



Enanta Announces the U.S. Food and Drug Administration has approved AbbVie's New, Once-Daily VIEKIRA XR™ (dasabuvir, ombitasvir, paritaprevir and ritonavir) for the Treatment of Genotype 1 Chronic Hepatitis C Virus

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- *New once-daily, extended-release co-formulation contains the three direct-acting antiviral components of VIEKIRA PAK® for adult patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection*
- *Paritaprevir is Enanta's lead protease inhibitor and one of the three direct-acting antivirals in VIEKIRA XR*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jul. 25, 2016-- 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) has approved AbbVie's New Drug Application (NDA) for VIEKIRA XR™ (dasabuvir, ombitasvir, paritaprevir and ritonavir) extended release tablets. VIEKIRA XR is a once-daily, extended-release co-formulation of the active ingredients in VIEKIRA PAK® (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) and is for the treatment of patients with chronic genotype 1 (GT1) hepatitis C virus (HCV) infection, including those with compensated cirrhosis (Child-Pugh A). VIEKIRA XR is not for HCV patients with decompensated cirrhosis.

Paritaprevir is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and is one of the three direct-acting antivirals in AbbVie's VIEKIRA XR™.

VIEKIRA XR is the first co-formulated, three-direct-acting-antiviral (DAA) treatment for adult patients with GT1 HCV. VIEKIRA XR is given once-daily as three oral tablets and must be taken with a meal. It is used without ribavirin (RBV) in GT1b patients and in combination with twice daily RBV in GT1a patients. The approval is supported by Phase 3 clinical trials for VIEKIRA PAK which include data that demonstrated 100 percent sustained virologic response 12 weeks following treatment (SVR₁₂) in GT1b patients with 12 weeks of therapy without ribavirin and 95 percent SVR₁₂ in GT1a patients when used with ribavirin for 12 or 24 weeks of therapy.

"Our collaborative partner AbbVie has made great progress in developing new treatments for patients living with HCV and we are pleased to see FDA approval of this new, once-daily formulation of the active ingredients in VIEKIRA PAK," commented Jay R. Luly, Ph.D., President and CEO.

There are six major HCV genotypes (GT1-6), with GT1 being the most prevalent form of HCV in the U.S., accounting for approximately 74 percent of all cases.¹ Hepatitis C continues to be an important public health issue, with The Centers for Disease Control and Prevention (CDC) estimating that in the U.S. approximately 2.7-3.9 million people are chronically infected with HCV.²

The approval of VIEKIRA XR is supported by data from seven Phase 3 clinical trials in more than 2,300 patients who received VIEKIRA PAK with or without RBV for 12 or 24 weeks and two bioavailability studies comparing the two formulations.

About Clinical Studies

The components of VIEKIRA XR (administered twice daily with a meal) have been studied in seven Phase 3 clinical trials where 1076 subjects (including 181 with compensated cirrhosis) received the recommended regimen of VIEKIRA +/- RBV for 12 weeks, or for 24 weeks in GT1a patients with compensated cirrhosis. 95 to 100 percent achieved SVR₁₂, which means the hepatitis C virus is not detectable in the blood three months after treatment ends. Cure rates varied by the subtype of hepatitis C and whether or not the person had cirrhosis. Individual results may vary.

About VIEKIRA XR

The components of VIEKIRA XR* have been studied in a broad range of genotype 1 (GT1) patients with chronic hepatitis C virus (HCV) infection, ranging from treatment-naïve to difficult-to-treat patients, such as those with compensated (mild, Child-Pugh A) cirrhosis of the liver or 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 XR, the extended-release co-formulation of the components of VIEKIRA PAK, , consists of 200 mg of dasabuvir, 8.33 mg of ombitasvir, 50 mg of paritaprevir, and 33.33 mg of ritonavir per tablet, and is dosed three tablets once daily. VIEKIRA XR must be taken with a meal, and tablets should be swallowed whole. People should not drink alcohol within four hours of taking VIEKIRA XR. VIEKIRA XR is contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B and C) due to risk of potential toxicity. VIEKIRA XR is taken for 12 weeks, except in GT1a patients with cirrhosis and all liver transplant recipients with normal hepatic function and mild fibrosis, who should take it for 24 weeks. Ribavirin should be co-administered in GT1a patients and in all patients who have received a liver transplant.

*Given as a fixed-dose combination of ombitasvir 25mg (an NS5A inhibitor), paritaprevir 150mg (an NS3/4A protease inhibitor), and ritonavir 100mg (an HIV-1 protease inhibitor), dosed once daily with a meal, and dasabuvir 250mg (a non-nucleoside NS5B palm polymerase inhibitor), dosed twice daily with a meal.

USE

VIEKIRA XR™ (dasabuvir, ombitasvir, paritaprevir, and ritonavir) extended-release tablets/VIEKIRA PAK® (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) (VIEKIRA) are prescription medicines used with or without ribavirin to treat adults with genotype 1 chronic (lasting a long

time) hepatitis C (hep C) virus infection.

VIEKIRA can be used in people who have compensated cirrhosis.

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

IMPORTANT SAFETY INFORMATION

When taking VIEKIRA 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 VIEKIRA?

