



Enanta Announces U.S. Food and Drug Administration Approves AbbVie's VIEKIRA PAK™ (Ombitasvir/Paritaprevir/Ritonavir Tablets; Dasabuvir Tablets) for the Treatment of Chronic Genotype 1 Hepatitis C Virus

December 19, 2014

[Download this Press Release](#)

- VIEKIRA PAK regimen contains Enanta's lead protease inhibitor, paritaprevir (formerly ABT-450)
- In Phase 3 clinical trials, VIEKIRA PAK cured 95-100 percent of hepatitis C patients, with less than two percent of patients experiencing virological failure
- Tolerability profile shows more than 98 percent of patients completed a full course of therapy
- All oral interferon-free regimen approved for HCV/HIV-1 co-infection and patients who have undergone a liver transplant

WATERTOWN, Mass.--(BUSINESS WIRE)--Dec. 19, 2014-- Enanta Pharmaceuticals, Inc., (NASDAQ: ENTA) a research and development-focused biotechnology company dedicated to creating small molecule drugs primarily in the infectious disease field, today announced the U.S. Food and Drug Administration (FDA) has approved AbbVie's VIEKIRA PAK™ (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets) with or without ribavirin for the treatment of genotype 1 (GT1) patients with chronic hepatitis C virus (HCV) infection, including those with compensated cirrhosis.

Paritaprevir (formerly known as ABT-450) is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and is one of three direct-acting antivirals (DAAs) in the VIEKIRA PAK regimen. AbbVie is responsible for all worldwide development and commercialization of VIEKIRA PAK and other regimens containing paritaprevir. The U.S. approval of VIEKIRA PAK triggers a \$75 million regulatory approval milestone payment to Enanta from AbbVie.

"Enanta is proud to have paritaprevir be part of such an important medicine for the treatment of HCV," stated Jay R. Luly, Ph.D., President and CEO. "This important achievement will fuel and energize Enanta's continued pursuit of drugs to treat infectious diseases where there is significant medical need."

The approval of VIEKIRA PAK is supported by a robust clinical development program conducted by AbbVie and designed to study the safety and efficacy of the regimen in more than 2,300 enrolled patients across 25 countries. The program consisted of six pivotal Phase 3 studies, which demonstrated that VIEKIRA PAK cured 95-100 percent of GT1a and GT1b hepatitis C patients, including patients new and experienced to treatment, and patients with compensated cirrhosis, with less than two percent of patients experiencing virological failure. Additionally, more than 98 percent of patients in clinical trials completed a full course of therapy.

VIEKIRA PAK's approval is also based on the results from Phase 2 clinical trials evaluating tougher-to-cure patient populations, which showed that VIEKIRA PAK cured 97 percent of liver transplant recipients with HCV and 92 percent of patients co-infected with HCV/HIV-1. Patients who achieve a sustained virologic response (SVR₁₂) are considered cured of HCV.

VIEKIRA PAK was granted priority review and designated as a Breakthrough Therapy by the U.S. FDA, a status given to medicines or regimens that may offer substantial improvement over available therapies.

About VIEKIRA PAK™

VIEKIRA PAK™ (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets) has been studied in a broad range of genotype 1 (GT1) patients with chronic hepatitis C virus (HCV) infection, ranging from treatment-naïve to some of the most difficult to treat, such as patients with compensated (mild, Child-Pugh A) cirrhosis of the liver, HCV/HIV-1 co-infection, liver transplant recipients with normal hepatic function and mild fibrosis, and those who have failed previous treatment with pegylated interferon (pegIFN) and ribavirin (RBV). VIEKIRA PAK is not recommended in patients with moderate hepatic impairment (Child-Pugh B), and is contraindicated in patients with severe hepatic impairment (Child-Pugh C). VIEKIRA PAK consists of the fixed-dose combination of ombitasvir 25mg (an NS5A inhibitor), paritaprevir 150mg (an NS3/4A protease inhibitor), and ritonavir 100mg (an approved HIV-1 protease inhibitor), dosed once daily with a meal, and dasabuvir 250mg (a non-nucleoside NS5B polymerase inhibitor), dosed twice daily with a meal. VIEKIRA PAK is taken for 12 weeks, except in patients with genotype 1a and cirrhosis, who should take it for 24 weeks. Ribavirin should be co-administered in GT1a patients, and in all patients who have cirrhosis or who have received a liver transplant.

Full Prescribing Information, including the Medication Guide, can be found [here](#).

Use and Important Safety Information from AbbVie

USE

VIEKIRA PAK™ (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) is a prescription medicine used with or without ribavirin to treat adults with genotype 1 chronic (lasting a long time) hepatitis C virus (HCV) infection, including people who have a certain type of cirrhosis (compensated).

