

## PRESS RELEASE

### **AbbVie Releases First of Six Phase III Results from Investigational All-Oral, Interferon-Free, 12-week Regimen, Showing 96 Percent SVR<sub>12</sub> in Genotype 1 Hepatitis C Patients New to Therapy**

- *Confirms results of phase II studies, with consistent virologic response and tolerability profile*
- *Largest all-oral, interferon-free clinical program in genotype 1 (GT1) patients to date<sup>1</sup>*
- *On track for major regulatory submissions in Q2 2014*
- *Worldwide, about 160 million people are chronically infected with hepatitis C<sup>2</sup>, most with GT1*

NORTH CHICAGO, Ill., Nov. 18, 2013 – AbbVie (NYSE: ABBV) released the first phase III results for the investigational three direct-acting-antiviral (3D) regimen plus ribavirin in patients chronically infected with genotype 1 (GT1) hepatitis C virus (HCV). In the 631-patient SAPPHIRE-I study, patients new to therapy receiving 12 weeks of AbbVie’s 3D regimen achieved a sustained virologic response at 12 weeks post-treatment (SVR<sub>12</sub>) of 96 percent. The majority of patients were GT1a, considered the more difficult-to-treat subtype, and the SVR<sub>12</sub> rates of GT1a and GT1b were 95 percent and 98 percent, respectively. The rate of virologic relapse or breakthrough was low, occurring in 1.7 percent of patients receiving the 3D regimen. In addition, discontinuation rates due to adverse events were low, and of an equal percentage (0.6 percent) in both active and placebo groups.

AbbVie’s multinational HCV program is the largest all-oral, interferon-free clinical program in GT1 patients being conducted to date. 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-I is the first of six phase III trials supporting AbbVie’s investigational 3D regimen for the treatment of GT1 hepatitis C patients.

“SAPPHIRE-I demonstrates that patients new to therapy with genotype 1 HCV achieved high rates of virologic response with AbbVie’s interferon-free, all-oral 3D regimen plus ribavirin, and the SVR rate is consistent with results from our phase II studies,” said Scott Brun, M.D., vice president, pharmaceutical development, AbbVie. “SAPPHIRE-I is the first of these studies to report results, and based on the progress of our clinical program to date, we are on track for major regulatory submissions in the second quarter of 2014.”

AbbVie will disclose detailed SAPPHIRE-I results at future scientific congresses and in publications.



### About Study M11-646 (SAPPHIRE-I)

SAPPHIRE-I 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-naïve adult patients.

The study population consisted of 631 GT1 treatment-naïve patients with no evidence of liver cirrhosis with 473 patients randomized to the 3D regimen plus ribavirin for 12 weeks, and 158 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.

Following 12 weeks of treatment with AbbVie's 3D regimen plus ribavirin, 96 percent (n=455/473) of patients achieved SVR<sub>12</sub> based on intent-to-treat analysis where patients with missing values for any reason were considered treatment failures. In the active treatment arm, patients with GT1b infection achieved 98 percent SVR<sub>12</sub> (148/151), while patients with GT1a achieved 95 percent SVR<sub>12</sub> (307/322).

The most commonly reported adverse events in the 3D and placebo arms, respectively, were fatigue, headache and nausea. Discontinuations due to adverse events were reported in 0.6 percent of patients receiving the 3D regimen and 0.6 percent of patients receiving placebo. The rate of virologic relapse or breakthrough was low, occurring in 1.7 percent of patients receiving the 3D regimen.

Additional information about AbbVie's phase III studies can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### AbbVie's HCV Development Program

The clinical program supporting our 3D regimen includes more than 2,300 genotype 1 patients in greater 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 five 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 programs is as follows:

Study	Patients (N)	Treatment Regimen	Treatment Duration
SAPPHIRE-I	GT1, treatment-naïve (631)	<ul style="list-style-type: none"><li>• ABT-450/r<sup>b</sup> +ABT-267<sup>c</sup></li><li>• ABT-333</li><li>• Ribavirin</li></ul>	12 weeks
		<ul style="list-style-type: none"><li>• Placebo</li></ul>	12 weeks, then active treatment for 12 weeks

SAPPHIRE-II	GT1, treatment-experienced (400 <sup>a</sup> )	<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	12 weeks
		<ul style="list-style-type: none"> <li>• Placebo</li> </ul>	12 weeks, then active treatment for 12 weeks
PEARL-II	GT1b, treatment-experienced (210 <sup>a</sup> )	<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	12 weeks
		<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> </ul>	12 weeks
PEARL-III	GT1b, treatment-naïve (400 <sup>a</sup> )	<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	12 weeks
		<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Placebo</li> </ul>	12 weeks
PEARL-IV	GT1a, treatment-naïve (300 <sup>a</sup> )	<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	12 weeks
		<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Placebo</li> </ul>	12 weeks
TURQUOISE-II	GT1, treatment-naïve and treatment-experienced (with compensated cirrhosis) (380 <sup>a</sup> )	<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	12 weeks
		<ul style="list-style-type: none"> <li>• ABT-450/r +ABT-267</li> <li>• ABT-333</li> <li>• Ribavirin</li> </ul>	24 weeks

<sup>a</sup> projected study population

<sup>b</sup> ABT-450/ritonavir

<sup>c</sup> 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 for 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  $\geq 6$ .

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](http://www.abbvie.com). Follow [@abbvie](https://twitter.com/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.

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<sup>1</sup> Comparison based on review of data from [clinicaltrials.gov](http://clinicaltrials.gov) for phase 3a programs of Gilead, BMS and BI as of November 15, 2013

<sup>2</sup> Lavanchy D. Evolving epidemiology of hepatitis C virus. *Clin Microbiol Infect.* 2011; 17(2):107-15.