AbbVie Completes Largest Phase III Program of an All-Oral, Interferon-Free Therapy for the Treatment of Hepatitis C Genotype 1

- Ninety-nine percent SVR(12) rates with and without ribavirin in certain patient types

- Even in difficult-to-treat patients (cirrhotic patients) achieved 92-96 percent SVR(12) rates

- AbbVie expects U.S. launch in 2014

NORTH CHICAGO, Ill., Jan. 31, 2014 -- AbbVie (NYSE: ABBV) announced the completion of its phase III clinical program and released results of four additional studies designed to assess AbbVie's investigational all-oral, interferon-free therapy with and without ribavirin (RBV) in patients with chronic genotype 1 (GT1) hepatitis C virus (HCV) infection. These results described below confirm previously reported AbbVie data and further demonstrate high sustained virologic response rates 12 weeks post treatment (SVR_{12}) and tolerability in these GT1 patients.

AbbVie Phase III Clinical Program Results

Study	Patients	Treatment Regimen	SVR_{12}
PEARL-II *(12 weeks)*	GT1b treatment-experienced *(N=179)*	AbbVie regimen + RBV (n=88)	**97%** *(85/88)*
		AbbVie regimen only (n=91)	**100%** *(91/91)*
PEARL-III *(12 weeks)*	GT1b treatment-naive *(N=419)*	AbbVie regimen + RBV (n=210)	**99%** *(209/210)*
		AbbVie regimen only (n=209)	**99%** *(207/209)*
PEARL-IV *(12 weeks)*	GT1a treatment-naive *(N=305)*	AbbVie regimen + RBV (n=100)	**97%** *(97/100)*
		AbbVie regimen only (n=205)	**90%** (185/205)
TURQUOISE-II *(12 & 24 weeks)*	GT1 treatment-naive and treatment-experienced with compensated cirrhosis *(N=380)*	AbbVie regimen + RBV, 12 weeks (n=208)	**92%** *(191/208)*
		AbbVie regimen + RBV, 24 weeks (n=172)	**96%** *(165/172)*
SAPPHIRE-I *(12 weeks)*	GT1 treatment-naive *(N=631)*	AbbVie regimen + RBV (n=473)	**96%** *(455/473)*
SAPPHIRE-II *(12 weeks)*	GT1 treatment-experienced *(N=394)*	AbbVie regimen + RBV (n=297)	**96%** *(286/297)*

"The outcomes of AbbVie's comprehensive phase III studies in 2,300 patients across 25 countries demonstrate how our investigational regimen performs across a broad spectrum of genotype 1 patients, including those with compensated liver cirrhosis," said Scott Brun, M.D., vice president, pharmaceutical development, AbbVie. "The high rates of response and tolerability of our regimen, coupled with the low rates of discontinuation are promising."

The AbbVie investigational regimen consists of the fixed-dose combination of ABT-450/ritonavir (150/100mg) co-formulated with ABT-267 (25mg), dosed once daily, and ABT-333 (250mg) with or without ribavirin (weight-based), dosed twice daily. 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 regimen with and without ribavirin for HCV GT1 was designated as a Breakthrough Therapy by the U.S. Food and Drug Administration (FDA). AbbVie is on track to begin major regulatory submissions early in the second quarter of 2014. AbbVie will disclose detailed study results at future scientific congresses and in publications.

About Study M13-389 (PEARL-II)
PEARL-II is a global, multi-center, randomized, open-label, controlled study to evaluate the efficacy and safety of 12 weeks of treatment with AbbVie's regimen with and without ribavirin in non-cirrhotic, GT1b HCV-infected, treatment-experienced adult patients.

The study population consisted of 179 GT1b treatment-experienced patients with no evidence of liver cirrhosis: 91 patients randomized to the regimen without ribavirin for 12 weeks, and 88 patients randomized to the regimen with ribavirin for 12 weeks. In the ribavirin-free arm, 100 percent (n=91/91) of patients achieved SVR_{12}, while 97 percent (n=85/88) achieved SVR_{12} in the ribavirin-containing arm.

