# Enanta Pharmaceuticals Announces Detailed Data from TURQUOISE-II Study in Chronic Hepatitis C Patients with Cirrhosis being Presented at the European Association for the Study of the Liver (EASL) Meeting

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- *In patients with compensated liver cirrhosis and genotype 1 (GT1) chronic hepatitis C virus, TURQUOISE-II demonstrated $SVR_{12}$ rates of 91.8% and 95.9% after 12 and 24 weeks of treatment, respectively*
- *TURQUOISE-II is the largest phase 3, all-oral, Interferon-free study in cirrhotic patients with hepatitis C virus conducted to date*

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 12, 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 TURQUOISE-II study, will be presented as a late-breaking oral presentation today at the International Liver Congress (ILC), which is the 49th Annual Meeting of the European Association for the Study of the Liver (EASL). Results from the TURQUOISE-II study were featured in the ILC press conference yesterday and were published on-line in the *New England Journal of Medicine*.

The TURQUOISE-II study reports results from AbbVie's investigational three direct-acting antiviral regimen containing ABT-450, Enanta's lead protease inhibitor discovered 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.

TURQUOISE-II is a global, multi-center, randomized, open-label study evaluating the efficacy and safety of 12 weeks or 24 weeks of treatment with AbbVie's three direct-acting antiviral regimen with ribavirin (RBV) in adult patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection with compensated liver cirrhosis. Patients achieved sustained virologic response rates 12 weeks post-treatment ($SVR_{12}$) of 91.8 percent and 95.9 percent in the 12-week and 24-week treatment arms, respectively. Patients in the study were either new to therapy or treatment-experienced (failed previous treatment with pegylated interferon and RBV).

**TURQUOISE-II Results**

| | **12-Week Arm $SVR_{12}$ (n=208)** | **24-Week Arm $SVR_{12}$ (n=172)** |
|---|---|---|
| **All GT1** | **91.8% (n=191/208)** | **95.9% (n=165/172)** |
| GT1a | 88.6% (n=124/140) | 94.2% (n=114/121) |
| New to therapy | 92.2% (n=59/64) | 92.9% (n=52/56) |
| GT1a treatment-experienced | | |
| Prior null responders | 80.0% (n= 40/50) | 92.9% (n=39/42) |
| Prior relapsers | 93.3% (n= 14/15) | 100.0% (n=13/13) |
| Prior partial responders | 100.0% (n= 11/11) | 100.0% (n=10/10) |
| GT1b | 98.5% (n=67/68) | 100.0% (n=51/51) |
| New to therapy | 100.0% (n= 22/22) | 100.0% (n=18/18) |
| GT1b treatment-experienced | | |
| Prior null responders | 100.0% (n=14/14) | 100.0% (n=10/10) |
| Prior relapsers | 100.0% (n=25/25) | 100.0% (n=20/20) |
| Prior partial responders | 85.7% (n= 6/7) | 100.0% (n=3/3) |

Discontinuation rates due to adverse events were 1.9 percent (four patients) and 2.3 percent (four patients) in the 12-week and 24-week arms, respectively. The most commonly reported adverse events (>10 percent in either arm) in TURQUOISE-II were fatigue, headache, nausea, pruritus, insomnia, diarrhea, asthenia, rash, cough, irritability, anemia and dyspnea.

On-treatment virologic failure occurred in one patient (0.5 percent) in the 12-week arm and three patients (1.7 percent) in the 24-week arm. In addition, 12 patients (5.9 percent) in the 12-week arm and one patient (0.6 percent) in the 24-week arm experienced relapse within 12 weeks post-treatment.

"Data presented to date from AbbVie's three direct-acting antiviral regimen with and without ribavirin have demonstrated high SVR rates across a range of GT1 patient populations," said Jay R. Luly, Ph.D., President and CEO. "In addition, the positive results from the TURQUOISE-II study have demonstrated that this regimen with ribavirin provides high SVR rates in the difficult-to-treat, cirrhotic GT1 patients."

Additional results from studies using AbbVie's three-direct-acting antiviral regimen containing ABT-450 being presented at the ILC today include:

- PEARL-III late-breaker poster: A phase 3 study examining the regimen for 12 weeks with or without RBV in non-cirrhotic GT1b HCV-infected adult patients who were new to therapy.
- M12-999 oral presentation: Interim results of a phase II examining the regimen with RBV for 24 weeks in non-cirrhotic liver transplant recipients with recurrent GT1 HCV infection

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 Disclaimer**

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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