



## Enanta Pharmaceuticals Announces 96 Percent SVR12 in Treatment Experienced Genotype 1 Hepatitis C Patients in SAPPHIRE-II Study

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### - Second of Six All-Oral, Interferon-Free Phase 3 Hepatitis C Studies Using Regimen Containing ABT-450

WATERTOWN, Mass.--(BUSINESS WIRE)--Dec. 10, 2013-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA) today announced results from the SAPPHIRE-II study, the second of six phase 3 registrational studies being conducted by AbbVie for the treatment of hepatitis C virus (HCV) genotype 1 (GT1) infection, using a regimen containing Enanta's lead protease inhibitor ABT-450. ABT-450 is part of AbbVie's investigational three direct-acting antiviral (3D) regimen, consisting of boosted protease inhibitor ABT-450/ritonavir, NS5A inhibitor ABT-267, and non-nucleoside polymerase inhibitor ABT-333. The SAPPHIRE-II study used this 3D regimen plus ribavirin.

Results from the 394-patient SAPPHIRE-II trial demonstrated a sustained virologic response at 12 weeks post-treatment (SVR<sub>12</sub>) of 96 percent in chronically infected GT1 HCV treatment experienced adult patients who had previously failed pegylated interferon and ribavirin treatment. Approximately 49 percent of these patients were prior null responders, namely patients defined as not achieving a significant reduction in the HCV virus during their prior treatment. The majority of patients were GT1a, considered the more difficult-to-treat subtype, and the SVR<sub>12</sub> rates of GT1a and GT1b were 96 percent and 97 percent, respectively. These results were based on an intent-to-treat analysis and were achieved after 12 weeks of treatment. Virologic relapse or breakthrough was noted in 2 percent of patients receiving the 3D regimen plus ribavirin. The treatment regimen was well tolerated, with 1 percent of patients discontinuing treatment due to adverse events.

"The high SVR rates in this SAPPHIRE-II trial and the previously reported SAPPHIRE-I trial further validate this 3D regimen plus ribavirin for both treatment-naïve and treatment-experienced patients," stated Jay R. Luly, Ph.D., President and Chief Executive Officer. "We look forward to the remaining phase 3 studies reading out using the same 3D regimen with and without ribavirin, as well as in the treatment of HCV patients with cirrhosis."

### About Study M13-098 (SAPPHIRE-II)

Following SAPPHIRE-I, SAPPHIRE-II is the second placebo-controlled trial and the second of six phase 3 trials supporting AbbVie's investigational 3D regimen for the treatment of GT1 hepatitis C patients. AbbVie will disclose detailed SAPPHIRE-II results at future scientific congresses and in publications.

SAPPHIRE-II is a global, multi-center, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of 12 weeks of treatment with ABT-333 (250mg), ribavirin (weight-based), both dosed twice daily, and the fixed-dose, co-formulated combination of ABT-450/ritonavir (150/100mg) and ABT-267 (25mg) dosed once daily in non-cirrhotic, GT1a and GT1b HCV-infected, treatment-experienced adult patients who previously failed treatment with pegylated interferon and ribavirin.

The study population consisted of 394 GT1 treatment-experienced patients with no evidence of liver cirrhosis. 297 patients were randomized to the 3D regimen plus ribavirin for 12 weeks, and 97 patients were randomized to placebo for the initial 12 weeks. Patients initially randomized to placebo for the first 12 weeks then received open-label treatment with the 3D regimen plus ribavirin for 12 weeks. In the study, 49 percent of patients were prior null responders to pegylated interferon and ribavirin, generally considered among the most difficult to treat successfully.

Following 12 weeks of treatment with AbbVie's 3D regimen plus ribavirin, 96 percent (n=286/297) of patients achieved SVR<sub>12</sub> based on an intent-to-treat analysis, where patients with missing values for any reason were considered treatment failures. The SVR<sub>12</sub> rates in GT1a and GT1b patients were 96 percent (166/173) and 97 percent (119/123), respectively. One subject had HCV genotype 1 and achieved SVR<sub>12</sub>, but was unable to be sub-genotyped.

