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

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Results among the Most Mature Data for an Interferon-Free Regimen, Including 36- Week Post-Treatment Sustained Viral Response for a 12-Week Treatment Regimen

"The sustained viral response rates in this study are very encouraging as there are currently no treatment options for patients with HCV who cannot take or are intolerant to interferon," said Eric Lawitz, M.D., medical director at Alamo Medical Research in San Antonio, and the lead investigator for the study. "This is one of the earliest looks at mature data and it continues to demonstrate that a 12-week combination regimen of direct-acting antiviral treatments has the potential to offer high cure rates while eliminating the use of interferon."

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 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.

About Study M12-267 (Pilot) and Key Findings

- The objectives of the 12-week, Phase 2 study were to assess the safety, tolerability, pharmacokinetics and antiviral activity of ABT-450/r 150/100 mg QD and ABT-072 400 mg QD + ribavirin administered for 12 weeks.
- The study was conducted in 11 treatment-naïve adults with host IL28B "CC" genotype from multiple ethnic backgrounds with non-cirrhotic HCV GT1 (8 GT 1a, 3 GT 1b). Ribavirin dose was weight-based (1,000-1,200 mg/day) and dosed twice daily.
- The primary endpoint was percentage of patients with HCV RNA <25 IU/mL from week 4 through 12. Other trial endpoints include early virologic response, RVR and SVR through 24 weeks.
- 100 percent of patients maintained HCV RNA levels <25 IU/mL from weeks 4 through 12 of treatment, and all had undetectable HCV RNA from week 5 to the end of treatment.
- 91 percent of patients (10 of 11) achieved SVR24.
- One relapse was observed 8 weeks post therapy and a second 36 weeks post therapy; overall, 82 percent of patients (9 of 11) achieved SVR36.
- No additional relapses were seen among the 10 patients with 48-week post-treatment data available.
- In the trial, the most common adverse events were headache (36%), fatigue (27%), nausea (27%) and dry skin (27%). Most adverse events were mild in severity and there were no discontinuations due to adverse events.
- Two bilirubin elevations, which consisted of indirect bilirubin with no associated transaminase elevations (i.e. no indication of liver damage), were reported during the study. The bilirubin elevations occurred one week after starting treatment and resolved with continued dosing.

"Abbott is proud to present some of the first sustained viral response data for short course, interferon-free regimens for the treatment of HCV," said Scott Brun, M.D., divisional vice president, Infectious Disease Development, Abbott. "With a research portfolio that encompasses multiple direct-acting antiviral treatments in different drug classes, Abbott has the ability to quickly study a variety of combination regimens for HCV, with a focus on interferon-free regimens, to determine which has the greatest potential to help the largest number of patients."

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).

The Co-Pilot study, results which were released earlier today, and the Pilot study, are important parts of Abbott's broader HCV development program. 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.

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