



Enanta Pharmaceuticals Announces U.S. Regulatory Approval of TECHNIVIE™ (ombitasvir, paritaprevir and ritonavir) tablets

July 24, 2015

[Download this Press Release](#)

The First and Only All-Oral Interferon-Free Treatment for Genotype 4 Chronic Hepatitis C in the U.S.

- Approval is supported by data from the PEARL-I study, which demonstrated 100 percent sustained virologic response rate at 12 weeks post-treatment (SVR₁₂) in Genotype 4 HCV patients who received TECHNIVIE and ribavirin for 12 weeks
- All-oral, two-direct-acting antiviral, interferon-free treatment regimen contains paritaprevir, Enanta's lead protease inhibitor

WATERTOWN, Mass.--(BUSINESS WIRE)--Jul. 24, 2015-- 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 U.S. Food and Drug Administration (FDA) approved AbbVie's TECHNIVIE™ (ombitasvir, paritaprevir and ritonavir) tablets in combination with ribavirin (RBV) for the treatment of non-cirrhotic adults with genotype 4 (GT4) chronic hepatitis C virus (HCV) infection. TECHNIVIE is the first and only all-oral, interferon-free, direct-acting antiviral treatment approved in the U.S. for adult patients with GT4 chronic HCV infection.

"The approval of TECHNIVIE is an important advancement in the care of patients with genotype 4 HCV," commented Jay R. Luly, President and CEO. "These difficult-to-treat patients now have a treatment option with high cure rates available to them and we are proud to have paritaprevir be part of this regimen."

Paritaprevir is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and is one of the two direct-acting antivirals (2-DAA) in AbbVie's TECHNIVIE. Forty five percent of AbbVie's worldwide net sales of the 2-DAA regimen will be included in the paritaprevir net sales on which Enanta is eligible to receive annually tiered royalties, ranging from the low double digits up to twenty percent. AbbVie is responsible for all worldwide development and commercialization of TECHNIVIE and other HCV treatment regimens. Paritaprevir/ritonavir and ombitasvir, AbbVie's NS5A inhibitor, are also included in AbbVie's VIEKIRA PAK™, which was approved in the U.S. in late 2014 for patients with GT1 HCV infection.

The Centers for Disease Control and Prevention (CDC) estimates that 2.7 million people have chronic HCV infection in the U.S.¹ There are six major HCV genotypes (GT1-6). While genotype 1 (GT1) is the most prevalent form of HCV in the U.S., accounting for approximately 74 percent of all cases², GT4 infection is estimated to account for approximately 1.1 percent of HCV infections in the U.S.³

About the PEARL-I Study

This approval of TECHNIVIE is based on data from the PEARL-I study, which demonstrated 100 percent sustained virologic response rates at 12 weeks post-treatment (SVR₁₂) in patients who received TECHNIVIE and RBV for 12 weeks. PEARL-I is an open-label Phase 2b study that evaluated the efficacy and safety of TECHNIVIE in GT4 chronic HCV patients without cirrhosis. The study included GT4 patients who were new to therapy (n=42/42) or who had failed previous treatment with pegylated interferon (pegIFN) and RBV (n=49/49). Additionally, 91 percent of patients who were new to therapy achieved SVR₁₂ (n=40/44) after taking TECHNIVIE without RBV. In the treatment-naïve group without RBV, on-treatment virologic breakthrough was reported in one patient (two percent), and two patients (five percent) experienced post-treatment relapse. There were no virologic failures in the other treatment arms.

There were no discontinuations due to adverse events in these patients. The most commonly reported treatment-emergent adverse events (greater than 10 percent in any group) observed in patients receiving TECHNIVIE or TECHNIVIE with RBV, respectively, were asthenia (weakness) (25-29 percent), fatigue (7-15 percent), nausea (9-14 percent) and insomnia (5-13 percent). Four patients who received TECHNIVIE with RBV experienced decreased hemoglobin (anemia) which required RBV dose reductions; however, none of these patients required blood transfusions or medication to boost their red blood cell production. All patients treated with TECHNIVIE and RBV achieved SVR₁₂.

About TECHNIVIE

TECHNIVIE is an all-oral antiviral treatment consisting of the fixed-dose combination of paritaprevir/ritonavir (150/100mg) co-formulated with ombitasvir (25mg) dosed once daily and taken with a meal, which is co-administered with weight-based RBV (1000mg or 1200mg in divided doses, twice daily), taken with food. The combination of two direct-acting antivirals, each with distinct mechanisms of action, targets and inhibits specific HCV proteins in the viral replication process.

Important Safety Information⁴

USE

TECHNIVIE™ (ombitasvir, paritaprevir, and ritonavir) tablets is a prescription medicine used with ribavirin to treat adults with genotype 4 chronic (lasting a long time) hepatitis C (hep C) virus infection without cirrhosis.

TECHNIVIE is not for people with certain types of liver problems.

IMPORTANT SAFETY INFORMATION

TECHNIVIE is taken in combination with ribavirin. People should read the Medication Guide that comes with ribavirin, especially the important pregnancy information.

What is the most important information to know about TECHNIVIE?

