abbvie

PRESS RELEASE

AbbVie's VIEKIRAX® (ombitasvir/paritaprevir/ritonavir) and EXVIERA ® (dasabuvir) Licensed for Use in the UK for the Treatment of Chronic Hepatitis C

- *First treatments for chronic hepatitis C to combine three direct-acting antiviral agents to target hepatitis C virus (HCV) at multiple steps in the viral lifecycle*
- *VIEKIRAX® and EXVIERA®, with or without* ribavirin (*RBV), cleared the virus in 97 percent of chronic genotype 1 (GT1) HCV patients and was generally well tolerated*
- *AbbVie Care in hepatitis C also launched in the UK to help people maintain motivation, focus and stability while on treatment*

MAIDENHEAD, UK, Jan. 19, 2015 – AbbVie's all-oral, short course (12 weeks for the majority of patients), interferon-free treatments VIEKIRAX® (ombitasvir/paritaprevir/ritonavir) and EXVIERA® (dasabuvir) are now licensed for use in the UK with or without ribavirin (RBV) for the treatment of patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection. VIEKIRAX® is also licensed for use in the UK with RBV in non-cirrhotic, genotype 4 (GT4) chronic hepatitis C patients.[1,2] The availability of VIEKIRAX® and EXVIERA® in the UK follows the granting of an EU Marketing Authorisation (MA) from the European Medicines Agency (EMA).

Hepatitis C is a blood borne virus that is spread when an infected person's blood enters the bloodstream of another person.[3] Some 75-85 percent of patients infected with HCV go on to develop the chronic form of the disease.[3] Chronic hepatitis C is a silent, progressive disease that can lead to liver damage, scarring of the liver (cirrhosis), liver cancer and death.[4] More than 200,000 people in the UK are chronically infected with hepatitis C[5]. Of those chronically infected, only an estimated 3% are treated each year, despite the advent of treatments that can offer viral elimination[5].

"New treatments, such as AbbVie's triple combination regimen containing three directly acting anti-virals, offer both naive and treatment experienced patients, including those with cirrhosis, a very high likelihood of clearing hepatitis C virus," said Professor Geoffrey Dusheiko, Emeritus Professor of Medicine, UCL Institute of Liver and Digestive Health and Royal Free Hospital. "Such highly efficacious, better tolerated and shorter treatments irrevocably change the field from interferon-based care."

VIEKIRAX® and EXVIERA® is the first treatment 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.[1,2] VIEKIRAX® and EXVIERA®, with or without 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.[1,2] Discontinuation rates due to adverse reactions was low (0.2 percent),[1,2] and in those receiving VIEKIRAX® and EXVIERA® without RBV, the overall rates of discontinuation due to adverse reactions was zero percent.

Charles Gore, Chief Executive of The Hepatitis C Trust, welcomed the news of AbbVie's UK licences, commenting: "We are now seeing a real paradigm shift in the way HCV can be treated; for many patients, these new treatments represent curative therapies, and therapies that are significantly more tolerable than interferon-based regimens. With the licensing of AbbVie's treatments there is now more choice for treating people affected by HCV. The next important step will be for the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC) to ensure access to the range of new therapies being licensed".

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

"AbbVie is committed to making a meaningful contribution to addressing the personal, societal and economic burden of hepatitis C. The licensing of VIEKIRAX® and EXVIERA® in the UK, and the launch of AbbVie Care in hepatitis C, brings us much closer to making this a reality and to making a positive difference in the lives of people living with and affected by hepatitis C," said Matt Regan, General Manager, AbbVie UK.

Robust Clinical Programme

The approval of VIEKIRAX® and EXVIERA® with or without RBV in chronic GT1 HCV patients is supported by a robust clinical development programme consisting of six pivotal Phase 3 studies – SAPPHIRE-I, SAPPHIRE-II, PEARL-II, PEARL-III, PEARL-IV, and TURQUOISE-II. AbbVie's treatment was evaluated in more than 2,300 GT1 patients in over 25 countries. Approval of VIEKIRAX® in chronic GT4 HCV patients was based on the Phase 2b, PEARL-I study (135 patients), in which 100 percent of GT4 patients without cirrhosis achieved SVR_{12} when receiving VIEKIRAX® with RBV.

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

About VIEKIRAX® and EXVIERA®

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®R.

Summary of Product Characteristics for VIEKIRAX® and EXVIERA® are available on request.

Important Safety Information for VIEKIRAX® and EXVIERA®
The safety summary is based on pooled data from phase 2 and 3 clinical trials in more than 2,600 subjects who received VIEKIRAX® and EXVIERA® with or without RBV.

VIEKIRAX® and EXVIERA®*with RBV in subjects with genotype 1 hepatitis C infection (including subjects with compensated cirrhosis)*
In subjects receiving VIEKIRAX® and EXVIERA® with RBV, the most commonly reported adverse reactions (greater than 20 percent of subjects) were fatigue and nausea. The proportion of subjects who permanently discontinued treatment due to adverse reactions was 0.2 percent (5/2,044). 0.2 percent (5/2,044) of subjects interrupted treatment due to adverse reactions. 4.8 percent (99/2,044) of subjects had RBV dose reductions due to adverse reactions.

With the exception of increased rates of transient hyperbilirubinemia, the safety profile of VIEKIRAX® and EXVIERA® with RBV in subjects with compensated cirrhosis was similar to that of subjects without cirrhosis.

VIEKIRAX® *and* EXVIERA® *without RBV in subjects with genotype 1 hepatitis C infection*
No subjects permanently discontinued treatment or had treatment interruptions due to adverse reactions.

Contraindications

Hypersensitivity to the active substances or to any of the excipients.

Patients with severe hepatic impairment (Child-Pugh C).

Use of ethinylestradiol-containing medicinal products such as those contained in most combined oral contraceptives or contraceptive vaginal rings.

For full details of drug-drug interactions and contraindications with VIEKIRAX® and EXVIERA®, please refer to Summary of Product Characteristics, available on request.

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.

###

UK Media Contacts:
Sarah Beck
sarah.beck@abbvie.com
+44 (0)7818 428111

Gwenan White
gwenan.white@abbvie.com
+44 (0)7876 391429

[1] VIEKIRAX™ tablets (ombitasvir/paritaprevir/ritonavir) Summary of product characteristics. Maidenhead, UK. AbbVie, Ltd.

[2] EXVIERA™ tablets (dasabuvir) Summary of product characteristics. Maidenhead, UK. AbbVie, Ltd.

[3] Chen SL, Morgan TR. The Natural History of Hepatitis C Virus (HCV) Infection. *Int J Med Sci* 2006; 3(2):47-52. doi:10.7150/ijms.3.47. Available from http://www.medsci.org/v03p0047.htm. Accessed December 2014

[4] Zaltron S, S.L., Biasi L, Baiguera C, Castelli, F, Chronic HCV infection: epidemiological and clinical relevance. BMC Infectious Diseases, 2012. 12(Suppl 2): p. 2-7

[5] Public Health England. Hepatitis C in the UK 2014 Report. 2014. Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/337115/HCV_in_the_UK_2014_24_July.pdf (date accessed 02/12/14)