News Release

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U.S. FDA Approves PREZISTA® (darunavir) for Use in Pregnant Women with HIV

Data shows PREZISTA® is a safe and effective treatment option in pregnant women, with no reports of mother-to-child HIV transmission among women who continued therapy through delivery

TITUSVILLE, NJ, July 18, 2016 – Janssen Therapeutics, Division of Janssen Products, LP (Janssen), today announced that the U.S. Food and Drug Administration (FDA) has approved an expansion to the PREZISTA® (darunavir) U.S. Prescribing Information to include data and results from a study investigating the use of PREZISTA® during pregnancy and the postpartum period. A human immunodeficiency virus (HIV-1) protease inhibitor, PREZISTA® is indicated for the treatment of HIV-1 infection in adult and pediatric patients three years of age and older in combination with ritonavir with other antiretroviral agents. The recent label update includes dosing recommendations for pregnant women with HIV, and data demonstrates that PREZISTA® taken with ritonavir was found to be well-tolerated during pregnancy and the postpartum period.[1]

An analysis of 34 women who received darunavir/ritonavir dosed at either 600 mg/100 mg twice daily or 800 mg/100 mg once daily in combination with a background regimen demonstrated that exposures to darunavir and ritonavir were lower during pregnancy compared with the postpartum period, but were well-tolerated, and virologic responses were preserved throughout the treatment period in both arms.[1,2] There were no reports of mother-to-child HIV transmission among the 29 women who continued therapy through delivery.[2] Nor were there any new

clinically relevant safety findings compared with the known safety profile of PREZISTA®/ritonavir in HIV-1 infected adults. [2]

In addition, based on prospective reports to the Antiretroviral Pregnancy Registry (APR) (through July 2015) of 532 live births following darunavir exposure during pregnancy, there was no difference in rates of overall birth defects for darunavir compared with the background rate for major birth defects in a U.S. reference population of the Metropolitan Atlanta Congenital Defects Program. [2] The prevalence of birth defects was 2.7% (95% CI, 1.2-5.1) among infants exposed to darunavir-containing regimens in the first trimester, and 1.5% (95% CI, 0.3-4.4) among exposed infants in the second or third trimester. [2]

“Many HIV treatments have limited data available to support their use during pregnancy,” said Richard Nettles, Vice President, Medical Affairs, Janssen Therapeutics. “This expansion of our label is an important advancement in addressing the needs of women living with HIV, and it demonstrates that PREZISTA® is a safe and effective treatment for pregnant women living with this disease. We are proud to be able to provide an option for physicians and mothers who are trying to determine the best approach for HIV treatment.”

The updated label now recommends that pregnant women receive 600 mg PREZISTA® taken with 100 mg ritonavir with food twice daily. [1] PREZISTA® 800 mg taken with ritonavir 100 mg once daily should only be considered in certain pregnant patients who are already on a stable PREZISTA® 800 mg with ritonavir 100 mg once daily regimen prior to pregnancy, are virologically suppressed (HIV-1 RNA less than 50 copies per mL), and in whom a change to twice daily PREZISTA® 600 mg with ritonavir 100 mg may compromise tolerability or compliance.[1]

The full PREZISTA® label is available via the PREZISTA® website here.

About HIV and Pregnancy

Mother-to-child transmission of HIV refers to the spread of the HIV virus from pregnant women to their children during pregnancy, during childbirth or through breastfeeding.[3] Mother-to-child HIV transmission is the most common way young children become infected with HIV. [3] Approximately 8,500 women living with HIV give birth annually.[3] Of the 104 children in the U.S. who were diagnosed with HIV in 2014, 88 percent of those children contracted the virus through perinatal transmission.[3] There is currently no cure for HIV; however, there are several medications available to help lower and stop the spread of HIV RNA. .[3]

What is PREZISTA®?

PREZISTA® (darunavir) is a prescription HIV-1 (Human Immunodeficiency Virus type-1) medicine used with NORVIR® (ritonavir) and other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

PREZISTA® should not be used in children under 3 years of age.

When used with other antiretroviral medicines to treat HIV-1 infection, PREZISTA® may help:

- reduce the amount of HIV-1 in your blood. This is called "viral load."
- increase the number of CD4+ (T) cells in your blood that help fight off other infections.

PREZISTA® is always taken with and at the same time as NORVIR® (ritonavir) in combination with other HIV-1 medicines for the treatment of HIV-1 infection in adults. PREZISTA® should also be taken with food.

PREZISTA® does not cure HIV-1 infection or AIDS. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Ask your healthcare provider if you have any questions on how to prevent passing HIV to other people.

Please read the Important Safety Information and talk to your healthcare provider to learn if PREZISTA® is right for you.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PREZISTA®?

