abbvie

PRESS RELEASE

AbbVie Receives CHMP Positive Opinion for Eight-Week Treatment Option with VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) for Patients with Genotype 1b Chronic Hepatitis C

- *CHMP opinion grants AbbVie approval of an eight-week regimen of VIEKIRAX + EXVIERA for previously untreated genotype 1b (GT1b) chronic hepatitis C virus (HCV) patients with minimal to moderate fibrosis**
- *AbbVie's EMA label expansion is supported by 98 percent cure rate in the dedicated Phase 3b GARNET study*[1]
- *GT1b is the most common subtype globally and accounts for 47 percent of the nine million people infected with chronic HCV in Europe*[2,3,4]

NORTH CHICAGO, Ill., Feb. 27, 2017 – AbbVie (NYSE: ABBV), a global biopharmaceutical company, announced today that the European Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted a positive opinion for a shorter, eight-week treatment of VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) as an option for previously untreated adult patients with genotype 1b (GT1b) chronic hepatitis C virus (HCV) and minimal to moderate fibrosis*.

VIEKIRAX + EXVIERA was previously approved in the European Union for use as a 12-week treatment for GT1b chronic HCV-infected patients without cirrhosis or with compensated cirrhosis.

"AbbVie continuously strives to expand the utility of our HCV treatments, including investigating a shorter path to virologic cure for people living with HCV," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "With this positive CHMP opinion, we will bring an eight-week treatment option for the many HCV patients with GT1b."

Approximately 160 million people worldwide are infected with HCV, with GT1b being the most common subtype globally.[2,5] In Europe, this subtype accounts for 47 percent of the nine million people infected with chronic HCV across the continent.[3,4]

"Nearly half of the people living with chronic hepatitis C in Europe are infected with genotype 1b," said Dr. Tania Mara Welzel, M.H.Sc., study author and Medical Lead of the Clinical Study Centre at the Department of Medicine at J.W. Goethe University in Frankfurt, Germany. "VIEKIRAX + EXVIERA has demonstrated high cure rates with only eight weeks of treatment in GT1b patients with minimal to moderate fibrosis."

The CHMP positive opinion is supported by data from the dedicated Phase 3b GARNET study. Results showed that with eight weeks of treatment with VIEKIRAX + EXVIERA, 98 percent (n=160/163) of previously untreated GT1b chronic HCV infected patients without cirrhosis achieved sustained virologic response at 12 weeks post-treatment (SVR_{12}).[1] The most commonly reported adverse events, occurring

at a rate equal to or greater than 5 percent, were headache (21 percent), fatigue (17 percent), nasopharyngitis (8 percent), pruritus (8 percent), nausea (6 percent) and asthenia (5 percent).

**When assessing severity of liver disease using non-invasive methods, additional blood tests improve accuracy and should be undertaken prior to 8 week treatment in all patients with moderate fibrosis.*

About the GARNET Study[1]

The Phase 3b GARNET study is a multicentre, open-label, single-arm study investigating the safety and efficacy of eight weeks of treatment with VIEKIRAX + EXVIERA without ribavirin in treatment-naïve patients with GT1b chronic HCV infection without cirrhosis.[1] The study enrolled 166 patients across 20 sites around the world. Of the 166 patients enrolled, 163 patients had GT1b chronic HCV infection without cirrhosis and three patients with other HCV genotypes were excluded from the efficacy analysis. The primary endpoint is the percentage of patients who achieved SVR_{12}.

Two patients experienced post-treatment relapse and one discontinued due to noncompliance. Less than one percent of patients experienced serious adverse events or clinically significant (Grade ≥3) laboratory abnormalities. One patient discontinued treatment on Day 45 due to an adverse event but achieved SVR_{12}.

Additional information about the GARNET study can be found on www.clinicaltrials.gov.

VIEKIRAX® + EXVIERA®

VIEKIRAX + EXVIERA is approved in the European Union for the treatment of genotype 1 (GT1) chronic hepatitis C virus (HCV) infection, including patients with compensated cirrhosis. VIEKIRAX is approved in the European Union for the treatment of genotype 4 (GT4) chronic HCV infection.

VIEKIRAX tablets consist of the fixed-dose combination of paritaprevir 150mg (NS3/4A protease inhibitor) and ritonavir 100mg with ombitasvir 25mg (NS5A inhibitor), dosed once daily. EXVIERA tablets consist of dasabuvir 250mg (non-nucleoside NS5B polymerase inhibitor) dosed twice daily. VIEKIRAX + EXVIERA is taken with or without ribavirin (RBV), dosed twice daily based on patient type. VIEKIRAX + EXVIERA is taken for 12 weeks with or without RBV, except in genotype 1a patients with compensated cirrhosis (Child-Pugh A), who should take it for 24 weeks with RBV.

Paritaprevir was discovered during the ongoing collaboration between AbbVie and Enanta Pharmaceuticals (NASDAQ: ENTA) for hepatitis C protease inhibitors and regimens that include protease inhibitors. Paritaprevir has been developed by AbbVie for use in combination with AbbVie's other investigational medicines for the treatment of chronic hepatitis C.

Full summary of product characteristics is available at www.medicines.org.uk/emc

Additional information about AbbVie's hepatitis C development programme can be found on www.clinicaltrials.gov.

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. Together with its wholly-owned subsidiary, Pharmacyclics, AbbVie

abbvie employs more than 28,000 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.

###

Media:
Sarah Beck
07818 428111
sarah.beck@abbvie.com

[1] Welzel, T. et al. GARNET: High SVR Rates Following Eight-Week Treatment with Ombitasvir/Paritaprevir/Ritonavir + Dasabuvir for Patients with HCV Genotype 1b Infection. Presented at the European Association for the Study of the Liver Special Conference: New Perspectives in Hepatitis C Virus Infection – The Roadmap for Cure, Paris, France on September 23-24, 2016.

[2] Gower E. et al. Global epidemiology and genotype distribution of the hepatitis C virus infection. Journal of Hepatology Update: Hepatitis C, 2014; 61: S45-S57.

[3] O'Leary JG, Davis GL. Hepatitis C. In: Feldman M, Friedman LS, Brandt LJ, eds. Sleisenger and Fordtran's Gastrointestinal and Liver Disease: Pathophysiology/Diagnosis/Management. 9th ed, Vol 1. Philadelphia, PA: Saunders Elsevier. 2010:1313-1335.

[4] Hatzakis A. et al. The state of hepatitis B and C in Europe: report from the hepatitis B and C summit conference. Journal of Viral Hepatitis, 2011; 18 (Suppl. 1): 1-16.

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

AXHCV170285
Date of preparation: February 2017