FUTURE DATA ANTICIPATED FROM ABBVIE'S CLINICAL TRIALS EXAMINES 3D REGIMEN WITH AND WITHOUT RIBAVIRIN, AS WELL AS TREATMENT OF HEPATITIS C IN PATIENTS WITH CIRRHOSIS

RESULTS FURTHER CONFIRM PHASE II STUDIES, WITH CONSISTENT VIROLOGIC RESPONSE AND TOLERABILITY PROFILE-

- SAPPHIRE-II IS THE SECOND OF SIX PHASE III TRIALS STUDYING THE INVESTIGATIONAL 3D REGIMEN-

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NORTH CHICAGO, Ill., Dec. 10, 2013 /PRNewswire/ -- AbbVie (NYSE: ABBV) released phase III results for the investigational three direct-acting-antiviral (3D) regimen plus ribavirin in patients with chronic, genotype 1 (GT1) hepatitis C virus (HCV) infection. In the 394-patient SAPPHIRE-II study, 96 percent of patients who previously failed pegylated interferon and ribavirin treatment, including approximately 49 percent of who were prior null responders, achieved sustained virologic response at 12 weeks (SVR12) with the regimen. The majority of patients were GT1a, considered a difficult-to-treat subtype, and the SVR12 rates of GT1a and GT1b were 96 percent and 97 percent, respectively. Virologic relapse or breakthrough was noted in 2 percent of patients receiving the 3D regimen plus ribavirin. In addition, the discontinuation rate due to adverse events was 1 percent.

Globally, approximately 160 million people are chronically infected with hepatitis C[1]. AbbVie's multinational HCV program is the largest all-oral, interferon-free clinical program in GT1 patients being conducted to date[2]. GT1 (with subtypes 1a and 1b) is the most prevalent genotype worldwide, with a higher prevalence of 1a in the U.S. and 1b in Europe.

"SAPPHIRE-II demonstrates that treatment-experienced genotype 1 HCV patients achieved high rates of virologic response with AbbVie's interferon-free, all-oral 3D regimen plus ribavirin," said Scott Brun, M.D., vice president, pharmaceutical development, AbbVie. "Completion of the two placebo-controlled SAPPHIRE studies is an important step in AbbVie's HCV clinical development program. We look forward to the results of studies looking at AbbVie's 3D regimen with and without ribavirin in different patients, as well as data from our dedicated study in patients with cirrhosis."

About Study M13-098 (SAPPHIRE-II)

Following SAPPHIRE-I, SAPPHIRE-II is the second placebo-controlled trial and the second of six phase III trials supporting AbbVie's investigational 3D regimen for the treatment of GT1 hepatitis C patients. AbbVie will disclose detailed SAPPHIRE-II results at future scientific congresses and in publications.

SAPPHIRE-II is a global, multi-center, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of 12 weeks of treatment with ABT-333 (250mg), ribavirin (weight-based), both dosed twice daily, and the fixed-dose combination of ABT-450/ritonavir (150/100mg) co-formulated with ABT-267 (25mg) and dosed once daily in non-cirrhotic, GT1a and GT1b HCV-infected, treatment-experienced adult patients who previously failed treatment with pegylated interferon and ribavirin.

The study population consisted of 394 GT1 treatment-experienced patients with no evidence of liver cirrhosis with 297 patients randomized to the 3D regimen plus ribavirin for 12 weeks, and 97 patients randomized to placebo for the initial 12 weeks. Patients initially randomized to placebo for the first 12 weeks then received open-label treatment with the 3D regimen plus ribavirin for 12 weeks. In the study, 49 percent of patients were prior null responders to pegylated interferon and ribavirin, generally considered among the most difficult to treat successfully.

Following 12 weeks of treatment with AbbVie's 3D regimen plus ribavirin, 96 percent (n=286/297) of patients achieved SVR12 based on intent-to-treat analysis where patients with missing values for any reason were considered treatment failures. The SVR12 rates in GT1a and GT1b patients were 96 percent (166/173) and 97 percent (119/123), respectively. One subject had HCV genotype 1 and achieved SVR12, but was unable to be subgenotyped.

The most commonly reported adverse events in both the 3D and placebo arms were headache, fatigue and nausea. Discontinuations due to adverse events were reported in three (1 percent) patients receiving the 3D regimen and no patients receiving placebo. Virologic relapse or breakthrough was noted in 2 percent of patients receiving the 3D regimen plus ribavirin.

Additional information about AbbVie's phase III studies can be found on www.clinicaltrials.gov.

AbbVie's HCV Development Program

The clinical program supporting our 3D regimen includes more than 2,300 GT1 patients in more than 25 countries around the world. The AbbVie HCV clinical development program is intended to advance scientific knowledge and clinical care by investigating an interferon-free, all-oral 3D regimen with or without ribavirin with the goal of producing high SVR rates in as many patients as possible, including those that typically do not respond well to treatment, such as previous non-responders to interferon-based therapy or patients with advanced liver fibrosis or cirrhosis. Results from the remaining four studies in AbbVie's phase III program will be available in the coming months, supporting regulatory submissions starting in the second quarter of 2014.

- See more at: http://hepatitiscresearchandnewsupdates.blogspot.com/2013/12/abbvie-demonstrates-96-percent-svr12-in.html#sthash.7W9WeiKf.dpuf