Abbott and Enanta Present Positive 12-Week Results and 3-Day Resistance Data from Phase 2 Study of ABT-450/r for Treatment of Hepatitis C

April 4, 2011
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ABBOTT PARK, Ill., and WATERTOWN, Mass., Apr. 4, 2011 — Abbott and Enanta Pharmaceuticals today announced 12-week results from a Phase 2 study of ABT-450/r, an investigational, oral protease inhibitor being developed for the treatment of hepatitis C (HCV) infection. Study results show that 92 percent (22 of 24) of patients taking ABT-450/r once daily, combined with standard of care, achieved complete early virologic response (HCV RNA levels <25 IU/mL) at 12 weeks. Results were presented today at the European Association for the Study of Liver Disease (EASL) annual meeting in Berlin.

Key findings:

- At week 12, 92 percent of patients receiving ABT-450/r (ABT-450 with 100 mg of ritonavir to support once-daily dosing) in combination with standard of care (SOC) – pegylated interferon alpha and ribavirin (pegIFN/RBV) – achieved HCV-RNA <25 IU/mL
- In a separate analysis of 3-day resistance data, ABT-450/r dosed at 200/100 mg appeared to more consistently suppress the emergence of ABT-450-associated resistant variants than the 50/100 mg and 100/100 mg doses
- Previously presented 3-day and 4-week results from the study had suggested the ABT-450/r demonstrated significant antiviral activity in treatment-naïve adults
- After three days, treatment with ABT-450/r alone resulted in 4-log (10,000- fold) mean reductions of HCV RNA, across the three dose ranges of ABT-450 (50 mg, 100 mg, 200 mg, once-daily dosing)

"A significant number of HCV patients are unable to begin treatment with peginterferon and ribavirin, and for those that do begin treatment, more than 50 percent will not be cured," said Fred Poordad, M.D., chief of hepatology at the Liver Disease and Transplant Center at Cedars-Sinai Medical Center in Los Angeles, and one of the investigators for the study. "These results suggest that ABT-450/r could be an important component in combination therapy approaches to treating HCV."

"Abbott is working to transform treatment options for patients with HCV infection by investigating ways to simplify treatment and increase cure rates," said Scott Brun, M.D., divisional vice president, infectious disease development, Abbott. "We will continue to explore the use of ABT-450/r and our other investigational HCV treatments in a variety of patient populations and combinations, with and without pegylated interferon alpha."

"We continue to be encouraged by the results for ABT-450/r and the potential it holds for treatment-experienced and treatment-naive patients with HCV," said Jay Luly, Ph.D, president and chief executive officer, Enanta Pharmaceuticals.

Study Objectives and Design
The objectives of the 48-week Phase 2 study are to assess the safety, tolerability, pharmacokinetics, and antiviral activity of multiple dose strengths of ABT-450/r in treatment-naïve adults infected with HCV genotype 1, which is the most common and difficult to treat form of the infection in the developed world. Trial endpoints include early virologic response and rapid virologic response. Initial antiviral activity was evaluated via a 3-day treatment period during which ABT-450/r was administered alone. Subsequently, ABT-450/r was administered with pegIFN/RBV (SOC) for 12 weeks, followed by treatment with SOC alone for an additional 36 weeks. Participants are then monitored post therapy for 24 weeks for sustained virologic response.

In the trial, the most common adverse events reported in subjects receiving ABT- 450/r in combination with pegIFN/RBV were headache, fatigue, insomnia and depression. A similar proportion of subjects reported at least one adverse event in all treatment groups, including placebo.

ABT-450 is being developed with low-dose ritonavir, 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.

About the Hepatitis C Virus
Hepatitis C is a liver disease affecting more than 180 million people worldwide.[5] The virus is primarily spread through direct contact with the blood of an infected person. [6] HCV increases a person's risk of developing chronic liver disease, cirrhosis, liver cancer and death. [7]

Liver disease associated with HCV infection is growing rapidly, and current therapies only cure about half of patients with the genotype 1 form of the virus.[4] Specifically targeted antiviral therapies for HCV, such as protease inhibitors and non-nucleoside polymerase inhibitors, may have the potential to increase the proportion of patients in whom the virus can be eradicated.

Ritonavir Use in Treatment of HIV
Ritonavir is in a class of medicines called the HIV protease inhibitors. Ritonavir is used in combination with other anti-HIV medicines to treat people with human immunodeficiency virus (HIV) infection. Ritonavir is for adults and for children age greater than 1 month and older.

Ritonavir does not cure HIV infection or AIDS and does not reduce the risk of passing HIV to others. People taking ritonavir may still get opportunistic

infections or other conditions that happen with HIV infection. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium complex* (MAC) infections.

Ritonavir Safety in Treatment of HIV
Patients should not take ritonavir with certain medicines, as these can cause serious or life-threatening problems such as irregular heartbeat, breathing difficulties, or excessive sleepiness. Patients should not take ritonavir if they have had a serious allergic reaction to any of its ingredients. Some patients taking ritonavir may develop liver and pancreas problems, which can cause death. Patients may develop large increases in triglycerides and cholesterol, diabetes, high blood sugar, changes in body fat, increased bleeding in people with hemophilia, allergic reactions, and/or changes in heart rhythm. Patients may develop signs and symptoms of infections that they already have after starting anti-HIV medicines.

For more information, please see the Important Safety Information and full Prescribing Information for ritonavir.

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 developing novel protease, NS5A, nucleoside(tide) polymerase, and cyclophilin-based inhibitors targeted against the Hepatitis C virus (HCV). Additionally, the Company has created a new class of macrolide antibiotics, called Bicyclolides, which overcomes bacterial resistance. Antibacterial focus areas include superbugs, respiratory tract infections, and intravenous and oral treatments for hospital and community MRSA. 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.

About Abbott
Abbott's HCV development programs include its partnership with Enanta Pharmaceuticals to discover protease inhibitors, as well as internal programs focused on additional viral targets, including polymerase inhibitors. Abbott currently has four HCV compounds in phase 2 clinical trials, including a protease inhibitor, two polymerase inhibitors and an NS5A inhibitor. Abbott is well positioned to explore combinations of these compounds, a strategy with the potential to markedly transform current treatment practices.

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacturing and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs nearly 90,000 people and markets its products in more than 130 countries.

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