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

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- *MAVIRET is a new, 8-week, pan-genotypic treatment for hepatitis C patients without cirrhosis and who are new to treatment **
- *Marketing authorization is supported by a 97.5 percent cure** rate across this group of patients[1]*
- *MAVIRET is approved for use in HCV patients who also have chronic kidney disease[1]*
- *Glecaprevir, one of the two new direct-acting antivirals (DAAs) in MAVIRET, is Enanta's second protease inhibitor being developed and commercialized by AbbVie*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jul. 28, 2017-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, today announced that the European Commission (EC) has granted AbbVie marketing authorization for MAVIRET® (glecaprevir/pibrentasvir), a once-daily, ribavirin-free treatment for adults with chronic hepatitis C virus (HCV) infection across all major genotypes (GT1-6). MAVIRET is a new, 8-week, pan-genotypic treatment for patients without cirrhosis and new to treatment*, who comprise the majority of the estimated 71 million people worldwide living with HCV.[2,3]

MAVIRET is also indicated for patients with specific treatment challenges, including those with compensated cirrhosis across all major HCV genotypes, and those who previously had limited treatment options, such as patients with severe chronic kidney disease (CKD) or those with genotype 3 chronic HCV infection.[1] MAVIRET is the only pan-genotypic treatment approved for use in patients across all stages of CKD.[1]

Following this marketing authorization of MAVIRET in the European Union (E.U.), Enanta expects to receive a $25 million milestone payment from AbbVie.

"This authorization means that MAVIRET now has the opportunity to address the majority of HCV patients in Europe with a simple, pan-genotypic, 8-week treatment option, and is also approved for use in patients across all stages of CKD," stated Jay R. Luly, Ph.D., President and CEO, Enanta. "We are thrilled to have our second protease inhibitor approved and be part of this exciting new HCV regimen."

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

EC authorization is supported by data from AbbVie's registrational studies showing a combined 97.5 percent (n=779/799)† cure** rate with just 8 weeks of treatment in GT1-6 patients without cirrhosis and new to treatment.[1] This high cure rate 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 studies for MAVIRET, less than 0.1 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]

MAVIRET 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 the efficacy of MAVIRET.

EC authorization follows the European Medicines Agency's review of MAVIRET under accelerated assessment, which is granted to new medicines of major public health interest. AbbVie's MAVIRET treatment is now licensed for use in all 28 member states of the E.U., as well as Iceland, Liechtenstein and Norway. AbbVie's investigational, pan-genotypic regimen has also been granted accelerated review designations by other regulatory authorities, including the U.S. Food and Drug Administration and the Japanese Ministry of Health, Labour and Welfare.

*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-week 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]

About MAVIRET® (glecaprevir/pibrentasvir)
MAVIRET® is approved in the European Union for the treatment of chronic hepatitis C virus (HCV) infection in adults across all major genotypes (GT1-6). MAVIRET is a pan-genotypic, once-daily, ribavirin-free treatment that combines glecaprevir (100mg), an NS3/4A protease inhibitor, and pibrentasvir (40mg), an NS5A inhibitor, dosed once-daily as three oral tablets.

MAVIRET is an 8-week, pan-genotypic option for patients without cirrhosis and new to treatment*, who comprise the majority of people living with HCV. MAVIRET is also approved as a treatment 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 chronic HCV infection. MAVIRET is a pan-genotypic treatment approved for use in patients across all stages of CKD.

EU Indication
MAVIRET is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults.

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, and 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.

About Enanta
Enanta Pharmaceuticals is a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs for viral infections and liver diseases. Enanta's research and development efforts are currently focused on the following disease targets: non-alcoholic steatohepatitis (NASH)/ primary biliary cholangitis (PBC), respiratory syncytial virus (RSV) and hepatitis B virus (HBV). Enanta has also discovered novel protease inhibitors that have been developed as part of AbbVie's hepatitis C virus (HCV) treatment regimens under a collaboration that now provides Enanta a payment stream, which it is using to fund its research and development programs. Please visit www.enanta.com for more information on Enanta's programs and pipeline.

FORWARD LOOKING STATEMENTS
This press release contains forward-looking statements, including statements with respect to the prospects for commercialization of MAVIRET in the E.U. and the prospects for commercialization regulatory approval for MAVIRET in other jurisdictions. Statements that are not historical facts are based on management's current expectations, estimates, forecasts and projections about Enanta's business and the industry in which it operates and management's beliefs and assumptions. The statements contained in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors and risks that may affect actual results include: the efforts of AbbVie (our collaborator developing MAVIRET) to commercialize MAVIRET successfully in the E.U. and to obtain regulatory approvals of the glecaprevir/pibrentasvir (G/P) combination and commercialize it successfully in other jurisdictions; the regulatory and marketing efforts of others with respect to competitive treatment regimens for HCV; regulatory and reimbursement actions affecting MAVIRET, any competitive regimen, or both; the need to obtain and maintain patent protection for glecaprevir and avoid potential infringement of the intellectual property rights of others; and other risk factors described or referred to in "Risk Factors" in Enanta's most recent Form 10-K for the fiscal year ended September 30, 2016 and other periodic reports filed more recently with the Securities and Exchange Commission. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this release, and Enanta undertakes no obligation to update or revise these statements, except as may be required by law.

[1] MAVIRET® tablets (glecaprevir/pibrentasvir) Summary of product characteristics. Maidenhead, UK. AbbVie, Ltd.
[2]Decisions Resources Group. Hepatitis C virus: disease landscape & forecast 2016. January 2017.
[3]World Health Organization. Global Hepatitis Report 2017. http://apps.who.int/iris/bitstream/10665/255016/1/9789241565455-eng.pdf?ua=1.

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