- **PREZISTA® can interact with other medicines and cause serious side effects. See "Who should not take PREZISTA®?"**
- **PREZISTA® may cause liver problems.** Some people taking PREZISTA®, together with NORVIR® (ritonavir), have developed liver problems which may be life-threatening. Your healthcare provider should do blood tests before and

during your combination treatment with PREZISTA®. If you have chronic hepatitis B or C infection, your healthcare provider should check your blood tests more often because you have an increased chance of developing liver problems.

- Tell your healthcare provider if you have any of these signs and symptoms of liver problems: dark (tea-colored) urine, yellowing of your skin or whites of your eyes, pale-colored stools (bowel movements), nausea, vomiting, pain or tenderness on your right side below your ribs, loss of appetite, or tiredness.

- **PREZISTA® may cause severe or life-threatening skin reactions or rash.** Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. You should call your healthcare provider immediately if you develop a rash. **Stop** taking PREZISTA® and ritonavir combination treatment and call your healthcare provider immediately if you develop any skin changes with these symptoms: fever, tiredness, muscle or joint pain, blisters or skin lesions, mouth sores or ulcers, red or inflamed eyes, like "pink eye." Rash occurred more often in people taking PREZISTA® and raltegravir together than with either drug separately, but was generally mild.

Who should not take PREZISTA®?

Do not take PREZISTA® if you are taking the following medicines: alfuzosin (Uroxatral®), ergot-containing medicines: dihydroergotamine (D.H.E. 45®, Embolex®, Migranal®), ergotamine tartrate (Cafergot®, Ergomar®, Ergostat®, Medihaler ergotamine ®, Migergot®, Wigraine®, Wigrettes®), methylergonovine (Ergotrate®, Methergine®), cisapride (Propulside®, Propulsid® Quicksolv), colchicine (Colcrys®, Mitigare®), if you have liver or kidney problems, dronedarone (Multaq®), pimozide (Orap®), midazolam (Versed®), when taken by mouth, ranolazine (Ranexa®), St. John's Wort (*Hypericum perforatum)* or a product that contains St. John's Wort, lovastatin or a product that contains lovastatin (Altoprev®, Advicor®, Mevacor®), simvastatin or a product that contains simvastatin (Simcor®, Vytorin®, Zocor®), rifampin or a product that contains rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®), sildenafil (Revatio®), when used for the treatment of pulmonary arterial hypertension (PAH), or triazolam (Halcion®)

Serious problems can happen if you or your child takes any of these medicines with PREZISTA®.

What should I tell my healthcare provider before taking PREZISTA®?

Before taking PREZISTA®, tell your healthcare provider if you:

- have liver problems (including hepatitis B or C), allergy to sulfa medicines, high blood sugar (diabetes), hemophilia, or any other medical conditions.
- are pregnant or planning to become pregnant. Tell your healthcare provider if you become pregnant while taking PREZISTA®.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take PREZISTA®. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. It is not known if PREZISTA® can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicine, vitamins, and herbal supplements. Some medicines interact with PREZISTA®. **Keep a list of your medicines to show your healthcare provider and pharmacist. Do not start taking a new medicine without telling your healthcare provider.**

What are the possible side effects of PREZISTA®?

PREZISTA® may cause serious side effects, including:

- **High blood sugar, diabetes or worsening of diabetes, and increased bleeding in people with hemophilia** have been reported in patients taking protease inhibitor medicines, including PREZISTA®.
- **Changes in body fat** can happen in people who take HIV medicines. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time.

The most common side effects of PREZISTA® include diarrhea, nausea, rash, headache, stomach pain, and vomiting.

This is not a complete list of all possible side effects. If you experience these or other side effects, talk to your healthcare provider. Do not change your dose or stop treatment with PREZISTA® without talking to your healthcare provider.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. You may also report side effects to Janssen Products, LP at 1-800-JANSSEN (1-800-526-7736).

Please refer to the NORVIR® (ritonavir) Patient Information Leaflet for additional information on precautionary measures.

Please see full Product Information for more details.

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at @JanssenUS.

Janssen Therapeutics, Division of Janssen Products, LP is part of the Janssen Pharmaceutical Companies.

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1. PREZISTA® (darunavir) Prescribing Information. United States. Janssen Therapeutics. June 2016.
2. U.S. Food and Drug Administration (FDA). HIV/AIDS Update – Updates for Prezista (darunavir) for use in pregnant women. 2016. Available at https://content.govdelivery.com/accounts/USFDA/bulletins/1501b3e. Accessed June 2016.
3. Centers for Disease Control and Prevention (CDC). HIV Among Pregnant Women, Infant and Children. 2016. Available at http://www.cdc.gov/hiv/group/gender/pregnantwomen/index.html. Accessed June 2016.