



Enanta Pharmaceuticals Announces 96 Percent SVR₁₂ in SAPPHIRE-I Study

November 18, 2013

[Download this Press Release](#)

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

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 18, 2013-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA) today announced results from the SAPPHIRE-I study, one 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 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-I study used this 3D regimen plus ribavirin.

Results from the 631 patient SAPPHIRE-I trial demonstrated a sustained virologic response at 12 weeks post-treatment (SVR₁₂) of 96 percent in treatment-naïve adult patients chronically infected with GT1 HCV. The majority of patients were GT1a, considered the more difficult-to-treat subtype, and the SVR₁₂ rates of GT1a and GT1b were 95 percent and 98 percent, respectively. These results were based on an intent-to-treat analysis and were achieved after 12 weeks of treatment. The rate of virologic relapse or breakthrough was low, occurring in 1.7 percent of patients receiving the 3D regimen. The treatment regimen was well tolerated, with an equal percentage of patients in the active and placebo arms (0.6 percent) discontinuing treatment due to adverse events.

"Achieving high SVR rates in this trial is an important step toward our goal of providing a well-tolerated and highly effective all-oral treatment option that doesn't currently exist for this important patient population," stated Jay R. Luly, Ph.D., President and Chief Executive Officer.

About Study M11-646 (SAPPHIRE-I)

SAPPHIRE-I 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 combination of ABT-450/ritonavir (150/100mg) co-formulated with ABT-267 (25mg) and dosed once daily in non-cirrhotic, GT1a and GT1b HCV-infected, treatment-naïve adult patients.

The study population consisted of 631 GT1 treatment-naïve patients with no evidence of liver cirrhosis. 473 patients were randomized to the 3D regimen plus ribavirin for 12 weeks, and 158 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.

Following 12 weeks of treatment with AbbVie's 3D regimen plus ribavirin, 96 percent (n=455/473) of patients achieved SVR₁₂ based on intent-to-treat analysis where patients with missing values for any reason were considered treatment failures. In the active treatment arm, patients with GT1b infection achieved 98 percent SVR₁₂ (148/151), while patients with GT1a achieved 95 percent SVR₁₂ (307/322).

The most commonly reported adverse events in the 3D and placebo arms, respectively, were fatigue, headache and nausea. Discontinuations due to adverse events were reported in 0.6 percent of patients receiving the 3D regimen and 0.6 percent of patients receiving placebo. The rate of virologic relapse or breakthrough was low, occurring in 1.7 percent of patients receiving the 3D regimen.

AbbVie has announced that results from the remaining five ABT-450 containing studies in AbbVie's phase 3 program will be available in the coming months, supporting regulatory submissions starting in the second quarter of 2014. AbbVie will disclose detailed SAPPHIRE-I results at future scientific congresses and in publications.

Overview of AbbVie's phase 3 clinical programs:

Study	Patients (N)	Treatment Regimen	Treatment Duration
SAPPHIRE-I	GT1, treatment-naïve (631)	• ABT-450/r ^b +ABT-267 ^c • ABT-333 • Ribavirin	12 weeks
		• Placebo	12 weeks, then active treatment for 12 weeks
SAPPHIRE-II	GT1, treatment-experienced (400 ^a)	• ABT-450/r +ABT-267 • ABT-333 • Ribavirin	12 weeks
		• Placebo	12 weeks, then active treatment for 12 weeks

PEARL-II	GT1b, treatment-experienced (210 ^a)	• ABT-450/r +ABT-267 • ABT-333 • Ribavirin	12 weeks
		• ABT-450/r +ABT-267 • ABT-333	12 weeks
PEARL-III	GT1b, treatment-naïve (400 ^a)	• ABT-450/r +ABT-267 • ABT-333 • Ribavirin	12 weeks
		• ABT-450/r +ABT-267 • ABT-333 • Placebo	12 weeks
PEARL-IV	GT1a, treatment-naïve (300 ^a)	• ABT-450/r +ABT-267 • ABT-333 • Ribavirin	12 weeks
		• ABT-450/r +ABT-267 • ABT-333 • Placebo	12 weeks
TURQUOISE-II	GT1, treatment-naïve and treatment-experienced (with compensated cirrhosis) (380 ^a)	• ABT-450/r +ABT-267 • ABT-333 • Ribavirin	12 weeks
		• ABT-450/r +ABT-267 • ABT-333 • Ribavirin	24 weeks

^a projected study population

^b ABT-450/ritonavir

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

ABT-450 is currently being studied in combination with other AbbVie compounds in multiple phase 3 all-oral, interferon-free clinical studies for HCV. Additional information about AbbVie's phase 3 studies can be found on 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.

Investor:

Carol Miceli, 617-607-0710

cmiceli@enanta.com

or

Media:

MacDougall Biomedical Communications

Kari Watson, 781-235-3060

kwatson@macbiocom.com