abbvie

PRESS RELEASE

AbbVie to Present Late-Breaking Results from TURQUOISE-II Study in Chronic Hepatitis C Patients with Cirrhosis at the 2014 International Liver Congress™

- *In patients with compensated liver cirrhosis and genotype 1 (GT1) chronic hepatitis C virus (HCV) infection, a difficult-to-treat population, TURQUOISE-II demonstrated SVR_{12} rates of 91.8 and 95.9 percent after 12 and 24 weeks of treatment, respectively*
- *TURQUOISE-II is the largest phase III study of an all-oral, interferon-free treatment regimen conducted to date exclusively in GT1 HCV patients with cirrhosis*
- *Results from TURQUOISE-II demonstrate high virologic response and similar tolerability profile as seen in GT1 patients in other AbbVie phase III studies*
- *Results from TURQUOISE-II were published online today in* The New England Journal of Medicine
- *AbbVie will also present detailed data from the phase II M12-999 study and phase III PEARL-III study*

LONDON, [April 12, 2014] – AbbVie (NYSE:ABBV) announced that new, detailed results from its hepatitis C development programme will be presented today at the International Liver Congress™ (ILC) 2014. Data from a pivotal phase III study, TURQUOISE-II, featured in the ILC press conference on Friday, will be presented as a late-breaker. Additionally, results from the study have been published online in *The New England Journal of Medicine*.

TURQUOISE-II is a global, multi-centre, randomised, open-label study evaluating the efficacy and safety of 12 weeks or 24 weeks of treatment with AbbVie's regimen with ribavirin (RBV) in adult patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection with compensated liver cirrhosis. Patients achieved sustained virologic response rates 12 weeks post-treatment (SVR_{12}) of 91.8 percent and 95.9 percent in the 12-week and 24-week treatment arms, respectively. Patients in the study were either new to therapy or treatment-experienced (failed previous treatment with pegylated interferon and RBV).

TURQUOISE-II Results

	12-Week Arm SVR_{12} (n=208)	**24-Week Arm SVR_{12} (n=172)**
All GT1	**91.8% (n=191/208)**	**95.9% (n=165/172)**
GT1a	88.6% (n=124/140)	94.2% (n=114/121)
New to therapy	92.2% (n=59/64)	92.9% (n=52/56)
GT1a treatment-experienced		
Prior null responders	80.0% (n= 40/50)	92.9% (n=39/42)
Prior relapsers	93.3% (n= 14/15)	100.0% (n=13/13)
Prior partial responders	100.0% (n= 11/11)	100.0% (n=10/10)
GT1b	98.5% (n=67/68)	100.0% (n=51/51)
New to therapy	100.0% (n= 22/22)	100.0% (n=18/18)

GT1b treatment-experienced		
Prior null responders	100.0% (n=14/14)	100.0% (n=10/10)
Prior relapsers	100.0% (n=25/25)	100.0% (n=20/20)
Prior partial responders	85.7% (n= 6/7)	100.0% (n=3/3)

"Results from the TURQUOISE-II study demonstrate that high SVR_{12} rates can be achieved in GT1 patients with compensated liver cirrhosis in both 12-week and 24-week treatment durations," said Fred Poordad, M.D., lead clinical investigator for TURQUOISE-II and Clinical Professor of Medicine at the University of Texas Health Science Center at San Antonio. "These data are encouraging, as cirrhotic patients are often a difficult-to-treat population in the HCV community."

Discontinuation rates due to adverse events were 1.9 percent (four patients) and 2.3 percent (four patients) in the 12-week and 24-week arms, respectively. The most commonly reported adverse events (>10 percent in either arm) in TURQUOISE-II were fatigue, headache, nausea, pruritus, insomnia, diarrhoea, asthenia, rash, cough, irritability, anaemia and dyspnoea.

On-treatment virologic failure occurred in one patient (0.5 percent) in the 12-week arm and three patients (1.7 percent) in the 24-week arm. In addition, 12 patients (5.9 percent) in the 12-week arm and one patient (0.6 percent) in the 24-week arm experienced relapse within 12 weeks post-treatment.

"We designed our comprehensive HCV clinical trial programme to generate important information about treating a range of GT1 patients," said Scott Brun, M.D., Vice President, Pharmaceutical Development, AbbVie. "These data will help the medical community better understand the use of our regimen for specific patient types they encounter with GT1 infection in actual practice."

In addition, AbbVie will present the following at the ILC today:

- PEARL-III late-breaker poster: A phase III study examining the AbbVie regimen for 12 weeks with or without RBV in non-cirrhotic GT1b HCV-infected adult patients who were new to therapy
- M12-999 oral presentation: Interim results of a phase II study examining the AbbVie regimen with RBV for 24 weeks in non-cirrhotic adult liver transplant recipients with recurrent GT1 HCV infection

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

About AbbVie's Investigational HCV Regimen

The AbbVie investigational regimen consists of the fixed-dose combination of ABT-450/ritonavir (150/100mg) co-formulated with ombitasvir (ABT-267) 25mg, dosed once daily, and dasabuvir (ABT-333) 250mg with or without RBV (weight-based), dosed twice daily. The combination of three different

mechanisms of action interrupts the HCV replication process with the goal of optimising SVR rates across different patient populations.

AbbVie's HCV Development Programme
The AbbVie HCV clinical development programme is intended to advance scientific knowledge and clinical care by investigating an interferon-free, all-oral regimen with and without RBV 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.co.uk.

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 2013 Annual Report on Form 10-K, 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.

###

Media:
Gwenan White
Gwenan.white@abbvie.com
Tel. 07876 391429

Sarah Beck
Sarah.beck@abbvie.com
Tel. 07818 428111

AXHCV140428g
Date of preparation: April 2014