



Enanta's Lead Hepatitis C Compound ABT-450 Advances into a Phase 3 Clinical Trial through its Collaboration with Abbott

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- Additional Data Updates to be Presented at AASLD -

WATERTOWN, Mass., October 17, 2012 —Enanta Pharmaceuticals, Inc., a research and development focused biotechnology company dedicated to creating small molecule drugs in the infectious disease field, announced that Abbott initiated an interferon-free combination Phase 3 clinical trial for hepatitis C (HCV) that included the collaboration's protease inhibitor, ABT-450. This trial was initiated following the release of positive results from the study known as "Aviator", a Phase 2b trial designed and conducted by Abbott. The initiation of this Phase 3 trial, part of Abbott's global registration program, triggered a collaboration milestone payment to Enanta.

The focus of ABT-450 development is to study the compound in combination with other antiviral agents in Abbott's HCV portfolio. The three direct acting antivirals, or triple DAA cocktail, studied in the Phase 2b interferon-free Aviator trial included ritonavir-boosted protease inhibitor ABT-450/r, non-nucleoside polymerase inhibitor ABT-333, and NS5A inhibitor ABT-267.

Initial results from the Aviator trial show sustained virological response at 12 weeks post-treatment (SVR12) in 99 percent of treatment-naïve (n=77), and 93 percent of null-responders (n=41), genotype 1 (GT1) HCV patients taking a combination of ABT-450 with ritonavir (ABT-450/r), ABT-267, ABT-333 and ribavirin for 12 weeks, based on an observed data analysis.

"The high SVR12 rates achieved in the genotype 1-infected population and the tough-to-treat IL28B non-CC genotype patient populations are very encouraging," commented Jay Luly, Ph.D., President and CEO of Enanta. "We look forward to the Phase 3 development of this interferon-free, oral treatment regimen containing our collaboration's HCV protease inhibitor, ABT-450."

Full results from the study will be presented at the Latebreaker Session during the 63rd Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), November 9-13, 2012, in Boston. Abstracts can be viewed on the AASLD website at www.aasld.org.

The observed data analysis used in this abstract does not include six patients who had not yet reached post-treatment week 12 or had missing values (data points) at the time of the abstract submission. All virologic failures and safety discontinuations were included in the analysis.

Study M11-652 (Aviator)

"A 12-Week Interferon-free Treatment Regimen with ABT-450/r, ABT-267, ABT-333 and Ribavirin Achieves SVR12 Rates (Observed Data) of 99% in Treatment-Naïve Patients and 93% in Prior Null Responders with HCV Genotype1 Infection"

Kris Kowdley, et al.,

Monday, November 12 (3:00 - 3:15 pm ET)

The objective of this Phase 2b study was to assess the safety and efficacy of ABT-450/r (dosed 100/100 to 200/100mg QD), ABT-267 (25mg QD), ABT-333 (400mg BID) and ribavirin in non-cirrhotic treatment-naïve patients and prior peg-interferon/ribavirin null responders for 8, 12, or 24 weeks.

Enrollment was open to GT1-infected patients regardless of IL28B host genotype, and ribavirin dosing was weight-based.

The 12-week regimen of three direct acting antivirals plus ribavirin had the highest SVR12 rates among the 8 and 12 week arms. Results from the 12 week treatment groups containing three direct acting antivirals plus ribavirin are summarized in the chart below.

	Treatment-naïve (N=79)	Null responders (N=45)
BL HCV RNA (log10 IU/mL)	6.5±0.6	6.6±0.5
BL IL28B non-CC genotype	72%	96%
SVR ₄	78/79 (99%)	42/45 (93%)
OD SVR ₁₂	76/77 (99%)	38/41 (93%)
PTW12 data missing*	2	4
Breakthrough	0	3
Relapse	1	0
OD SVR ₁₂ (GT1a)	52/53 (98%)	24/27 (89%)
OD SVR ₁₂ (GT1b)	24/24 (100%)	14/14 (100%)
OD SVR ₁₂ (IL28B non-CC)	54/55 (98%)	36/39 (92%)

*Did not follow up (2 treatment-naïve patients and 1 null responder) or have not yet reached post-treatment week 12 (PTW12) (3 null responders)

Additional data presented in the abstract represent all 8- and 12-week arms (n=448) of this 14-arm study (571 patients enrolled: 438 treatment-naïve and 133 prior null responders). SVR12 rates for other 8- and 12-week regimens ranged from 89-92 percent. Complete SVR12 data for 8- and 12-week arms will be presented at the AASLD Meeting.

Four of 448 patients (one percent) in the 8- and 12-week arms discontinued due to adverse events. Of five serious adverse events (1 percent), 1 (arthralgia or joint pain) was possibly study drug-related. In the trial, the most common adverse events were fatigue (28 and 27 percent) and headache (28 and 31 percent) for treatment naive and null responders, respectively.

Additional presentations at AASLD

- **Poster #758, "Pharmacokinetics and Safety of Co-administered ABT-450 plus Ritonavir (ABT- 450/r), ABT-267 and ABT-333 as a Single Dose in Subjects with Normal Hepatic Function and in Subjects with Mild, Moderate and Severe Hepatic Impairment"**
Amit Khatri, et al.; Sunday, November 11, 2012, 8:00 am - 5:30 pm
- **Poster #779 – "Characterization of Resistant Variants in NS3 and NS5B Detected in Subjects Treated with ABT-450/r, ribavirin, and either ABT-072 or ABT-333 in the Pilot and Co-Pilot studies Who Experienced Virologic Breakthrough or Relapse"**
Tami Pilot-Matias, et al.; Sunday, November 11, 2012, 8:00 am - 5:30 pm
- **Poster #1895 – "EDP-546, a Potent and Novel Cyclophilin Inhibitor with Favorable Preclinical Pharmacokinetic and Safety Profiles"**
L.J. Jiang, et al., Tuesday, November 13, 8:00 am - 12:00 pm

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 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 Abbott), 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 current focus on developing an intravenous and oral treatment for hospital and community MRSA infections. Enanta is a privately-held company headquartered in Watertown, Massachusetts. Enanta's news releases and other information are available on its website at www.enanta.com.

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.

Collaboration with Abbott

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. Under the agreement, Abbott is responsible for all development and commercialization activities for ABT-450, the program's lead compound. Enanta received a \$57 million upfront payment upon signing the collaboration agreement and is eligible to receive additional pre-commercial milestones, as well as, double-digit royalties 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 fund 40 percent of U.S. development costs and U.S. commercialization efforts (sales and promotion costs) in exchange for 40 percent of any U.S. profits ultimately achieved after regulatory approval.

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