Enanta Pharmaceuticals Announces Detailed Data from SAPPHIRE-I and SAPPHIRE-II Phase 3 Studies in Patients with Chronic Hepatitis C Virus Being Presented at the European Association for the Study of the Liver (EASL) Meeting

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- *SVR_{12} rates of 96% were demonstrated in both treatment-naïve and treatment-experienced genotype 1 (GT1) patients with chronic hepatitis C virus*
- *SVR_{12} rates of 95% to 100% were demonstrated in treatment-experienced GT1 patient sub-populations (SAPPHIRE-II)*

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 11, 2014-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs in the infectious disease field, today announced that detailed results from AbbVie's pivotal phase 3 SAPPHIRE-I study, will be presented today at the International Liver Congress (ILC), which is the 49th Annual Meeting of the European Association for the Study of the Liver (EASL) and featured in the ILC press conference. Results from the SAPPHIRE-II study were presented at the congress yesterday. Additionally, results from both the SAPPHIRE-I and SAPPHIRE-II studies have been published on-line in the *New England Journal of Medicine*.

The SAPPHIRE-I and SAPPHIRE-II studies report results from AbbVie's investigational three direct-acting antiviral regimen containing ABT-450, Enanta's lead protease inhibitor developed through Enanta's collaboration with AbbVie. The regimen consists of boosted protease inhibitor ABT-450/ritonavir, NS5A inhibitor ABT-267, and non-nucleoside polymerase inhibitor ABT-333.

In the SAPPHIRE-I (N=631) and SAPPHIRE-II (N=394) placebo-controlled studies, adult, non-cirrhotic patients with chronic genotype 1 (GT1) hepatitis C virus (HCV) infection receiving the investigational three-direct-acting antiviral regimen with ribavirin (RBV) for 12 weeks achieved sustained virologic response rates 12 weeks post-treatment (SVR_{12}) of 96.2 percent (n=455/473) and 96.3 percent (n=286/297), respectively.

In SAPPHIRE-II, treatment-experienced sub-populations randomized to the three direct-acting antiviral regimen with RBV in the study were prior null responders (49.2 percent), prior relapsers (29.0 percent) and prior partial responders (21.9 percent) to pegylated interferon and RBV.

SAPPHIRE-I and SAPPHIRE-II Results

	SAPPHIRE-I SVR_{12} (n=473)	**SAPPHIRE-II SVR_{12} (n=297)**
All GT1	**96.2% (n=455/473)**	**96.3% (n=286/297)***
GT1a	95.3% (n=307/322)	96.0% (n=166/173)
GT1b	98.0% (n=148/151)	96.7% (n=119/123)
Treatment-experienced (GT1a and GT1b)		
Prior null responders	n/a	95.2% (n=139/146)
Prior relapsers	n/a	95.3% (n=82/86)
Prior partial responders	n/a	100.0% (n=65/65)

*Subgenotype could not be determined for one patient

In SAPPHIRE-I, high response rates were seen across patients with certain variable characteristics, including gender, race, body mass index, fibrosis stage and baseline HCV viral load, as some of these patients have historically had a reduced response to treatment.

Discontinuations due to adverse events were reported in 0.6 percent of patients in both arms in SAPPHIRE-I and in 1.0 percent of patients receiving the AbbVie regimen in SAPPHIRE-II and no patients receiving placebo. The most commonly reported treatment-emergent adverse events (>10 percent in either arm) for both SAPPHIRE-I and SAPPHIRE-II were fatigue, headache, nausea, asthenia, insomnia, pruritus and diarrhea. Additional common adverse events occurring in the studies were rash in SAPPHIRE-I and dyspnea, cough and myalgia in SAPPHIRE-II. In SAPPHIRE-I, the adverse events that occurred with a significantly greater frequency in the treatment arm compared to placebo were pruritus, insomnia, diarrhea, nausea and asthenia; in SAPPHIRE-II, only pruritus.

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 the three direct-acting antiviral regimen with RBV in non-cirrhotic, GT1a and GT1b HCV-infected adult patients new to therapy.

The study population consisted of 631 patients: 473 were randomized to the three direct-acting antiviral regimen with RBV 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 AbbVie regimen with RBV for 12 weeks.

Of the 473 patients randomized to the three direct-acting antiviral regimen with RBV, one case (0.2 percent) of on-treatment virologic failure occurred and seven patients (1.5 percent) experienced post-treatment relapse. In addition, three patients (0.6 percent) were lost to follow-up and seven patients (1.5 percent) discontinued the study prematurely. Patients lost to follow-up were considered treatment failures.

About Study M13-098 (SAPPHIRE-II)

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 the three direct-acting antiviral regimen with RBV in non-cirrhotic, GT1a and GT1b HCV-infected, treatment-experienced adult patients who previously failed treatment with pegylated interferon and RBV.

The study population consisted of 394 patients: 297 were randomized to the three direct-acting antiviral regimen with RBV 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 three direct-acting antiviral regimen with RBV for 12 weeks.

Of the 297 patients randomized to the three direct-acting antiviral regimen with RBV, there were no cases of on-treatment virologic failure and seven patients (2.4 percent) experienced post-treatment relapse. Of these patients, six were prior null responders and one was a prior relapser. Three patients (1.0 percent) prematurely discontinued therapy due to adverse events and one patient (0.3 percent) prematurely discontinued the study.

Additional information about AbbVie's phase III studies can be found on www.clinicaltrials.gov.

About ABT-450

ABT-450 is an NS3 protease inhibitor discovered through Enanta's collaboration with AbbVie. AbbVie and Enanta have an agreement to collaborate on the discovery, development and commercialization of HCV NS3 and NS3/4A protease inhibitors. Protease inhibitors play an essential role in the viral life cycle of the hepatitis C virus (HCV). Inhibition of the protease prevents non-structural (NS) proteins from forming and thereby prevents replication and survival of the HCV virus. ABT-450 is part of AbbVie's investigational regimen for HCV that consists of boosted protease inhibitor ABT-450/ritonavir (referred to as ABT-450/r), NS5A inhibitor ABT-267 and non-nucleoside polymerase inhibitor ABT-333.

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. Patients with compensated cirrhosis have a liver that is heavily scarred but that can still perform many important bodily functions with few or no symptoms. 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 Disclaimers

This press release contains forward-looking statements, including statements with respect to the prospects for AbbVie's HCV treatment regimen containing ABT-450 that is being developed as a potential treatment across a range of GT1 patient populations. 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 ABT-450) to obtain regulatory approvals and commercialize treatment regimens containing ABT-450, the development, regulatory and marketing efforts of others with respect to competitive treatment regimens, regulatory actions affecting any ABT-450-containing regimen, any competitive regimen, or both, and the level of market acceptance and the rate of reimbursement for any ABT-450-containing regimen. 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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