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PRESS RELEASE

For medical & consumer media

AbbVie Receives CHMP Positive Opinion for VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) Without Ribavirin for the Treatment of Chronic Hepatitis C in Genotype 1b Patients with Compensated Cirrhosis (Child-Pugh A) in Europe

- *EU label expansion supported by high cure rates shown in TURQUOISE-III study, a dedicated Phase 3b study of VIEKIRAX + EXVIERA without ribavirin for 12 weeks*
- *100 percent SVR_{12} (n=60/60) achieved in genotype 1b patients with compensated cirrhosis (Child-Pugh A); no patients discontinued treatment due to adverse events*

NORTH CHICAGO, Ill., February 26, 2016 – 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 the use of VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) without ribavirin (RBV) in chronic hepatitis C virus (HCV) infected genotype 1b (GT1b) patients with compensated cirrhosis (Child-Pugh A).

"This positive CHMP opinion brings us one step closer to delivering a ribavirin-free treatment option for GT1b patients with compensated cirrhosis that has demonstrated high cure rates with no treatment discontinuations in our clinical trial," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "This milestone reinforces our continued commitment to provide additional treatment options for the HCV community, and we look forward to the final decision by the European Commission."

Approximately 160 million people worldwide are infected with HCV.[1] Genotype 1 is the most common type of HCV genotype, accounting for 60 percent of cases worldwide.[2] In Europe, the most prevalent genotype is 1b, accounting for 47 percent of the nine million people infected with chronic HCV.[3,4]

The CHMP opinion of the Type-II variation application for VIEKIRAX + EXVIERA is supported by data from the Phase 3b TURQUOISE-III study, which is part of AbbVie's larger clinical programme investigating efficacy and safety in a broad range of GT1 patients. TURQUOISE-III is a dedicated Phase 3 study of VIEKIRAX + EXVIERA without RBV for 12 weeks in GT1b patients with compensated cirrhosis. Results from the TURQUOISE-III study showed 100 percent (n=60/60) of GT1b chronic HCV infected patients with compensated cirrhosis (Child-Pugh A) achieved sustained virologic response at 12 weeks post-treatment (SVR_{12}) with VIEKIRAX + EXVIERA without RBV for 12 weeks.[5] No patients discontinued treatment due to adverse events. The most commonly reported adverse events (>10 percent) were fatigue (22 percent), diarrhoea (20 percent) and headache (18 percent).[5]

About VIEKIRAX and EXVIERA

VIEKIRAX + EXVIERA are the first treatments for chronic hepatitis C to combine three direct-acting antiviral agents with distinct mechanisms of action to target HCV at multiple steps in the viral lifecycle.[3,4] VIEKIRAX + EXVIERA, with or without ribavirin (RBV) (for 12 or 24 weeks) cleared the virus in 97 percent of GT1 patients, including 96 percent of those with compensated cirrhosis. Overall, 1.3 percent experienced a relapse and 0.5 percent experienced on-treatment virologic failure.[2,3] Discontinuation rates due to adverse reactions was low (0.2 percent),[2,3] and in those receiving VIEKIRAX + EXVIERA without RBV, the overall rates of discontinuation due to adverse reactions was zero percent.

Each tablet of VIEKIRAX consists of the fixed dose combination of ombitasvir 12.5mg, paritaprevir 75mg and ritonavir 50mg. The recommended oral dose of VIEKIRAX is two tablets taken once daily with food.

Each tablet of EXVIERA contains dasabuvir 250mg (non-nucleoside NS5B polymerase inhibitor). The recommended oral dose of Exviera is 250mg (one tablet) twice daily (morning and evening). EXVIERA must always be administered together with VIEKIRAX.

AbbVie UK also offers AbbVie Care in hepatitis C, a support programme designed to help people maintain motivation, focus and stability while on treatment with VIEKIRAX + EXVIERA.

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

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 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.

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

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