Enanta Announces New Data From Phase 2b Interferon-Free Combination Studies with Protease Inhibitor ABT-450 for Hepatitis C Treatment to be Presented at EASL

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- Poster Presentations to Include Enanta's Cyclophilin Inhibitor Program and Additional ABT-450 Data -

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 23, 2013-- Enanta Pharmaceuticals, Inc., (NASDAQ: ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs in the infectious disease field, announced today that new Phase 2b data related to ABT-450, Enanta's lead HCV protease inhibitor identified in its ongoing collaboration with AbbVie, as well as new preclinical data on Enanta's proprietary cyclophilin inhibitor, EDP-546, will be presented at the International Liver Congress, (ILC), which is the 48th Annual Meeting of the European Association for the Study of the Liver (EASL) taking place in AmsterdamApril 24-28, 2013.

Results from "Aviator," AbbVie's Phase 2b clinical trial of ABT-450 combined with two of AbbVie's proprietary investigational direct-acting antivirals (DAAs), for the treatment of hepatitis C virus (HCV) infection, continue to demonstrate high sustained viral response (SVR) rates against genotype 1 HCV, across patient types. SVR rates of 96% to 99% after 12 weeks of treatment were achieved in patients new to treatment (naïve) and 93% in patients who had previously failed treatment with pegylated interferon and ribavirin (null responders). In addition, similarly high SVR rates over 90% observed after 24 weeks of treatment in the Phase 2b trial reinforce the adequacy of the 12-week treatment duration for the investigational interferon-free, triple DAA combination. The triple-DAA combination is currently being studied in Phase 3 clinical trials. Data from the "Aviator" study will be presented during the official ILC press conference in Amsterdam on Wednesday, April 24 at 11:00 am CEST and also in an oral presentation on Thursday, April 25.

About Study M11-652 (Aviator)

The objective of this Phase 2b study was to assess the safety, and efficacy of ABT-450/r (dosed 100/100 to 200/100mg once daily), ABT-267 (25mg once daily), ABT-333 (400mg twice daily) and ribavirin in non-cirrhotic, treatment-naïve patients and prior peg-interferon/ribavirin null responders administered for 8, 12 or 24 weeks. Enrollment was open to GT1-infected patients regardless of IL28B host genotype, and ribavirin dosing was weight-based.

A summary of key data from the trial is below:

	Treatment-Naïve						Null Responders		
Duration	**8 weeks**	**12 weeks**				**24 Weeks**	**12 weeks**		**24 weeks**
Regimen	ABT-450/r ABT-267 ABT-333 RBV	ABT-450/r ABT-333 RBV	ABT-450/r ABT-267 RBV	ABT-450/r ABT-267 ABT-333	ABT-450/r ABT-267 ABT-333 RBV	ABT-450/r ABT-267 ABT-333 RBV	ABT-450/r ABT-267 RBV	ABT-450/r ABT-267 ABT-333 RBV	ABT-450/r ABT-267 ABT-333 RBV
Number dosed	80	41	79	79	79	80	45	45	43
Breakthrough	0	1	1	1	0	0	0	3	1
Relapse	10	4	8	5	1	2	5	0	0
SVR_{12} (ITT)	89%	85%	91%	90%	99%	93%	89%	93%	98%
SVR_{24} (ITT)	88%	83%	89%	87%	96%	90%	89%	93%	95%

For the 12-week triple-DAA regimen with ribavirin that is being studied in the Phase 3 trials, these Phase 2b Aviator data show:

- 99% of treatment-naïve patients achieved SVR_{12}, 96% achieved SVR_{24} in this intent-to-treatanalysis
- 93% of prior null responders achieved SVR_{12} and SVR_{24}
- The single relapse with this regimen occurred at post-treatment week two

With the triple-DAA plus ribavirin regimen, comparable SVR_{24} response rates were also seen in treatment naïve patients and null responder patients across HCV subtype, IL28B genotype, baseline HCV-RNA levels and severity of fibrosis.

