

Abbott Announces Phase 3 Hepatitis C Program Details

PR Newswire

- Interferon-free Hepatitis C Regimens will be Studied in Broad Patient Populations across Multiple Countries

ABBOTT PARK, Illinois, Nov. 13, 2012 /PRNewswire/ -- Abbott today released details on its phase 3 hepatitis C registrational program following promising results from its phase 2b clinical trial, known as Aviator, presented at the Annual Meeting of the American Association for the Study of Liver Disease (AASLD) in Boston. The phase 3 clinical trials are designed to evaluate safety and efficacy of a 12-week regimen of three direct acting antivirals (DAA), with and without ribavirin, for the treatment of HCV in genotype 1 (GT1) non-cirrhotic, treatment-naïve and treatment-experienced patients. An additional phase 3 trial will study triple-DAA, with ribavirin, in patients with cirrhosis for 12 or 24 weeks.

The phase 3 program, which is currently open for enrollment, will include more than 2,000 patients with HCV genotype 1, with trial sites in 29 countries. The DAAs in the studies include ABT-450/r (protease inhibitor and ritonavir), ABT-267 (NS5A inhibitor) and ABT-333 (non-nucleoside polymerase inhibitor). Treatment duration will be 12 weeks in non-cirrhotic patients, and 12 or 24 weeks in cirrhotic patients. All patients will be followed for 48 weeks post-treatment. Co-formulated tablets of ABT-450/r and ABT-267 will be used in the phase 3 trials.

More information on the trials is available at www.clinicaltrials.gov.

"Abbott is committed to investigating a short-course HCV therapy without the use of interferon to achieve high SVR rates," said Scott Brun, M.D., divisional vice president, Infectious Disease Development, Abbott. "Our trial enrollment strives to reflect a broad range of populations, including those that have been difficult to treat. We have been very encouraged by the data from the phase 2 studies, and look forward to confirming the findings in our phase 3 program."

Topline intent-to-treat results from the 12-week, triple-DAA regimens with ribavirin presented at the AASLD meeting this week found that 97.5 percent (77 of 79) of treatment-naïve GT1 patients and 93.3 percent (42 of 45) in GT1 null responder patients achieved SVR12.

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.

Of the six main genotypes of hepatitis C, genotypes 1, 2 and 3 are the most widespread. Genotype 1 is the most common genotype in the U.S. and the most difficult to treat with interferon based therapies. Patients with genotypes 2 and 3 are more likely than individuals with genotype 1 to respond to therapy with peg-interferon or the combination of peg-interferon and ribavirin.

About Abbott's HCV Development Programs Abbott's HCV portfolio includes investigational medicines with three different mechanisms of action, including protease (ABT-450/r), polymerase (ABT-333) and NS5A (ABT-267) inhibitors, currently being studied in clinical trials. ABT-450 is being developed with low-dose (non-therapeutic) ritonavir which enhances the pharmacokinetic properties of ABT-450. The use of ritonavir 100mg with ABT-450 for the treatment of HCV is investigational.

ABT-450 was discovered during the course of a collaboration between Abbott and Enanta Pharmaceuticals for HCV protease inhibitors and regimens that include protease inhibitors. ABT-450 is being developed by Abbott for use in combination with Abbott's other investigational medicines for the treatment of HCV. Abbott is well-positioned to explore combinations and co-formulations of these medicines.

Ritonavir Use in Treatment of HI 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 HI 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 [http://www.rxabbott.com/pdf/norvirtab_pi.pdf].

About 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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