- VIEKIRA may cause severe liver problems, especially in people with certain types of cirrhosis. These severe liver problems can lead to the need for a liver transplant, or can lead to death.
- VIEKIRA 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. If these medicines are used as a method of birth control, another method must be used during treatment with VIEKIRA, and for about 2 weeks after treatment with VIEKIRA 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 VIEKIRA 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 VIEKIRA: tiredness, weakness, loss of appetite, nausea, vomiting, yellowing of the skin or eyes, color changes in stools, confusion, or swelling of the stomach area.

VIEKIRA must not be taken if people:

- have certain liver problems
- take any of the following medicines: alfuzosin hydrochloride (Uroxatral®) • carbamazepine (Carbatrol®, Eptol®, Equetro®, Tegretol®, TEGRETOL®-XR, TERIL®) • cisapride (Propulsid®)
- colchicine (Colcris®), in patients who have certain kidney or liver problems • dronedarone (Multaq®) • efavirenz (Atripla®, Sustiva®) • ergot-containing medicines, including ergotamine tartrate (Cafergot®, Ergomar®, Ergostat®, Medihaler®, Migergot®, Wigraine®, Wigrettes®), dihydroergotamine mesylate (D.H.E. 45®, Migranal®), methylethergonovine (Ergotrate®, Methergine®) • ethinyl estradiol-containing medicines • gemfibrozil (Lopid®) • lovastatin (Advicor®, Altoprev®, Mevacor®) • lurasidone (Latuda®) • midazolam (when taken by mouth) • phenytoin (Dilantin®, Phenytek®) • phenobarbital (Luminal®) • pimozone (Orap®) • ranolazine (Ranexa®) • rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®) • sildenafil citrate (Revatio®), when taken for pulmonary artery hypertension (PAH) • simvastatin (Simcor®, Vytorin®, Zocor®) • 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 doctor before taking VIEKIRA?

- If they have: liver problems other than hep C 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 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 VIEKIRA.
- If they are pregnant or plan to become pregnant or if they are breastfeeding or plan to breastfeed. It is not known if VIEKIRA 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 VIEKIRA.
- About all the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with VIEKIRA.
- A new medicine must not be started without telling a doctor. A doctor will provide instruction on whether it is safe to take VIEKIRA with other medicines.
- When VIEKIRA 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 VIEKIRA treatment.

What are the common side effects of VIEKIRA?

- For VIEKIRA used with ribavirin, side effects include tiredness, nausea, itching, skin reactions such as redness or rash, sleep problems, and feeling weak.
- For VIEKIRA used without ribavirin, side effects include nausea, itching, and sleep problems.

These are not all of the possible side effects of VIEKIRA. 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 VIEKIRA. For more information, talk to 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.

Please see VIEKIRA XR full Prescribing Information, including the Medication Guide.

Please see VIEKIRA PAK full Prescribing Information, including the Medication Guide.

Protease Inhibitor Collaboration with AbbVie (formerly the research-based pharmaceutical business of Abbott Laboratories)

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 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 second protease inhibitor. Enanta is eligible to receive annually tiered, double-digit royalties on AbbVie's worldwide net sales allocable to each of the collaboration's protease inhibitor products and is eligible to receive up to \$80 million in commercial regulatory approval milestones for ABT-493.

About HCV

Hepatitis C is inflammation of the liver caused by an infection with the hepatitis C virus. It is transmitted when an infected person's blood enters the bloodstream of an uninfected person. The Centers for Disease Control (CDC) estimates that approximately 2.7-3.9 million people have chronic HCV infection in the U.S. There are six major HCV genotypes (GT1-6), with genotype 1 (GT1) as the most prevalent form in the U.S. It is estimated that of people infected with chronic HCV about 5 to 20 percent will go on to develop cirrhosis over a period of 20–30 years, and with HCV-related liver transplants on the rise, HCV is a critical public health issue. Presently, there is no vaccine to protect against HCV infection.

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 is currently focused on four disease targets: Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), Non-alcoholic Steatohepatitis (NASH) and Respiratory Syncytial Virus (RSV).

Enanta has developed direct-acting-antiviral (DAA) inhibitors designed for use against HCV. Enanta's protease inhibitors, developed through its collaboration with AbbVie, include paritaprevir, which is contained in AbbVie's marketed DAA regimens for HCV, and ABT-493, Enanta's second protease inhibitor, which AbbVie is developing in phase 3 studies in combination with ABT-530, AbbVie's NS5A inhibitor. Enanta has also discovered a cyclophilin inhibitor, EDP-494, a novel, host-targeting mechanism for HCV, which is now in phase 1 clinical development, and EDP-305, an FXR agonist, which Enanta plans to advance into clinical development for NASH later in 2016. In addition, Enanta has early lead candidates for HBV and RSV in preclinical testing. 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 VIEKIRA XR. 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 on paritaprevir that is marketing VIEKIRA XR) to commercialize VIEKIRA XR; the development, regulatory and marketing efforts of others with respect to competitive HCV treatment regimens; regulatory and reimbursement actions affecting VIEKIRA XR, any competitive regimen, or both; 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, 2015 and any 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.

¹Wedemeyer H. Hepatitis C. Chapter 80: In: Feldman M, Friedman LS, Brandt LJ, eds. Sleisenger and Fordtran's Gastrointestinal and Liver Disease. Vol 2. 10th ed. Philadelphia, PA: Saunders Elsevier; 2016.

²Centers for Disease Control and Prevention (CDC). Hepatitis C FAQs for health professionals. <http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>. Accessed July 11, 2016.

³AbbVie 2016 Impact by the Numbers. <http://www.abbvie.com/responsibility/home.html>



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