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PRESS RELEASE

European Commission Grants AbbVie's MAVIRET® (glecaprevir/pibrentasvir) Marketing Authorisation for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT1-6)

- *MAVIRET is a new 8-week, pan-genotypic treatment for adult hepatitis C patients without cirrhosis and who are new to treatment**
- *Marketing authorisation is supported by 97 percent cure** rate across this group of patients[1] (** patients who achieve a sustained virologic response at 12 weeks post treatment (SVR_{12}) are considered cured of hepatitis C)*
- *MAVIRET is a pan-genotypic treatment indicated for use in patients across all stages of chronic kidney disease[1]*
- *AbbVie's investigational, pan-genotypic HCV treatment is also under Priority Review by the U.S. FDA*

MAIDENHEAD, UK, July 28, 2017 – AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced that the European Commission has granted marketing authorisation for MAVIRET®, 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).

"Maviret represents a new 8-week pan-genotypic treatment option for adult patients without cirrhosis and who are new to treatment*, who comprise the majority of the estimated 214,000 people living with HCV in the UK. The treatment combines two distinct antiviral agents and has high efficacy against most HCV genotypes, including those commonly associated with resistance to treatment," said Dr Alice Butler, Medical Director, AbbVie UK.

Glecaprevir/pibrentasvir is also indicated 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.[1]

The marketing authorisation of glecaprevir/pibrentasvir is supported by data from eight registrational studies in AbbVie's clinical development programme, which evaluated more than 2,300 patients in 27 countries across all major HCV genotypes (GT1-6) and special populations.

"Maviret is an 8-week, pan-genotypic treatment for non-cirrhotic patients new to treatment with chronic hepatitis C that met all primary efficacy endpoints in its extensive HCV clinical trial programme, achieving high cure rates," said Stefan Zeuzem, M.D., chief of the department of medicine at the J.W.

AXHCV171055(1)
Date of preparation: July 2017

Goethe University Hospital in Frankfurt, Germany. “Maviret offers a new therapy for the majority of HCV patients and removes many complexities of pre-treatment patient evaluation.”

Authorisation is supported by 97 percent (n=807/828)[†] cure[**] rate with just 8 weeks of treatment in GT1-6 patients without cirrhosis and who were new to treatment.[1] This was achieved in patients with varied patient and viral characteristics and including those with CKD.[1] For compensated cirrhotic patients, a 98 percent (n=201/205)[‡] cure rate was achieved with 12 weeks of treatment.[1] For GT3 treatment-experienced patients with or without compensated cirrhosis, a 96 percent (n=66/69) cure rate was achieved with 16 weeks of treatment.[1] In registrational phase 2/3 studies (n=2,265) for glecaprevir/pibrentasvir, less than one percent of patients discontinued treatment due to adverse reactions.[1] The most commonly reported adverse reactions (incidence greater than or equal to 10 percent) were headache and fatigue.[1]

Glecaprevir/pibrentasvir combines two new, potent[§] direct-acting antivirals that target and inhibit proteins essential for the replication of the hepatitis C virus. The presence of most genotypes or baseline mutations that are commonly associated with resistance have been shown to have minimal impact on efficacy of glecaprevir/pibrentasvir.

The marketing authorisation of glecaprevir/pibrentasvir follows a review under accelerated assessment by the European Medicines Agency, which is granted to new medicines of major public health interest. AbbVie’s treatment is now licensed for use in all 28 member states of the European Union, as well as Iceland, Liechtenstein and Norway. AbbVie's investigational, pan-genotypic treatment has also been granted accelerated review designations by other regulatory authorities including the U.S. Food and Drug Administration and Japanese Ministry of Health, Labour and Welfare and is not yet approved in those countries.

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.

[*]Patients without cirrhosis and new to treatment [either treatment-naive or not cured with previous IFN-based treatments ([peg]IFN +/- RBV or SOF/RBV +/- pegIFN)].
[**]Patients who achieve a sustained virologic response at 12 weeks post treatment (SVR12) are considered cured of hepatitis C.
[†]Data were pooled from 8-week arms of the ENDURANCE-1 and 3, and SURVEYOR-2 studies.
[‡]Data were pooled from 12-wek GT3 treatment-naive, compensated cirrhotic arm of the SURVEYOR-2 and EXPEDITION-1 studies.
§ Based on EC50 values of glecaprevir and pibrentasvir against full-length or chimeric replicons encoding NS3 or NS5A from laboratory strains and chimeric replicons from clinical isolates.[1]

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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 and follow @abbvieuk on Twitter.

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[1] MAVIRET® tablets (glecaprevir/pibrentasvir) Summary of product characteristics. Maidenhead, UK. AbbVie, Ltd.
[2] Public Health England, Hepatitis C in the UK 2016 report