

AbbVie's Investigational HCV Regimen Receives Breakthrough Therapy Designation from the U.S. Food and Drug Administration

- Interferon-free, direct-acting antiviral combination therapy currently in Phase 3 development

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NORTH CHICAGO, Ill., May 6, 2013 /PRNewswire/ -- AbbVie (NYSE: ABBV) today announced that its investigational direct-acting antiviral (DAA) combination with and without ribavirin for the treatment of genotype 1 (GT1) hepatitis C virus (HCV) infection has been designated as a Breakthrough Therapy by the U.S. Food and Drug Administration (FDA).

The designation is based, in part, on positive data from AbbVie's clinical development program, including the Phase 2b clinical trial M11-652, known as "Aviator." The Aviator study was conducted in 571 patients infected with HCV GT1. Results from the treatment arms evaluating ABT-450/r + ABT-267 + ABT-333 with and without ribavirin demonstrated that the regimen provided high sustained viral response rates (SVR) with 12 weeks of therapy in patients who had not been previously treated (treatment naive) and in those who had failed prior therapy with pegylated interferon and ribavirin (null responders), regardless of sex, HCV subtype, stage of fibrosis, viral load or IL28B genotype.

According to the FDA, Breakthrough Therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy designation includes preliminary clinical evidence demonstrating a drug may have substantial improvement on at least one clinically significant endpoint compared to available therapy. A Breakthrough Therapy designation conveys all of the fast track program features, as well as more intensive FDA guidance on an efficient drug development program.(1)

"AbbVie is pleased that the FDA has granted Breakthrough Therapy designation to our 3-DAA combination with and without ribavirin. We feel it reflects the potential of this regimen to be important in the treatment of HCV," said John M. Leonard, M.D., senior vice president and chief scientific officer, AbbVie. "Our HCV program is one part of our advancing pipeline which is focused on delivering innovative therapies to address pressing areas of unmet clinical need."

New results from Aviator were recently presented at the 2013 International Liver Congress® in Amsterdam. These results continued to demonstrate high SVR rates against GT1 HCV with the 12-week, triple-DAA regimen with ribavirin, across patient types. Specifically,

99 percent of treatment-naive patients (n=79) achieved SVR12, 96 percent achieved SVR24 in an intent-to-treat analysis

93 percent of prior null responders (n=45) achieved SVR12 and SVR24

A single relapse with this regimen occurred at post-treatment week two

Of the 247 patients treated for 12 and 24 weeks with triple DAA with ribavirin, four patients (1.6 percent) discontinued the study because of drug-related adverse events. Serious adverse events were noted in four patients (1.6 percent), with one (arthralgia) considered possibly drug-related. Other events reported in more than 10 percent of patients included headache, fatigue, nausea, insomnia, and diarrhea. Grade 3-4 laboratory abnormalities in total bilirubin (six patients) and ALT (one patient) were noted; all resolved with continued dosing.

AbbVie's all-oral, triple-DAA combination is currently being studied in Phase 3 clinical trials. The Phase 3 program includes 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 durations under investigation are 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 are being used in the Phase 3 trials.