The most commonly reported adverse events in both the 3D and placebo arms were headache, fatigue and nausea. Discontinuations due to adverse events were reported in three (1 percent) patients receiving the 3D regimen and no patients receiving placebo. Virologic relapse or breakthrough was noted in 2 percent of patients receiving the 3D regimen plus ribavirin.

AbbVie has announced that results from the remaining four ABT-450 containing studies in AbbVie's phase 3 program will be available in the coming months.

### Overview of AbbVie's phase 3 clinical programs:

Study	Patients (N)	Treatment Regimen	Treatment Duration
SAPPHIRE-I	GT1, treatment-naïve (631)	<ul style="list-style-type: none"> <li>• ABT-450/r<sup>b</sup> +ABT 267<sup>c</sup></li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	12 weeks
		<ul style="list-style-type: none"> <li>• Placebo</li> </ul>	12 weeks, then active treatment for 12 weeks

SAPPHIRE-II	GT1, treatment-experienced (394)	<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	12 weeks
		<ul style="list-style-type: none"> <li>• Placebo</li> </ul>	12 weeks, then active treatment for 12 weeks
PEARL-II	GT1b, treatment-experienced (210 <sup>a</sup> )	<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	12 weeks
		<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> </ul>	12 weeks
PEARL-III	GT1b, treatment-naïve (400 <sup>a</sup> )	<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	12 weeks
		<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Placebo</li> </ul>	12 weeks
PEARL-IV	GT1a, treatment-naïve (300 <sup>a</sup> )	<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	12 weeks
		<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Placebo</li> </ul>	12 weeks
TURQUOISE-II	GT1, treatment-naïve and treatment-experienced (with compensated cirrhosis) (380 <sup>a</sup> )	<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	12 weeks
		<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	24 weeks

<sup>a</sup> projected study population

<sup>b</sup> ABT-450/ritonavir

<sup>c</sup>ABT-267 is co-formulated with ABT-450/r, administered as two pills once daily

Additional information about AbbVie's phase 3 studies can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### **Protease Inhibitor Collaboration with AbbVie (formerly the research-based pharmaceutical business of Abbott Laboratories)**

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. ABT-450 is a protease inhibitor identified as a lead compound through the collaboration. Under the agreement, AbbVie is responsible for all development and commercialization activities for ABT-450. Enanta received \$57 million in connection with signing the collaboration agreement, has received \$55 million in subsequent clinical milestone payments, and is eligible to receive an additional \$195 million in payments for regulatory milestones, as well as double-digit royalties worldwide on any revenue allocable to the collaboration's protease inhibitors. Also, for any additional collaborative HCV protease inhibitor product candidate developed under the agreement, Enanta holds an option to modify the U.S. portion of it rights to receive milestone payments and worldwide royalties. With this option, Enanta can fund 40 percent of U.S. development costs and U.S. commercialization efforts (sales and promotion costs) for the additional protease inhibitor in exchange for 40 percent of any U.S. profits ultimately achieved after regulatory approval, instead of receiving payments for U.S. commercial regulatory approval milestones and royalties on U.S. sales of that protease inhibitor.

#### **About Hepatitis C Virus (HCV)**

Hepatitis C is a liver disease affecting over 170 million people worldwide. The virus is typically spread through direct contact with the blood of an infected person. Hepatitis C increases a person's risk of developing chronic liver disease, cirrhosis, liver cancer and death. There is an acute need for new HCV therapies that are safer and more effective for many variants of the virus.

#### **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 in the infectious disease field. 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 (partnered with Novartis) and nucleotide polymerase – as well as a host-targeted antiviral (HTA) inhibitor class targeted against cyclophilin. Additionally, Enanta has created a new class of antibiotics, called Bicyclolides, for the treatment of multi-drug resistant bacteria, with a focus on developing an intravenous and oral treatment for hospital and community MRSA (methicillin-resistant *Staphylococcus aureus*) infections.

#### **Forward Looking Statements Disclaimer**

This press release contains forward-looking statements, including with respect to clinical data, plans for announcing additional data, and the planned clinical development and regulatory submissions for ABT-450. 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 final results of ongoing clinical trials, the development and marketing efforts of AbbVie (our collaborator on ABT-450), regulatory actions affecting clinical development of ABT-450 and clinical development of competitive product candidates. 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.

Source: Enanta Pharmaceuticals, Inc.

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