



PRESS RELEASE

AbbVie Announces New Phase 3b Results in Genotype 1b Chronic Hepatitis C Patients with Compensated Liver Cirrhosis

- 100 percent SVR₁₂ rate achieved with VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) without ribavirin¹

NORTH CHICAGO, Ill., June 24, 2015 – AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced TURQUOISE-III study results demonstrating 100 percent (n=60/60) sustained virologic response at 12 weeks post-treatment (SVR₁₂) in genotype 1b (GT1b) chronic hepatitis C virus (HCV) infected adult patients with compensated liver cirrhosis.¹ Patients received 12 weeks of VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets) without ribavirin (RBV). These new results from AbbVie’s Phase 3b study will be presented at the 15th Annual International Symposium on Viral Hepatitis and Liver Diseases in Berlin, Germany.

Approximately 160 million people worldwide are infected with HCV.² Genotype 1 is the most common type of HCV genotype, accounting for 60 percent of cases worldwide³ and in Europe, the most prevalent genotype is 1b (47 percent).⁴ Over time, chronic HCV may lead to liver complications, including compensated cirrhosis, in about 10-20 percent of people infected.²

“Genotype 1b represents a large portion of HCV patients globally, as it is the most prevalent sub-genotype, and there is a need to continue to explore additional treatment regimens,” said Jordan J. Feld, M.D., MPH, research director and clinician scientist, Toronto Center for Liver Disease, Toronto, Canada. “The results of TURQUOISE-III are promising, demonstrating that genotype 1b HCV patients with compensated liver cirrhosis have the potential to achieve high response rates with an interferon and ribavirin-free treatment in 12 weeks.”

Patients in TURQUOISE-III were either treatment-naïve or treatment-experienced (failed previous therapy with pegylated interferon and RBV). No patients discontinued treatment due to adverse events.¹ The most commonly reported adverse events (>10 percent) were fatigue (22 percent), diarrhea (20 percent) and headache (18 percent).¹

“In the TURQUOISE-III study, GT1b patients with compensated liver cirrhosis achieved a 100 percent cure rate with VIEKIRAX + EXVIERA without ribavirin,” said Scott Brun, M.D., vice president, pharmaceutical development, AbbVie. “TURQUOISE-III is part of our Phase 3b program, which aims to further enhance our understanding of AbbVie’s regimen in HCV populations seen in clinical practice, and supports our commitment to continued investigation in this field.”

About TURQUOISE-III Study

TURQUOISE-III is a multi-center, open-label Phase 3b study to evaluate the safety and efficacy of 12 weeks of treatment with VIEKIRAX® + EXVIERA® without ribavirin (RBV) in adult patients (n=60) with



genotype 1b chronic hepatitis C virus infection and compensated liver cirrhosis who were treatment-naïve or treatment-experienced (failed previous therapy with pegylated interferon and RBV). The primary endpoint is the rate of sustained virologic response 12 weeks after treatment (SVR₁₂).¹

No patients experienced virologic failure during treatment and no patients experienced virologic relapse following the end of treatment.¹

About 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 are 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 and GT4 patients with compensated cirrhosis, 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.

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

About AbbVie's HCV Clinical Development Program

The AbbVie HCV clinical development program is intended to advance scientific knowledge and clinical care by investigating interferon-free, all-oral treatments with or without ribavirin with the goal of achieving high sustained virologic response rates in as many patients as possible. AbbVie's global Phase 3b program plans to include more than 2,800 genotype 1 patients in over 200 study centers worldwide, including the U.S., Canada, Europe, Russia and Brazil.

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

VIEKIRAX® + EXVIERA® EU Indication

VIEKIRAX is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults. EXVIERA is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults.



Important EU Safety Information

Contraindications:

VIEKIRAX + EXVIERA are contraindicated in patients with severe hepatic impairment (Child-Pugh C). Patients taking ethinyl estradiol-containing medicinal products must discontinue them and switch to an alternative method of contraception prior to initiating VIEKIRAX + EXVIERA. Do not give VIEKIRAX with certain drugs that are sensitive CYP3A substrates or strong inhibitors of CYP3A. Do not give VIEKIRAX and EXVIERA with strong or moderate enzyme inducers. Do not give EXVIERA with certain drugs that are strong inhibitors of CYP2C8.

Special warnings and precautions for use:

VIEKIRAX and EXVIERA are not recommended as monotherapy and should be used in combination with other medicinal products for the treatment of hepatitis C infection.

Pregnancy and concomitant use with ribavirin

When VIEKIRAX + EXVIERA are used in combination with ribavirin, women of childbearing potential or their male partners must use an effective form of contraception during the treatment and 6 months after the treatment. Refer to the Summary of Product Characteristics for ribavirin for additional information.

ALT elevations

Transient elevations of ALT to >5x ULN without concomitant elevations of bilirubin occurred in clinical trials with VIEKIRAX + EXVIERA and were more frequent in a subgroup who were using ethinyl estradiol-containing contraceptives.

Use with concomitant medicinal products

Use caution when administering VIEKIRAX with fluticasone or other glucocorticoids that are metabolized by CYP3A4. A reduction in colchicine dosage or interruption in colchicine is recommended in patients with normal renal or hepatic function. VIEKIRAX with or without EXVIERA is expected to increase exposure of statins so certain statins need to be discontinued or dosages reduced. Low dose ritonavir, which is part of VIEKIRAX, may select for PI resistance in HIV co-infected patients without ongoing antiretroviral therapy. HIV co-infected patients without suppressive antiretroviral therapy should not be treated with VIEKIRAX.

Adverse Reactions

Most common (>20 percent) adverse reactions for VIEKIRAX + EXVIERA with RBV were fatigue and nausea.

Full summary of product characteristics is available at www.ema.europa.eu

Globally, prescribing information varies; refer to the individual country product label for complete 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. 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.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 2014 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.

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¹ Feld J, et al. TURQUOISE-III: Safety and Efficacy of 12-week Ribavirin-free Treatment for Patients with HCV Genotype 1b and Cirrhosis. Presented at the 15th Annual International Symposium on Viral Hepatitis and Liver Diseases (ISVHLD) in Berlin, Germany, June 26-28, 2015

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

³ Global Alert and Response (GAR): Hepatitis C. World Health Organisation Web site.

<http://www.who.int/csr/disease/hepatitis/whocdscsrlyo2003/en/index2.html#HCV>. Published 2003. Accessed November, 2013

⁴ 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