PRESS RELEASE

The National Institute for Health and Care Excellence (NICE) Issues Positive Guidance for AbbVie's MAVIRET®▼(glecaprevir/pibrentasvir) for the Treatment of Adults with All Major Genotypes (GT1-6) of Chronic Hepatitis C in England and Wales[1]

MAIDENHEAD, UK, December 7, 2017 – Today, the National Institute for Health and Care Excellence (NICE) published guidance in the form of a Final Appraisal Determination (FAD), confirming that AbbVie's Maviret®, a once-daily, ribavirin-free treatment that combines glecaprevir (100mg), an NS3/4A inhibitor and pibrentasvir (40mg), an NS5A inhibitor (glecaprevir/pibrentasvir), is recommended within its marketing authorisation, as an option for treating chronic hepatitis C infection in adults[1].

Maviret® is licensed as a treatment in the EU for adults with chronic hepatitis C virus (HCV) infection across all major genotypes (GT1-6). It is also licensed for patients with specific treatment challenges, including those with compensated cirrhosis across all major genotypes, and those who previously had limited treatment options, such as patients with severe chronic kidney disease (CKD) or those with genotype 3 (GT3) chronic HCV infection[2].

Chronic HCV is a silent, progressive disease that can lead to liver damage (fibrosis or cirrhosis), liver cancer and death.[3] More than 200,000 people in the UK are estimated to be chronically infected with hepatitis C.[3] Of those chronically infected, only an estimated three percent receive treatment each year, despite the advent of treatments that can offer viral elimination.[3]

David Rowlands, HCV patient champion for the Leicester Operational Delivery Network explains: *"This is great news. People living with hepatitis C have been eagerly awaiting these new pan-genotypic treatments and it is now vital that NHS England ensures patients have access to them as quickly and widely as possible. These drugs are cost effective and allow patients to be cured in as little as 8 weeks, so the UK government should now seize the opportunity in front of it to make good on its publically stated commitment to eliminate hepatitis C as a public health threat by the World Health Organization's target of 2030. As a minimum, we need to work together to develop community outreach clinics to find people who are not yet engaged in treatment. As a minimum, we need to work together to develop community outreach clinics to find people who are not yet engaged in treatment."*

Dr Alice Butler, UK Medical Director, AbbVie said: *"We welcome the NICE decision as we believe that treatments, like MAVIRET®, have an important role to play in not only helping people clear the hepatitis C*

virus and move on with their lives, but also in opening up new approaches to how and where patients can be treated. Rather than traditionally focusing on treating within hospital settings, once-daily, pan-genotypic options enable treatment to be delivered to patients more locally, within their own communities. This could be an important strategy to reach patients who don't typically engage with healthcare services.

We look forward to seeing NHS England implementing the NICE guidance swiftly and in full as soon as possible to benefit all eligible patients", Dr Butler concluded.

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.

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 (≥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.

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 follow @abbvieuk on Twitter.

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References:

[1] National Institute for Health and Care Excellence, *Final Appraisal Determination, glecaprevir-pibrentasvir for treating chronic hepatitis C*, (ID1085), December 2017, https://www.nice.org.uk/guidance/gid-ta10169/documents/final-appraisal-determination-document (Accessed December 2017)

[2] 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

[3] Public Health England, *Hepatitis C in the UK 2017 Report*, 28 July 2017