

Abbott Presents Positive Results from Interferon-Free Phase 2 "Co-Pilot" Study for the Treatment of Hepatitis C

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More than 90 Percent of Patients New to HCV Treatment Achieved Sustained Viral Response through 12 Weeks

ABBOTT PARK, Ill., and Watertown, Mass., Apr. 19, 2012 – Abbott and Enanta Pharmaceuticals announced data from "Co-Pilot," an interferon-free, Phase 2 study of Abbott's direct-acting antiviral medicines for the treatment of hepatitis C (HCV) that found that more than 90 percent of patients new to HCV treatment achieved sustained viral response through 12 weeks (SVR12). Results were released today at a press conference at the International Liver Congress 2012 (ILC 2012), the annual meeting of the European Association for the Study of the Liver (EASL), in Barcelona, Spain, and will also be presented in an oral platform presentation at the latebreaking trials session on Saturday, April 21.

In a three-arm 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 95 percent and 93 percent of treatment-naïve genotype 1 (GT1) patients, with no post-treatment relapses. 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 nonresponders to past HCV treatment.

"As we get our first look at longer term response data for interferon-free regimens for the treatment of HCV, we remain extremely encouraged by the levels of sustained response we are seeing in patients new to treatment and in patients who had failed prior treatment," said Fred Poordad, M.D., chief of hepatology at Cedars-Sinai Medical Center in Los Angeles, and the lead investigator for Co-Pilot. "We are seeing this level of sustained response with only 12 weeks of therapy, supporting the goal of introducing an interferon-free, all-oral regimen of direct-acting antiviral medications as an important new treatment option for HCV."

Current treatments for HCV remain interferon-based. A significant number of HCV patients are unable or unwilling to take interferon due to contraindications and/or some of the most commonly reported side effects, which may include flu-like symptoms, depression and insomnia. 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.

Key Findings – Arm 1 in Treatment-Naïve Patients

- ABT-450/r 250/100 mg dosed once daily (QD) + ABT-333 400 mg dosed twice daily (BID) + ribavirin in treatment-naïve patients infected with HCV GT1
- 95 percent (18 of 19) achieved SVR12
- There were no post-treatment relapses in these patients
- One patient discontinued due to asymptomatic isolated ALT/AST elevations at week 2
- HCV Genotype breakdown: 17 GT 1a, 2 GT 1b
- IL28 Genotype breakdown: 10 C/C, 7 C/T, 2 T/T

Key Findings – Arm 2, Treatment-Naïve Patients

- ABT-450/r 150/100 mg QD + ABT-333 400 mg BID + ribavirin in treatment naïve patients infected with HCV GT1
- 93 percent (13 of 14) of patients achieved SVR12
- There were no post-treatment relapses in these patients
- One patient discontinued due to noncompliance in week 1
- HCV Genotype breakdown: 11 GT 1a, 3 GT 1b
- IL28 Genotype breakdown: 5 C/C, 7 C/T, 2 T/T

Key Findings – Arm 3, prior non-responders

- ABT-450/r 150/100 mg QD + ABT-333 400 mg BID + ribavirin in patients who had previously not responded to other HCV treatments

- 47 percent (8 of 17) patients achieved SVR12
- HCV Genotype breakdown: 16 GT 1a, 1 GT 1b
- IL28 Genotype breakdown: 0 C/C, 12 C/T (50% achieved SVR12), 5 T/T (40% achieved SVR12)
- Six patients experienced viral breakthrough while on treatment and three patients relapsed after treatment stopped
- Prior non-responders included null responders (patients who failed to achieve 2 log reduction by week 12 while taking peg-interferon and ribavirin) and partial responders (patients who failed to achieve HCV RNA below the limit of detection during treatment with peg-interferon and ribavirin); the response rate was similar in both populations
- Null responder subgroup (6 patients): 50% of patients achieved SVR12
- Partial responder subgroup (11 patients): 45% achieved SVR12

In the trial, the most common adverse events were fatigue (42 percent), nausea (22 percent) and headache (20 percent)

"Co-Pilot was an exploratory study that demonstrates the potential to cure a large percentage of treatment-naïve genotype 1 patients with two of our direct-acting antiviral medicines, and no peg-interferon, in a short, 12-week course of treatment," said Scott Brun, M.D., divisional vice president, Infectious Disease Development, Abbott. "We continue to research a variety of combination regimens with additional agents, including our NS5A inhibitor, with the potential to improve outcomes in patients who have failed prior treatments and look forward to presenting those results in the future."

About Study M12-746 (Co-Pilot)

- The objectives of this Phase 2 study were to assess safety and tolerability of 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.

ABT-450 is being developed with low dose ritonavir which enhances the pharmacokinetic properties of ABT-450. The use of ritonavir 100 mg with ABT-450 for the treatment of HCV is investigational.

ABT-450 was discovered during the course of collaboration between Abbott and Enanta Pharmaceuticals for protease inhibitors. ABT-450 is being developed by Abbott for use in combination with Abbott's non-nucleoside polymerase inhibitors (ABT-333 and ABT-072) and NS5A inhibitor (ABT-267). Additional data from larger, ongoing Phase 2 clinical trials is expected later this year.

About the Hepatitis C Virus

Hepatitis C is a liver disease affecting as many as 170 million people worldwide. The virus is primarily spread through direct contact with the blood of an infected person. HCV increases a person's risk of developing chronic liver disease, cirrhosis, liver cancer and death; and liver disease associated with HCV infection is growing rapidly.

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 greater than 1 month in age 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 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. 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.

About Abbott's HCV Development Programs

In addition to its partnership with Enanta Pharmaceuticals for protease inhibitors, including ABT-450 and ABT-450 containing regimens, Abbott has internal programs focused on additional viral targets. Abbott currently has investigational medicines with three different mechanisms of action in its ongoing clinical trials, including protease, polymerase and NS5A inhibitors. Abbott is well-positioned to explore combinations of these compounds, a strategy with the potential to markedly transform current treatment practices by shortening therapy duration, improving tolerability and increasing cure rates.

About Abbott

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 approximately 91,000 people and markets its products in more than 130 countries. Abbott's news releases and other information are available on the company's website at www.abbott.com.

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