SVR_{24} by patient subtype in the "Aviator" study

Characteristic	Treatment Naïve	Null Responders
GT1a	91% (n=108)	93% (n=55)

GT1b	98% (n=50)	97% (n=33)
Non-CC IL28B genotype	95% (n=115)	94% (n=85)
CC IL28B genotype	89% (n=44)	100% (n=3)
Viral Load (=7 log)	89% (n=35)	91% (n=22)
Viral load (<7 log)	94% (n=124)	96% (n=66)
Fibrosis Stage (F0-F1)*	94% (n=113)	95% (n=41)
Fibrosis Stage (F2-F3)*	91% (n=42)	93% (n=45)
Male	92% (n=78)	93% (n=55)
Female	94% (n=81)	97% (n=33)

*The fibrosis analysis was post-hoc based on biopsy or non-invasive testing at screening.

The safety profile seen in this study is consistent with the initial presentation of results in November 2012. Of the 247 patients included in this analysis, four patients (1.6 percent) discontinued the study because of drug-related adverse events. Serious adverse events were noted in 4 patients (1.6 percent), with one (arthralgia) considered possibly drug-related. Other events reported in more than 10 percent of patients included headache, fatigue, nausea, insomnia, and diarrhea. Grade 3-4 laboratory abnormalities in total bilirubin (six patients) and ALT (one patient) were noted; all resolved with continued dosing.

"Results from treatment utilizing ABT-450 in combination with other antiviral agents in AbbVie's portfolio continue to generate high SVR rates across multiple HCV patient types," stated Jay R. Luly, Ph.D., President and Chief Executive Officer. "These results are especially promising for those who have failed previous therapy and for those with more advanced disease."

The focus of ABT-450 development is to study the compound in combination with other antiviral agents in AbbVie's 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.

Abstracts for the three presentations can be viewed at the EASL website at www.easl.eu

ABT-450 containing data presentations are as follows:

- **Oral Presentation – Kris V. Kowdley, *et al.*, Thursday, April 25 from 1:30 – 3:30 p.m. CEST**
  "Safety and Efficacy of Interferon-Free Regimens of ABT-450/r, ABT-267, ABT-333 ± ribavirin in Patients with Chronic HCV GT1 Infection: Results from the Aviator Study"

- **Poster # 1190 – Michael Epstein, *et al.*, Saturday, April 27 from 12:30 – 1:30 p.m. CEST**
  "Study of ABT-267 2-Day Monotherapy Followed by 12-Week Combination Therapy in Treatment Naïve Patients with Chronic HCV Genotype 1 Infection"

Enanta's proprietary cyclophilin inhibitor data presentation:

- **Poster #1213 – C.M. Owens, *et al.*, Saturday, April 27 from 9:00 a.m. – 6:00 p.m. CEST**
  "Cyclophilin Inhibitor EDP-546 is a Potential Cornerstone Drug for Use in Combination with NS5A and Protease Inhibitors Due to Its High Barrier to Resistance"

"We continue to advance our lead cyclophilin candidates in preclinical studies and are continuing to generate and characterize a number of additional candidates," commented Yat Sun Or, Ph.D., Senior Vice President and Chief Scientific Officer. "We expect to select a preclinical candidate to advance during 2013."

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 AbbVie (formerly the research-based pharmaceutical business of Abbott Labs)

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, AbbVie 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.

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 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 current focus on developing an intravenous and oral treatment for hospital and community MRSA (methicillin-resistant Staphylococcus aureus) infections.

Forward Looking Statement

This press release contains forward-looking statements, including with respect to our expectation that we will select a preclinical cyclophilin inhibitor candidate to advance to clinical trials during 2013 and expectations regarding the successful completion of clinical development of 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 our ability to successfully identify appropriate candidates for clinical development of our future product candidates, the development efforts of our collaborators, regulatory actions affecting clinical development 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.

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