



Enanta Announces New Data on VIEKIRA PAK® (ombitasvir, paritaprevir, ritonavir tablets; dasabuvir tablets) in Patients with Chronic Hepatitis C Virus Infection With or Without Compensated Cirrhosis

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- *AbbVie's ongoing TOPAZ-II study evaluates long-term treatment outcomes in genotype 1a and genotype 1b chronic HCV patients with or without compensated cirrhosis*
- *Patients treated with VIEKIRA PAK, with or without ribavirin, achieved 95 percent sustained virologic response rates at 12 weeks post-treatment (SVR₁₂)*
- *VIEKIRA PAK contains Enanta's lead protease inhibitor, Paritaprevir*

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 14, 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 new data from AbbVie's ongoing Phase 3b TOPAZ-II study evaluating VIEKIRA PAK® (ombitasvir, paritaprevir, ritonavir tablets; dasabuvir tablets), taken with or without ribavirin (RBV), in adult patients with genotype 1a (GT1a) or genotype 1b (GT1b) chronic hepatitis C virus (HCV) infection.¹ Interim data show that 95 percent (n=586/615) of patients in the TOPAZ-II trial achieved a sustained virological response at 12 weeks post-treatment after 12 or 24 weeks of treatment, a secondary endpoint for the study.¹ These data were presented today at The Liver Meeting® 2015, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco.

Paritaprevir is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and is one of the three DAAs in AbbVie's VIEKIRA PAK.

The TOPAZ-II study, a multicenter trial in the U.S., evaluates the impact of SVR₁₂ on the progression of liver diseases over the course of five years in a diverse patient population, including GT1 HCV patients with or without cirrhosis and those who were treatment-naïve or pegylated interferon (pegIFN)/RBV treatment-experienced. Patients were treated with VIEKIRA PAK with or without RBV, according to the dosing recommendations found in the U.S. prescribing information.¹

VIEKIRA PAK with or without RBV is indicated for the treatment of patients with GT1 chronic HCV infection, including those with compensated cirrhosis (Child-Pugh A). VIEKIRA PAK is contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B and C) due to risk of potential toxicity.

About the TOPAZ-II Study

TOPAZ-II is an ongoing, single arm, open-label, Phase 3b multicenter study in the U.S. evaluating the safety and efficacy of 12 or 24 weeks of treatment with VIEKIRA PAK, with or without ribavirin, in treatment-naïve or pegIFN/RBV treatment-experienced, adult patients with GT1 chronic HCV infection with or without compensated cirrhosis.¹ Patients in the TOPAZ-II study will be followed up for a period of five years post-treatment to evaluate the long-term impact of SVR₁₂ on progression of liver disease.

The trial includes 615 patients, 115 (19 percent) with compensated cirrhosis and 500 (81 percent) without cirrhosis.¹ On-treatment virologic failure was experienced by 0.8 percent (n=5/615) of study patients, while 1.9 percent (n=11/590) experienced relapse. One percent (n=6/615) of patients prematurely discontinued treatment due to adverse events.¹ Four percent (n=25/615) experienced serious adverse events. Ribavirin dosage was reduced due to anemia in 30/474 (6.3 percent) patients or due to hemoglobin decreases in 20/474 (4.2 percent) patients who received RBV. The most commonly-reported adverse events (in ≥10 percent of patients) were fatigue, nausea, headache, pruritus and insomnia.¹

Genotype 1 subjects who were either treatment-naïve or previously treated with IFN or pegIFN/ RBV received VIEKIRA PAK. Subjects with GT1a and all GT1 subjects with compensated cirrhosis also received RBV. The treatment duration was 12 weeks for all subjects except GT1a subjects with compensated cirrhosis who received treatment for 24 weeks. Treatment for 12 weeks was considered for some of these patients based on prior treatment history.¹ The primary endpoint is the incidence of all-cause death, liver-related death, liver decompensation, liver transplantation, hepatocellular carcinoma, and the composite of any of the above outcomes observed during the post-treatment period. Key secondary endpoints included the percentage of subjects with SVR₁₂ (HCV undetectable in the blood 12 weeks following the final dose of the study drug), on-treatment virologic failure and post-treatment relapse.¹

About VIEKIRA PAK

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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 (hep C) virus infection, including people who have a certain type of cirrhosis (compensated).

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®, Epitol®, Equetro®, Tegretol®) • colchicine (Colcrys®) • 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 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. Pregnant females who have both hep C and HIV infection should talk with a doctor 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.
 - **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 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.

Visit AbbVie's website for full Prescribing Information, including the Medication Guide.

If people cannot afford their medication, they should contact www.pparx.org for assistance.

Additional Information about VIEKIRA PAK®

VIEKIRA PAK® has 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, 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 contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B and C) due to risk of potential toxicity. 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 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 GT1a patients with 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.

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 is a protease inhibitor identified through the collaboration, as is ABT-493, Enanta's next-generation protease inhibitor that is completing Phase 2 development as part of AbbVie's investigational next-generation regimen for HCV. AbbVie is Abbott's successor under the agreement and is responsible for all development and commercialization activities for paritaprevir, as well as ABT-493.

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 has developed novel protease and NS5A inhibitors that are members of the direct-acting-antiviral (DAA) inhibitor classes designed for use against the hepatitis C virus (HCV). Enanta's protease inhibitors partnered with AbbVie include paritaprevir, which is contained in AbbVie's marketed DAA regimens for HCV, and ABT-493, Enanta's next-generation protease inhibitor completing phase 2 development in combination with ABT-530, AbbVie's next-generation NS5A inhibitor. Enanta also has a program to develop a host-targeted antiviral (HTA) inhibitor class for HCV targeted against cyclophilin, as well as another DAA program to develop nucleotide polymerase inhibitors. In addition, Enanta has a preclinical program in non-alcoholic steatohepatitis, or NASH, which is a condition that results in liver inflammation and liver damage caused by a buildup of fat in the liver.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including statements with respect to the prospects for AbbVie's VIEKIRA PAK and other treatment regimens for HCV containing paritaprevir. 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 clinical development of paritaprevir-containing regimens; regulatory approvals and other regulatory actions regarding paritaprevir-containing regimens; the impact of competitive products on the regulatory requirements, use and sales of any paritaprevir-containing regimen; 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.

¹ Reau, N., et al. Preliminary Safety and Efficacy Results from TOPAZ-II: A Phase 3b Study Evaluating Long-Term Clinical Outcomes in HCV Genotype 1-infected Patients Receiving Ombitasvir/Paritaprevir/r and Dasabuvir +/-Ribavirin. Poster #1065; presented at The Liver Meeting®, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco, November 13-17, 2015.



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