The most commonly reported adverse events were fatigue and headache. Discontinuations due to adverse events were reported in none of the patients in the ribavirin-free arm and two (2 percent) patients in the ribavirin-containing arm. There were no patients in either arm of the study that experienced virologic relapse or breakthrough.

About Study M13-961 (PEARL-III)
PEARL-III is a global, multi-center, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of 12 weeks of treatment with AbbVie's regimen with and without ribavirin in non-cirrhotic, GT1b HCV-infected, treatment-naive adult patients.

The study population consisted of 419 GT1b treatment-naive patients with no evidence of liver cirrhosis: 209 patients randomized to the regimen without ribavirin for 12 weeks, and 210 patients randomized to the regimen with ribavirin for 12 weeks. Following 12 weeks of treatment, 99 percent receiving the regimen without ribavirin (n=207/209) and 99 percent receiving the regimen with ribavirin (n=209/210) achieved SVR_{12}.

The most commonly reported adverse events were headache and fatigue. No patient discontinued study drug due to adverse events. Virologic relapse or breakthrough was noted in none of the patients receiving the regimen without ribavirin and 0.5 percent of patients receiving the regimen with ribavirin.

About Study M14-002 (PEARL-IV)
PEARL-IV is a global, multi-center, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of 12 weeks of treatment with AbbVie's regimen with and without ribavirin in non-cirrhotic, GT1a HCV-infected, treatment-naive adult patients.

The study population consisted of 305 GT1a treatment-naive patients with no evidence of liver cirrhosis: 205 patients randomized to the regimen without ribavirin for 12 weeks, and 100 patients randomized to the regimen with ribavirin for 12 weeks. Following 12 weeks of treatment, 90 percent of patients receiving the regimen without ribavirin (n=185/205) and 97 percent receiving the regimen with ribavirin (n=97/100) achieved SVR_{12}.

The most commonly reported adverse events were fatigue, headache and nausea. Discontinuations due to adverse events were reported in two (1 percent) patients receiving the regimen without ribavirin and no patients in the ribavirin-containing arm. Virologic relapse or breakthrough was noted in 8 percent of patients receiving the regimen without ribavirin and 2 percent of patients receiving the regimen with ribavirin.

About Study M13-099 (TURQUOISE-II)
TURQUOISE-II is the first phase III study completed exclusively in GT1 cirrhotic patients investigating an all-oral, interferon-free regimen. It is a global, multi-center, randomized, open-label study evaluating the efficacy and safety of 12 or 24 weeks of treatment with AbbVie's regimen with ribavirin in cirrhotic, GT1a and GT1b HCV-infected, treatment-naive and treatment-experienced adult patients.

The study population consisted of 380 GT1a and GT1b, treatment-naive and treatment-experienced patients with compensated cirrhosis: 208 patients randomized to the regimen with ribavirin for 12 weeks, and 172 patients randomized to the regimen with ribavirin for 24 weeks. Following 12 weeks of treatment, 92 percent of patients (n=191/208) achieved SVR_{12}. Following 24 weeks of treatment, 96 percent of patients (n=165/172) achieved SVR_{12}.

The most commonly reported adverse events were fatigue, headache and nausea. Discontinuations due to adverse events were reported in four (2 percent) patients receiving the regimen with ribavirin for 12 weeks and four (2 percent) patients in the 24-week arm. Virologic relapse or breakthrough was noted in 6 percent of patients in the 12-week arm and 2 percent in the 24-week arm.

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

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.

AbbVie's HCV Development Program
The AbbVie HCV clinical development program is intended to advance scientific knowledge and clinical care by investigating an interferon-free, all-oral regimen with and 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.

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, autoimmune 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 Laboratories. 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. AbbVie employs approximately 25,000 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 www.clinicaltrials.gov for phase 3a programs of Gilead, BMS and BI as of November 15, 2013.

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