being developed in combination with ABT-530, AbbVie's NS5A inhibitor*

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 16, 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 with eight weeks of treatment, 97-98 percent of genotype 1, 2 or 3 (GT1-3) chronic hepatitis C virus (HCV) infected patients without cirrhosis treated with AbbVie's investigational, once-daily, pan-genotypic regimen of ABT-493 and ABT-530, without ribavirin (RBV), achieved sustained virologic response at 12 weeks post-treatment (SVR_{12}).[1,2] Results for GT1 (n=33/34), GT2 (n=53/54) and treatment-naïve GT3 (n=28/29) patients were based on an Intent-to-Treat (ITT) analysis.[1,2] Additionally, 100 percent (n=34/34) of genotype 4, 5 or 6 (GT4-6) chronic HCV infected patients without cirrhosis achieved SVR_{12} with 12 weeks of treatment.[4] These new data from the Phase 2 SURVEYOR-1 and SURVEYOR-2 studies will be presented at The International Liver Congress™ (ILC) 2016, in Barcelona, Spain.

In separate late-breaking data from the SURVEYOR-2 study, 100 percent of GT3 chronic HCV infected patients with compensated cirrhosis (Child-Pugh A) and new to therapy achieved SVR_{12} with 12 weeks of treatment with or without RBV (n=24/24 in each arm).[3] No patients discontinued treatment due to adverse events. Data in GT3 chronic HCV infected patients with or without cirrhosis were featured in the official ILC 2016 press program.

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 SURVEYOR-1 and SURVEYOR-2 studies.

"We are pleased that this ABT-493-containing regimen is demonstrating high sustained virologic response rates across multiple genotypes and without ribavirin," commented Jay R. Luly, Ph.D. President and Chief Executive Officer. "We are particularly pleased with the results in genotype 1-3 patients with only 8 weeks of treatment, as well as in difficult-to-treat genotype 3 patients with compensated cirrhosis and 12 weeks of treatment. We look forward to additional data later this year from AbbVie's ongoing phase 3 registrational program."

In a pooled analysis of 531 patients across both SURVEYOR studies of the five treatment regimens of ABT-493 and ABT-530 evaluated, the most commonly reported adverse events were fatigue (18 percent), headache (17 percent), nausea (13 percent) and diarrhea (10 percent).[5] Three patients across all study arms evaluated to date, two of whom received RBV, discontinued study drugs early due to adverse events.[5]

Overview of SURVEYOR-1 and SURVEYOR-2 Clinical Data Presented at ILC:

Patient Profile/Study	Patient number (n)/ Patient Population	Duration of Treatment	Treatment Regimen	SVR_{12} Rates ITT *
GT1 Non-cirrhotic[1] SURVEYOR-1	n=34 Treatment-naïve=85% pegIFN/RBV treatment experienced=15%	8 weeks	ABT-493 (300mg) + ABT-530 (120mg) once daily	97% (n=33/34)
GT2 Non-cirrhotic[1] SURVEYOR-2	n=54 Treatment-naïve=87% pegIFN/RBV treatment experienced=13%	8 weeks	ABT-493 (300mg) + ABT-530 (120mg) once daily	98% (n=53/54)

GT3 Non-cirrhotic[2] SURVEYOR-2	n=29 Treatment-naïve =100%	8 weeks	ABT-493 (300mg) + ABT-530 (120mg) once daily	97% (n=28/29)
GT3 Cirrhotic[3] (Child-Pugh A)	n=24 Treatment-naïve= 100%	12 weeks	ABT-493 (300mg) + ABT-530 (120mg) (without RBV) once daily	100% (n=24/24)
SURVEYOR-2	n=24 Treatment-naïve= 100%	12 weeks	ABT-493 (300mg) + ABT-530 (120mg) + RBV (800mg) once daily	100% (n=24/24)
GT 4,5,6 Non-cirrhotic[4] SURVEYOR-1	n=34 (GT4=22; GT5=1; GT6=11) Treatment-naïve=85% pegIFN/RBV treatment experienced=15%	12 weeks	ABT-493 (300mg) + ABT-530 (120mg) once daily	100% (n=34/34)

* Intent-to-treat (ITT) population is defined as all patients who received at least one dose of the study drugs

About SURVEYOR-1[1,4,5]
SURVEYOR-1 is an ongoing Phase 2, two-part study designed to evaluate the safety and efficacy of ABT-493 and ABT-530, with or without RBV, for eight or 12 weeks, in cirrhotic and non-cirrhotic adult GT1 patients, and in non-cirrhotic GT4, 5 or 6 adult patients, with chronic HCV infection who were new to therapy or did not respond to previous treatment with pegylated interferon (pegIFN)/RBV (null responder).

About SURVEYOR-2[1,2,3,5]
SURVEYOR-2 is an ongoing Phase 2, four-part study designed to evaluate the safety and efficacy of ABT-493 and ABT-530, with or without RBV, in adult patients with GT2, 3, 4, 5 or 6 chronic HCV infection who were new to therapy or had failed previous treatment with pegylated interferon (pegIFN)/RBV.

The primary endpoint of both studies is the percentage of subjects achieving SVR_{12}.

Safety and efficacy data for Part 1 of the studies were presented at The Liver Meeting® 2015, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco.

About pooled safety analysis of SURVEYOR-1 and SURVEYOR-2[5]
531 patients were included in this safety analysis: 26 percent GT1, 24 percent GT2, 43 percent GT3, and 6 percent with GT4, 5, or 6 infection. Patients across genotypes received ABT-493/ABT-530 at five doses: 300/120mg (n=258), 300/120mg with RBV (n=27), 200/120mg (n=121), 200/120mg with RBV (n=56), and 200/40mg (n=69).

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 second 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 investigational treatment regimens containing ABT-493. 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 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 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 SVR Rates with the Combination of ABT-493 + ABT-530 for 8 Weeks in Non-Cirrhotic Patients with HCV Genotype 1 or 2 Infection. Poster presentation #SAT-157; 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.

[2] Muir, A et al. High SVR Rates with ABT-493 + ABT-530 Co-Administered for 8 Weeks in Non-Cirrhotic Patients with HCV Genotype 3 Infection. Oral presentation #PS098; 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.

[3] Kwo, P et al. 100% SVR_4 With ABT-493 and ABT-530 With or Without Ribavirin in Treatment-naïve HCV Genotype 3-infected Patients With Cirrhosis; Late Breaker presentation #LB01; 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

[4] Gane, E et al. 100% SVR_4 and Favorable Safety of ABT-493 + ABT-530 Administered for 12 Weeks in Non-Cirrhotic Patients with Genotypes 4,5, or 6 Infection (SURVEYOR-I). Poster presentation #SAT-137; 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.

[5] Kwo, P et al. Safety of ABT-493 and ABT-530 Co-Administered in Patients with HCV Genotype 1-6 Infection: Results From the SURVEYOR-I and SURVEYOR-II Studies; Poster presentation #SAT-239; 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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