



PRESS RELEASE

AbbVie's MAVIRET® ▼ (glecaprevir/pibrentasvir) recommended for use within NHS Wales

- *All Wales Medicines Strategy Group recommends MAVIRET® for the treatment of adults in Wales with chronic hepatitis C virus (HCV) infection*

MAIDENHEAD, UK, Oct. 20, 2017 – AbbVie, a global research and development based biopharmaceutical company, today announced that its pan-genotypic hepatitis C regimen, Maviret®, has been recommended for use within NHS Wales, following an assessment by the All Wales Medicines Strategy Group (AWMSG)¹. Maviret® is recommended for use for the treatment of chronic hepatitis C virus (HCV) infection in adults.

Chronic hepatitis C is a silent, progressive disease that can lead to liver damage, scarring of the liver (cirrhosis), liver cancer and death². It is estimated that in Wales 12,000 people are living with chronic hepatitis C³.

“New treatments, such as Maviret®, offer patients with all the major genotypes of hepatitis C a chance of clearing the virus with as little as 8 weeks of treatment. This is good news for patients who now have a number of treatment choices that can benefit their quality of life and health. Treatment is cost effective and can also make a positive impact on overall public health as the pool of disease is reduced through treatment. It will also help Wales achieve targets in relation to the World Health Organization’s (WHO) elimination agenda,” said Dr Brendan Healy, Consultant in Infectious Diseases & Microbiology, University Hospital of Wales.

Charles Gore, Chief Executive of The Hepatitis C Trust comments, “This is good news for Wales but we now need to see England and Scotland following Wales’s lead quickly if we are to achieve the WHO goal of eliminating hepatitis C as a public health threat by 2030.”

About Maviret®

Maviret® is a once-daily, ribavirin-free treatment that combines glecaprevir (100mg), an NS3/4A inhibitor and pibrentasvir (40mg), an NS5A inhibitor (glecaprevir/pibrentasvir), for adults with chronic hepatitis C virus (HCV) infection across all major genotypes (GT1-6).

Glecaprevir (GLE) was discovered during the ongoing collaboration between AbbVie and Enanta Pharmaceuticals (NASDAQ: ENTA) for HCV protease inhibitors and regimens that include protease inhibitors.

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

Important EU Safety Information

Contraindications:

Maviret® is contraindicated in patients with severe hepatic impairment (Child-Pugh C). Concomitant use with atazanavir containing products, atorvastatin, simvastatin, dabigatran etexilate, ethinyl oestradiol-containing products, strong P-gp and CYP3A inducers, such as rifampicin, carbamazepine, St. John’s wort, phenobarbital, phenytoin, and primidone.

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Special warnings and precautions for use:

Hepatitis B virus reactivation

Cases of hepatitis B virus (HBV) reactivation, some of them fatal, have been reported during or after treatment with direct-acting antiviral agents. HBV screening should be performed in all patients before initiation of treatment.

Hepatic impairment

Maviret[®] is not recommended in patients with moderate hepatic impairment (Child-Pugh B).

Patients who failed a prior regimen containing an NS5A- and/or an NS3/4A-inhibitor

Maviret[®] is not recommended for the re-treatment of patients with prior exposure to NS3A/4A and/or NS5A-inhibitors.

Adverse Reactions

Most common ($\geq 10\%$) adverse reactions for Maviret[®] were headache and fatigue.

▼ Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to AbbVie UK Ltd. Please contact ukadverseevents@abbvie.com. With biological medicines, healthcare professionals should report adverse reactions by brand name and batch number.

-ENDS-

Notes to editors:

About AbbVie

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at www.abbvie.co.uk and follow @abbvieuk on Twitter.

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References

¹AWMSG Final Appraisal Recommendation, advice no. 1917
<http://www.awmsg.org/awmsgonline/app/appraisalinfo/3007> (accessed October 2017)

² Harris, R. J. et al. 2016. New treatments for hepatitis C virus (HCV): scope for preventing liver disease and HCV transmission in England. *J Viral Hepat*, 23: 631–643

³ NHS Wales and Welsh Government, Liver Disease: Annual Statement of Progress, June 2017, <http://gov.wales/docs/dhss/publications/170630liver-diseaseen.pdf> (accessed October 2017)

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⁴ MAVIRET® tablets (glecaprevir/pibrentasvir) Summary of product characteristics. Maidenhead, UK. AbbVie, Ltd. Full summary of product characteristics is available at www.medicines.org.uk/emc