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PRESS RELEASE

Early Access to Medicines Scheme (EAMS) Granted to AbbVie's Investigational Pan-genotypic Regimen for Chronic Hepatitis C – the First EAMS in HCV

- *AbbVie's glecaprevir/pibrentasvir (G/P) is an investigational, pan-genotypic, ribavirin-free regimen being evaluated by the European Medicine's Agency as a cure for hepatitis C virus (HCV) infection in patients across all genotypes (GT)* [1,2]
- *It is the first treatment for HCV to be made available through the Early Access to Medicines Scheme (EAMS)*[3,4]

Maidenhead, UK, 10 May, 2017 – AbbVie, a global biopharmaceutical company, today announced that the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has granted glecaprevir/pibrentasvir (G/P), it's investigational, pan-genotypic, ribavirin-free regimen, a positive scientific opinion through the Early Access to Medicines Scheme (EAMS). The decision means that the following patients may now potentially gain access to G/P while the relevant regulatory bodies continue to review the Marketing Authorisation Application:

Adults with compensated cirrhosis and at least one of the following:
- GT 1, 4, 5 or 6 infection and prior treatment with an NS5A inhibitor
- GT 2, 3, 5 or 6 infection and chronic kidney disease stage 4 or 5
- GT 3 infection previously treated with peg-interferon, ribavirin and/or sofosbuvir

An estimated 214,000 [5] people in the UK are thought to be infected with the hepatitis C virus and, although now curable, without treatment people with HCV can develop potentially fatal liver cancer or end stage liver disease[5].

The aim of EAMS is to provide access to promising innovative medicines for UK patients prior to marketing authorisation, where there is a clear unmet clinical need. Post-marketing authorisation, EAMS products that undergo a National Institute of Health and Care Excellence (NICE) Health Technology Appraisal, and are found to be cost-effective, are then commissioned by NHS England within 30 days of the NICE guidance, rather than the standard three months.[6]

"AbbVie is committed to helping eliminate HCV and so we are delighted to receive the EAMS positive scientific opinion, which will help ensure that eligible patients with limited current treatment options gain access to this therapy as soon as possible," says Dr Alice Butler, Medical Director, AbbVie UK. "AbbVie is proud to have entered into the voluntary EAMS and today's positive announcement marks another important step for patients with HCV."

G/P is a once-daily regimen that combines two distinct antiviral agents. G/P is a fixed-dose combination of glecaprevir (300mg), an NS3/4A protease inhibitor, and pibrentasvir (120mg), an NS5A inhibitor, dosed once-daily as three oral tablets.

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.

Glecaprevir/pibrentasvir is currently under review by the European Medicines Agency (EMA).

***Patients who are treatment-naive or had prior treatment experience with IFN-based treatments ([peg]IFN +/- RBV or SOF/RBV +/- pegIFN).*

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 approximately 29,000 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.

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

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[1] Foster, GR et al. ENDURANCE-3: safety and efficacy of glecaprevir/pibrentasvir compared to sofosbuvir plus daclatasvir in treatment-naïve HCV genotype 3-infected patients without cirrhosis. Presented at The International Liver Congress™ (ILC) in Amsterdam, The Netherlands, April 19-23, 2017

[2] Forns, X et al. EXPEDITION-1: Efficacy and Safety of Glecaprevir/Pibrentasvir in Adults with Chronic Hepatitis C Virus Genotype 1, 2, 4, 5 or 6 Infection and Compensated Cirrhosis. Presented at The International Liver Congress™ (ILC) in Amsterdam, The Netherlands, April 19-23, 2017

[3] UK Government. Early access to medicines scheme (EAMS): scientific opinions. Available at: https://www.gov.uk/government/collections/early-access-to-medicines-scheme-eams-scientific-opinions. Accessed April 2017

[4] UK Government. Expired early access to medicines scheme scientific opinions. Available at: https://www.gov.uk/government/publications/early-access-to-medicines-scheme-expired-scientific-opinions/expired-early-access-to-medicines-scheme-scientific-opinions. Accessed April 2017

[5] Public Health England, Hepatitis C in the UK, July 2016

[6] NICE Centre for Health Technology Evaluation, Note to describe procedures at NICE to support the Early Access to Medicines Scheme, Introduction to the Early Access to Medicines Scheme, January 2016, https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/eams-process-jan-16.pdf, Accessed April 2017

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