



## Enanta Announces Positive Phase 2 Results From Interferon-Free Combination Studies with ABT-450 for Hepatitis C Treatment to be Presented at EASL

April 4, 2012

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### - Poster Presentations to Include Enanta's Nucleotide HCV Polymerase Inhibitor Program and Additional ABT-450 Data-

WATERTOWN, Mass., April. 4, 2012 Enanta Pharmaceuticals, Inc. - , a research and development company dedicated to creating best-in-class small molecule drugs in the infectious disease field, announced today that key data from two of its hepatitis C (HCV) programs will be presented at the International Liver Congress™ 2012 (ILC2012), the annual meeting of the European Association for the Study of the Liver (EASL), April 18-22 in Barcelona, Spain. Oral presentations will discuss Phase 2 results from "Pilot" and "Co-Pilot", which investigated two different interferon-free combination regimens containing ABT-450, the lead candidate from Enanta's collaborative HCV protease inhibitor program with Abbott. ABT-450 will be included in two additional poster presentations and a third poster presentation will report *in vitro* data from Enanta's proprietary nucleotide HCV polymerase inhibitor program. Abstracts are available at [www.easl.eu](http://www.easl.eu).

### Phase 2 Data Highlights

In the study known as "Co-Pilot," different doses of ABT-450/r, plus ABT-333 and ribavirin administered for 12 weeks showed sustained virological response at 12 weeks post treatment (SVR12) in 93 percent and 95 percent of treatment-naïve genotype 1 (GT1) patients. In these patients, response was independent of HCV subtype, host IL28B genotype or dose of ABT-450/r. In addition, SVR12 was achieved in 47 percent of patients who were previous non-responders to past HCV treatment.

In a separate study, known as "Pilot", 91 percent of genotype 1 infected, treatment-naïve patients taking ABT-450/r and ABT-072 combined with ribavirin administered for 12 weeks, achieved sustained viral response at 24 weeks (SVR24).

"The results from Pilot and Co-Pilot showed very encouraging levels of sustained response and suggest that ABT-450 could be an important component in new interferon-free, all-oral regimens for previously treated and treatment-naïve patients with HCV," said Jay Luly, Ph.D., President and CEO of Enanta. "Enanta's involvement in five distinct HCV drug classes provides multiple avenues to pursue our goal of bringing to patients innovative therapies that are safer and more effective than current treatments."

### Oral Presentations

*Oral Presentation, Eric Lawitz et al.; Thursday, April 19, 16:00-18:00 CET / 10:00 am - 12:00 pm EDT.*

A 12-week Interferon-Free Regimen of ABT-450/r, ABT-072, and Ribavirin was Well Tolerated and Achieved Sustained Virologic Response in 91% Treatment-Naïve HCV IL28B-CC Genotype-1-Infected Subjects

- The objectives of the 12-week, phase 2 study were to assess the safety, tolerability, pharmacokinetics, and antiviral activity of ABT-450/r 150/100 mg QD and ABT-072 400 mg QD + ribavirin administered for 12 weeks.
- The study was conducted in 11 treatment naïve adults from multiple ethnic backgrounds with non-cirrhotic HCV GT1 (8 GT 1a, 3 GT 1b). Ribavirin 1000-1200 mg/day was weight-based and dosed twice daily.
- The primary endpoint was percentage of patients with HCV RNA <25 IU/ml from week 4 through 12. Other trial endpoints include early virologic response, RVR and SVR through 24 weeks.
- 100 percent of patients maintained HCV RNA levels <25 IU/mL from weeks 4 through 12 of treatment, and all had undetectable HCV RNA from week 5 to the end of treatment.
- 91 percent of patients achieved SVR24,
- In the trial, the most common adverse events reported were headache, fatigue, nausea and dry skin. There were no premature discontinuations.

*Late-Breaking Oral Presentation, Fred Poordad, et al.; Saturday, April 21, 15:30-17:30 CET / 9:30-11:30 am EDT.*

12-Week Interferon-Free Regimen of ABT-450/r+ABT-333+Ribavirin Achieved SVR12 in More Than 90% of Treatment-Naïve HCV Genotype-1-Infected Subjects and 47% of Previous Non-Responders

- The objectives of this phase 2 study were to assess safety and tolerability 12-week interferon-free regimens in HCV GT1 patients who were either treatment naïve or previous non-responders. The trial had three arms with three primary endpoints – rapid virological response (RVR) at week 4 and SVR at weeks 4 and 12.
- Enrollment was open to GT1-infected patients regardless of IL28B host genotype and ribavirin dosing was weight-based.
- 95 percent (18 of 19) of treatment-naïve patients infected with HCV GT1 (17 GT 1a, 2 GT 1b) achieved SVR12 with ABT 450/r 250/100 mg dosed once daily (QD) + ABT-333 400 mg dosed twice daily (BID) + ribavirin (Arm 1).

