AbbVie Demonstrates 96 percent SVR(12) in its Phase III Study of Treatment-Experienced Patients with Genotype 1 Hepatitis C

-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-

-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-

NORTH CHICAGO, Ill., Dec. 10, 2013 -- 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 (SVR_{12}) with the regimen. The majority of patients were GT1a, considered a difficult-to-treat subtype, and the SVR_{12} 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 SVR_{12} based on intent-to-treat analysis where patients with missing values for any reason were considered treatment failures. The SVR_{12} 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 SVR_{12}, 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.

Overview of AbbVie's phase III clinical program is as follows:

Study	Patients (N)	Treatment Regimen	Treatment Duration
SAPPHIRE-I	GT1, treatment-naive (631)	• ABT-450/r[b] +ABT-267[c] • ABT-333 • Ribavirin	12 weeks
		• Placebo	12 weeks, then active treatment for 12 weeks
SAPPHIRE-II	GT1, treatment-experienced (394)	• ABT-450/r +ABT-267 • ABT-333 • Ribavirin	12 weeks
		• Placebo	12 weeks, then active treatment for 12 weeks
PEARL-II	GT1b, treatment-experienced (210[a])	• ABT-450/r +ABT-267 • ABT-333 • Ribavirin	12 weeks
		• ABT-450/r +ABT-267 • ABT-333	12 weeks
PEARL-III	GT1b, treatment-naive (400[a])	• ABT-450/r +ABT-267 • ABT-333	12 weeks

		• Ribavirin	
		• ABT-450/r +ABT-267 • ABT-333 • Placebo	12 weeks
PEARL-IV	GT1a, treatment-naive (300 [a])	• ABT-450/r +ABT-267 • ABT-333 • Ribavirin	12 weeks
		• ABT-450/r +ABT-267 • ABT-333 • Placebo	12 weeks
TURQUOISE-II	GT1, treatment-naive and treatment-experienced (with compensated cirrhosis) (380 [a])	• ABT-450/r +ABT-267 • ABT-333 • Ribavirin	12 weeks
		• ABT-450/r +ABT-267 • ABT-333 • Ribavirin	24 weeks

[a] projected study population

[b] ABT-450/ritonavir

[c] ABT-267 is co-formulated with ABT-450/r, administered as two pills once daily

The 3D regimen consists of boosted protease inhibitor ABT-450/ritonavir, NS5A inhibitor ABT-267, and non-nucleoside polymerase inhibitor ABT-333. The combination of three different mechanisms of action interrupts the HCV replication process with the goal of optimizing SVR rates across different patient populations. In May of 2013, AbbVie's investigational 3D regimen with and without ribavirin for HCV GT1 was designated as a Breakthrough Therapy by the U.S. Food and Drug Administration (FDA).

ABT-450 was discovered during the ongoing collaboration between AbbVie and Enanta Pharmaceuticals (NASDAQ: ENTA) for HCV protease inhibitors and regimens that include protease inhibitors. ABT-450 is being developed by AbbVie for use in combination with AbbVie's other investigational medicines for the treatment of HCV.

Safety Information for Ribavirin and Ritonavir

Ribavirin and ritonavir are not approved for the investigational use discussed above, and no conclusions can or should be drawn regarding the safety or efficacy of these products for this use.

There are special safety considerations when prescribing these drugs in approved populations.

Ritonavir must not be used with certain medications due to significant drug-drug interactions and in patients with known hypersensitivity to ritonavir or any of its excipients.

Ribavirin monotherapy is not effective for the treatment of chronic hepatitis C virus and must not be used alone for this use. Ribavirin causes significant teratogenic effects and must not be used in women who are pregnant or breast-feeding and in men whose female partners are pregnant. Ribavirin must not be used in patients with a history of severe pre-existing cardiac disease, severe hepatic dysfunction or decompensated cirrhosis of the liver, automimmune hepatitis, hemoglobinopathies, or in combination with peginterferon alfa-2a in HIV/HCV co-infected patients with cirrhosis and Child-Pugh score ≥6.

See approved product labels for more information.

About AbbVie

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. In 2013, AbbVie employs approximately 21,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.com. Follow @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

Forward-Looking Statements

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements.

Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry.

Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," in AbbVie's 2012 Annual Report on Form 10-K/A, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

[1] Lavanchy D. Evolving epidemiology of hepatitis C virus. *Clin Microbiol Infect.* 2011; 17(2):107-15.

[2] Comparison based on review of data from clinicaltrials.gov for phase 3a programs of Gilead, BMS and BI as of November 15, 2013

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