VIEKIRA PAK is not for people with advanced cirrhosis (decompensated). If people have cirrhosis, they should talk to a healthcare provider before

taking VIEKIRA PAK.

IMPORTANT SAFETY INFORMATION

When taking VIEKIRA PAK in combination with ribavirin, people should also read the Medication Guide that comes with ribavirin, especially the important pregnancy information.

What is the most important information to know about VIEKIRA PAK?

VIEKIRA PAK 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 VIEKIRA PAK. If these medicines are used as a method of birth control, another method must be used during treatment with VIEKIRA PAK, and for about 2 weeks after treatment with VIEKIRA PAK ends. A healthcare provider can provide instruction on when to begin taking ethinyl estradiol-containing medicines.
- A healthcare provider should do blood tests to check liver function during the first 4 weeks of treatment and then as needed.
- A healthcare provider may tell people to stop taking VIEKIRA PAK if signs or symptoms of liver problems develop. A healthcare provider must be notified right away if any of the following symptoms develop or if they worsen during treatment with VIEKIRA PAK: tiredness, weakness, loss of appetite, nausea, vomiting, yellowing of the skin or eyes, or color changes in stools.

VIEKIRA PAK must not be taken if people:

- have severe liver problems
- take any of the following medicines: alfuzosin hydrochloride (Uroxatral®) • carbamazepine (Carbatrol®, Eptol®, 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 • gemfibrozil (Lopid®) • 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®)

What should people tell a healthcare provider before taking VIEKIRA PAK?

- If they have: liver problems other than HCV infection, HIV infection, or any other medical conditions.
- If they have had a liver transplant. If they take the medicines tacrolimus (Prograf®) or cyclosporine (Gengraf®, Neoral®, Sandimmune®), a healthcare provider 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 VIEKIRA PAK.
- If they are pregnant or plan to become pregnant or if they are breastfeeding or plan to breastfeed. It is not known if VIEKIRA PAK will harm a person's unborn baby or pass into breast milk. A healthcare provider should be consulted about the best way to feed a baby if taking VIEKIRA PAK. For pregnant females that have both HCV and HIV infection, they should talk with a healthcare provider about enrolling in the antiretroviral pregnancy registry.
- About all the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with VIEKIRA PAK.
- A new medicine must not be started without telling a healthcare provider. A healthcare provider will provide instruction on whether it is safe to take VIEKIRA PAK with other medicines.
- When VIEKIRA PAK is finished, a healthcare provider should be consulted on what to do if one of the usual medicines taken was stopped or if the dose changed during VIEKIRA PAK treatment.

What are the common side effects of VIEKIRA PAK?

- For VIEKIRA PAK used with ribavirin, side effects include tiredness, nausea, itching, skin reactions such as redness or rash, sleep problems, and feeling weak.

- For VIEKIRA PAK used without ribavirin, side effects include nausea, itching, and sleep problems.

These are not all of the possible side effects of VIEKIRA PAK. A healthcare provider 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 VIEKIRA. For more information, talk with a healthcare provider.

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.

Protease Inhibitor Collaboration with AbbVie

In December 2006, Enanta and Abbott announced a worldwide agreement to collaborate on the discovery, development and commercialization of HCV NS3 and NS3/4A protease inhibitors and HCV- protease-inhibitor-containing drug combinations. Paritaprevir (ABT-450) and ABT-493 are protease inhibitors identified through the collaboration. Under the agreement, AbbVie is responsible for all development and commercialization activities for the collaboration's lead compound, paritaprevir, as well as ABT-493, the collaboration's next-generation protease inhibitor.

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 primarily in the infectious disease field. 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.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including with respect to the prospects for milestone and royalty payments to Enanta related to AbbVie's paritaprevir-containing VIEKIRA PAK and Enanta's prospects for its continued pursuit of other potential drugs. 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 commercialization efforts of AbbVie (our collaborator on paritaprevir) regarding VIEKIRA PAK and other treatment regimens containing paritaprevir, market acceptance of those regimens, the impact of competitive products on the use and sales of those regimens, and regulatory actions affecting clinical development of paritaprevir and clinical development of competitive product candidates outside of the United States. 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.

Source: Enanta Pharmaceuticals, Inc.

Investor Contact

Enanta Pharmaceuticals, Inc.
Carol Miceli, 617-607-0710
cmiceli@enanta.com

or

Media Contact

MacDougall Biomedical Communications
Kari Watson, 781-235-3060
kwatson@macbiocom.com