- 93 percent (13 of 14) of treatment-naïve patients infected with HCV GT1 (11 GT 1a, 3 GT1b) achieved SVR12 with ABT 450/r 150/100 mg QD + ABT-333 400 mg BID + ribavirin (Arm 2).
- 47 percent (8 of 17) of patients with HCV GT1 (16 GT1a, 1 GT1b) who had previously not responded to other HCV treatments achieved SVR12 with ABT 450/r 150/100 mg QD + ABT-333 400 mg BID + ribavirin (Arm 3).
- One patient in Arm 1 discontinued due to asymptomatic isolated ALT/AST elevations at week 2. One patient in Arm 2 discontinued due to noncompliance in week 1. All remaining patients in Arms 1 and 2 completed treatment and achieved SVR12. In Arm 3, six patients experienced viral breakthrough while on treatment and three patients relapsed after treatment stopped.
- In the trial the most common adverse events were fatigue (42 percent), nausea (22 percent) and headache (20 percent).

Abbott is developing ABT-450 with low dose ritonavir (ABT-450/r) which enhances the pharmacokinetic properties of ABT-450, allowing for once daily dosing. The use of ritonavir 100 mg with ABT-450 for the treatment of HCV is investigational.

#### Poster Presentations

Poster #867, Tami Pilot-Matias et al.; Friday, April 20 (11:00-11:30, 12:30-14:00, 15:30-16:00 CET) *"In vitro combinatory effect of HCV NS3/4A protease inhibitor ABT-450, NS5A inhibitor ABT-267, and non-nucleoside NS5B polymerase inhibitor ABT-333"*

Poster #1187, Eric Lawitz et al; Saturday, April 21 (11:00-11:30, 12:30-13:30, 15:00-15:30 CET) *"ABT-450/ritonavir (ABT-450/r) combined with pegylated interferon alpha-2a/ribavirin after 3-day monotherapy in genotype 1 (GT1) HCV-infected treatment-naïve subjects: 12-week sustained virologic response (SVR12) and safety results"*

Poster #1200, Christopher M. Owens et al.; Saturday, April 21 (11:00 – 11:30, 12:30 – 13:30, 15:00 – 15:30 CET)

*"Antiviral Activity of EP-NI266, a Potent Nucleotide HCV Polymerase Inhibitor"*

#### About the Hepatitis C Virus

Hepatitis C is a liver disease affecting over 170 million people worldwide. The virus is 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. Liver disease associated with HCV infection is growing rapidly, and there is an acute need for new therapies that are safer and more effective. Specifically targeted antiviral therapies for HCV, such as NS3/4a protease and NS5A inhibitors, may have the potential to increase the proportion of patients in whom the virus can be eradicated.

#### About Enanta

Enanta Pharmaceuticals is a research and development company that uses its novel chemistry approach and drug discovery capabilities to create best in class small molecule drugs in the infectious disease field. Enanta is discovering and developing novel inhibitors and combinations of inhibitors targeted against the Hepatitis C virus (HCV). These inhibitors include members of the direct acting antiviral (DAA) inhibitor classes— protease (partnered with Abbott), NS5A (partnered with Novartis), nucleotide polymerase, and a host targeted antiviral (HTA) inhibitor class targeted against cyclophilin. Through its partnership with Abbott, collaboration protease inhibitor ABT-450 is being evaluated in combination with Abbott's non-nucleoside polymerase and NS5A inhibitors. Additionally, the Company has created a new class of antibiotics, called Bicyclolides, which overcomes bacterial resistance. Antibacterial focus areas include overcoming resistance to superbugs, treating respiratory tract infections, and developing intravenous and oral treatments for hospital and community MRSA infections. Enanta is a privately held company headquartered in Watertown, Mass. Enanta's news releases and other information are available on the company's web site at [www.enanta.com](http://www.enanta.com).

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