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# PRESS RELEASE

## AbbVie Announces High SVR Rates with VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) Regardless of the Presence of Resistance-Associated Variants Prior to Treatment in Genotype 1 Chronic Hepatitis C Patients

- *100 percent of genotype 1b patients, who received VIEKIRAX + EXVIERA without ribavirin for 12 weeks, achieved $SVR_{12}$ in a post-hoc analysis no matter whether baseline NS5A RAVs were present*[1]
- *97 percent of genotype 1a patients, both with or without baseline NS5A RAVs, who received the regimen with RBV achieved $SVR_{12}$*[1]

BARCELONA, April 14, 2016 — AbbVie (NYSE: ABBV), a global biopharmaceutical company, has announced data showing that patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection who received the recommended regimen of VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets), with or without ribavirin (RBV), achieved high sustained virologic response rates at 12 weeks post-treatment ($SVR_{12}$), regardless of the presence of baseline resistance-associated variants (RAVs).[1] These late-breaking data from a post-hoc analysis of five completed Phase 3 clinical trials were presented at The International Liver Congress™ (ILC) 2016 in Barcelona, Spain.

The study found that no matter whether certain RAVs, called NS5A, were present, 100 percent (n=148/148) of patients with genotype 1b (GT1b) chronic HCV infection, who received VIEKIRAX + EXVIERA without RBV for 12 weeks, achieved $SVR_{12}$.[1] Results also showed 97 percent of patients with genotype 1a (GT1a) chronic HCV infection with or without baseline NS5A RAVs (n=57/59 and n=351/361 respectively) achieved $SVR_{12}$ when receiving the recommended regimen of VIEKIRAX + EXVIERA with RBV.[1] These findings included both patients new to therapy and pegylated interferon/ribavirin (pegIFN/RBV) treatment-experienced, as well as those with compensated cirrhosis.[1]

“These results show that high virologic cure rates were achieved in HCV genotype 1a and 1b infected patients no matter their NS5A RAV status when treated with VIEKIRAX plus EXVIERA with and without ribavirin as recommended, a regimen which contains the NS5A inhibitor ombitasvir,” said Christoph Sarrazin, M.D., professor of medicine at J.W. Goethe University Hospital in Frankfurt, Germany.

As the hepatitis C virus replicates, variants of the viral NS5A protein are produced.[2] The impact of these variants on treatment response, including the possibility of becoming resistant to therapy or achieving SVR, has yet to be fully determined.[3]

“It’s important that we understand emerging issues in treating people with chronic HCV, including RAVs, so that we can meet the needs of patients and physicians,” said Rob Scott, M.D., vice president, development and chief medical officer, AbbVie. “As we learn more about the role of resistance to direct-acting antiviral regimens, it is vital to further investigate treatment options that are not affected by baseline RAVs.”

To understand more about the impact of variants on treatment response, next-generation sequencing was used to assess baseline samples for variants in NS5A, which were detected in 11 percent of GT1a

patients and 19 percent of GT1b patients, with a detection threshold of 15 percent, consistent with the limits of detection for variants by population sequencing.[1] The post-hoc analysis was performed on data from five completed Phase 3 studies:[1] PEARL-IV (GT1a treatment-naïve, n=90), SAPPHIRE-II (GT1a pegIFN/RBV treatment-experienced, n=214), TURQUOISE-II (GT1a compensated cirrhosis – 24 week treatment arm, n=118), PEARL-II (GT1b pegIFN/RBV treatment-experienced, n=89) and TURQUOISE-III (GT1b compensated cirrhosis, n=59). Patients who did not achieve SVR for reasons other than virologic failure (such as early treatment discontinuations or $SVR_{12}$ data unavailable) were excluded from the analysis.

**About VIEKIRAX® + EXVIERA®.**

VIEKIRAX and 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. VIEKIRAX and 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 [4, 5]. Discontinuation rates due to adverse reactions was low (0.2 percent) [4, 5], and in those receiving VIEKIRAX and 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 and 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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[1] Sarrazin C, et al. Effect of Baseline Resistance-Associated Variants on SVR With the 3D Regimen Plus RBV. Late Breaker Poster #LBP503; presented at the International Liver Congress™ (ILC), the Annual Meeting of the European Association for the Study of the Liver (EASL) in Barcelona, April 13-17, 2016.

[2] Schneider MD, et al. Antiviral therapy of hepatitis C in 2014: do we need resistance testing? Antiviral Res. 2014 May;105:64-71.

[3] American Association for the Study of Liver Diseases. Monitoring patients who are starting hepatitis C treatment, are on treatment, or have completed therapy, February 24, 2016, http://www.hcvguidelines.org/full-report/monitoring-patients-who-are-starting-hepatitis-c-treatment-are-treatment-or-have. Accessed March 15, 2016.

[4] VIEKIRAX tablets (ombitasvir/paritaprevir/ritonavir) Summary of product characteristics. Maidenhead, UK. AbbVie, Ltd. Full summary of product characteristics is available https://www.medicines.org.uk/emc/medicine/29784 Last accessed April 2016

[5] EXVIERA tablets (dasabuvir) Summary of product characteristics. Maidenhead, UK. AbbVie, Ltd. Full summary of product characteristics is available at https://www.medicines.org.uk/emc/medicine/29785 Last accessed April 2016