- TECHNIVIE can cause increases in liver function blood test results, especially if people use ethinyl estradiol-containing medicines (such as some birth control products).
- Ethinyl estradiol-containing medicines (combination birth control pills or patches, such as Lo Loestrin® FE, Norinyl®, Ortho Tri-Cyclen Lo®, Ortho Evra®; hormonal vaginal rings such as NuvaRing®; and the hormone replacement therapy medicine, Fem HRT®) must be stopped before starting treatment with TECHNIVIE. If these medicines are used as a method of birth control, another method must be used during treatment with TECHNIVIE, and for about 2 weeks after treatment with TECHNIVIE ends. A doctor can provide instruction on when to begin taking ethinyl estradiol-containing medicines.
- A doctor should do blood tests to check liver function during the first 4 weeks of treatment and then as needed.
- A doctor may tell people to stop taking TECHNIVIE if signs or symptoms of liver problems develop. A doctor must be notified right away if any of the following symptoms develop or if they worsen during treatment with TECHNIVIE: tiredness, weakness, loss of appetite, nausea, vomiting, yellowing of the skin or eyes, or color changes in stools.

TECHNIVIE must not be taken if people:

- **have severe liver problems**
- **take any of the following medicines:** alfuzosin hydrochloride (Uroxatral®) • carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®) • efavirenz (Sustiva®, Atripla®) • ergot containing medicines, including ergotamine tartrate (Cafergot®, Migergot®, Ergomar®, Ergostat®, Medihaler®, Wigraine®, Wigrettes®), dihydroergotamine mesylate (D.H.E. 45®, Migranal®), methylergonovine (Ergotrate®, Methergine®) • ethinyl estradiol-containing medicines • lovastatin (Advicor®, Altoprev®, Mevacor®) • midazolam (when taken by mouth) • phenytoin (Dilantin®, Phenytek®) • phenobarbital (Luminal®) • pimozone (Orap®) • rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®) • sildenafil citrate (Revatio®), when taken for pulmonary artery hypertension (PAH) • simvastatin (Zocor®, Vytorin®, Simcor®) • St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort • triazolam (Halcion®)
- **have had a severe skin rash after taking ritonavir (Norvir®)**

Before taking TECHNIVIE people should tell a doctor about all their medical conditions, including:

- if they have liver problems other than hep C infection or have HIV infection.
- if they have had a liver transplant. If they take the medicines tacrolimus (Prograf®) or cyclosporine (Gengraf®, Neoral®, Sandimmune®), a doctor should check blood levels and, if needed, may change the dose of these medicines or how often they are taken, both during and after treatment with TECHNIVIE.
- if they are pregnant or plan to become pregnant or if they are breastfeeding or plan to breastfeed. It is not known if TECHNIVIE will harm a person's unborn baby or pass into breast milk. A doctor should be consulted about the best way to feed a baby if taking TECHNIVIE.
- **all the medicines they take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with TECHNIVIE.
 - **a new medicine must not be started without telling a doctor.** A doctor will provide instruction on whether it is safe to take TECHNIVIE with other medicines.
 - when TECHNIVIE is finished, a doctor should be consulted on what to do if one of the usual medicines taken was stopped or if the dose changed during TECHNIVIE treatment.

What are the common side effects of TECHNIVIE?

TECHNIVIE with ribavirin side effects include feeling weak, tiredness, nausea, and sleep problems. These are not all of the possible side effects of TECHNIVIE. A doctor should be notified if there is any side effect that is bothersome or that does not go away.

This is the most important information to know about TECHNIVIE. For more information, talk with a doctor.

People are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For full Prescribing Information, click here or visit rxabbvie.com/pdf/technivie_pi.pdf.

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 is discovering, and in some cases developing, novel inhibitors designed for use against the hepatitis C virus (HCV). These inhibitors include members of the direct acting antiviral (DAA) inhibitor classes – protease (partnered with AbbVie), NS5A, and nucleotide polymerase – as well as a host-targeted antiviral (HTA) inhibitor class targeted against cyclophilin. Enanta's lead protease inhibitor, paritaprevir, is part of AbbVie's recently approved HCV treatment regimens. In addition, Enanta has a preclinical program in non-alcoholic steatohepatitis, or NASH, which is a condition that results in liver inflammation and damage caused by a buildup of fat in the liver.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including with respect to the prospects for AbbVie's TECHNIVIE. Statements that are not historical facts are based on our management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our 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 that may affect actual results include the efforts of AbbVie (our collaborator on paritaprevir) regarding commercialization of TECHNIVIE; the level of market acceptance and the pricing and rate of reimbursement for TECHNIVIE; the impact of competitive products on the use and sales of TECHNIVIE; 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, 2014 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.

¹Centers for Disease Control and Prevention. Hepatitis C FAQs for Health Professionals. Centers for Disease Control and Prevention website. <http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>.

² O'Leary JG, Davis GL. Hepatitis C. In: Feldman M, Friedman LS, Brandt LJ, eds. Sleisenger and Fordtran's Gastrointestinal and Liver Disease: Pathophysiology/Diagnosis/Management. 9th ed, Vol 1. Philadelphia, PA: Saunders Elsevier.2010:1313-1335

³ Manos MM, Shvachko VA, Murphy RC, et al. Distribution of hepatitis C virus genotypes in a diverse US integrated healthcare population. J Med Virol. 2012 Nov; 84(11):1744-50.

⁴ TECHNIVIE [package insert]. North Chicago, IL: AbbVie Inc.



View source version on businesswire.com: <http://www.businesswire.com/news/home/20150724005749/en/>

Source: Enanta Pharmaceuticals, Inc.

Investor Contact

Enanta Pharmaceuticals, Inc.

Carol Miceli, 617-607-0710

cmiceli@enanta.com

or

MacDougall Biomedical Communications

Media Contact

Kari Watson, 781-235-3060

kwatson@macbiocom.com