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For immediate release

U.S. FDA Approves EDURANT® PED (rilpivirine) for Certain Pediatric Patients Living with HIV-1

This approval offers a new HIV-1 treatment option for children in the U.S. at least 2 years of age, weighing 14 kg – 25 kg and living with HIV

Titusville, NJ (March 19, 2024) – Johnson & Johnson today announced that the U.S. Food and Drug Administration (FDA) has approved EDURANT® PED (rilpivirine) for the treatment of HIV-1 in combination with other antiretroviral therapies (ARVs) in treatment-naïve children (with HIV-1 RNA <100,000 copies/mL) at least 2 years of age and weighing at least 14 kg and less than 25 kg. This approval builds on Johnson & Johnson's longstanding commitment to ensuring that people living with HIV, including children, have treatment options that may work for them.

"Decades of experience with the global HIV epidemic have made it clear that new and improved treatment options are needed to support the diverse population of people living with HIV on their treatment journey," said Penny Heaton, M.D., Global Therapeutic Area Head, Infectious Diseases and Vaccines at Johnson & Johnson. "While the population of young children living with HIV is small, additional treatment options remain key to ensuring that each person living with HIV can be matched to a treatment regimen that is right for them."

The FDA's decision is based on results from the PAINT (NCT00799864) and PICTURE (NCT04012931) studies in pediatric subjects, which showed that rilpivirine, in combination with other ARVs, effectively suppresses the virus in treatment-naïve (with HIV-1 RNA <100,000 copies/mL) pediatric patients. Rilpivirine can be administered to children at least 2 years of age and weighing at least 25 kg via standard 25 mg oral tablets (EDURANT®) or new 2.5 mg oral tablets (EDURANT® PED) that were developed to aid administration and weight-adjusted dosing for children.

About EDURANT® and EDURANT® PED

EDURANT® and EDURANT® PED are a human immunodeficiency virus type 1 (HIV-1) specific, non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment naïve patients at least 2 years of age and weighing at least 14 kg with HIV-1 RNA less than or equal to 100,000 copies/mL.

Limitations of Use:

- More EDURANT® treated subjects with HIV-1 RNA great er than 100,000 copies/mL at the start of therapy experienced virologic failure (HIV-1 RNA ≥50 copies/mL) compared to EDURANT® treated subjects with HIV-1 RNA less than or equal to 100,000 copies/mL.

Please see full Prescribing Information for important safety information.

EDURANT® is indicated in combination with VOCABRIA (cabotegravir), for short-term treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

IMPORTANT SAFETY INFORMATION

Do not take EDURANT® or EDURANT® PED if you are taking any of the following medicines:

- carbamazepine
- oxcarbazepine

- phenobarbital
- phenytoin
- rifampin
- rifapentine
- dexamethasone (more than a single dose)
- St. John's wort (*Hypericum perforatum*)
- esomeprazole
- lansoprazole
- omeprazole
- pantoprazole
- rabeprazole

Before taking EDURANT® or EDURANT® PED, tell your healthcare provider about all your medical conditions, including if you:

- have ever had a severe skin rash or an allergic reaction to medicines that contain rilpivirine
- have or had liver problems, including hepatitis B or C virus infection
- have kidney problems
- have ever had a mental health problem
- are pregnant or plan to become pregnant. It is not known if EDURANT® or EDURANT® PED will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with EDURANT® or EDURANT® PED. **Pregnancy Registry**: There is a pregnancy registry for women who take EDURANT® during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. EDURANT® or EDURANT® PED can pass into your breast milk. Talk with your healthcare provider about the following risks of breastfeeding during treatment with EDURANT® or EDURANT® PED:
    - The HIV-1 virus may pass to your baby if your baby does not have the HIV-1 infection.
    - The HIV-1 virus may become harder to treat if your baby has HIV-1 infection.
    - Your baby may get side effects from EDURANT® or EDURANT® PED.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with EDURANT® or EDURANT® PED Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with EDURANT® or EDURANT® PED.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take EDURANT® or EDURANT® PED with other medicines.

HOW SHOULD I TAKE EDURANT® OR EDURANT® PED?

See the "Instructions for Use" for detailed instructions on how to prepare and give a dose of EDURANT® PED tablets for oral suspension.

- Take EDURANT® or EDURANT® PED every day exactly as your healthcare provider tells you to.
- **Take EDURANT® or EDURANT® PED 1 time each day with a meal.** A protein drink or yogurt alone does not replace a meal.
- EDURANT® and EDURANT® PED must be used with other HIV-1 medicines.
- Do not change your dose or stop taking EDURANT® or EDURANT® PED without first talking with your healthcare provider.
- Stay under the care of your healthcare provider during treatment with EDURANT® or EDURANT® PED.

- **EDURANT® PED tablets for oral suspension provided in a blister package are not the same as EDURANT® tablets provided in a bottle and cannot be substituted for each other**. Contact your pharmacist or healthcare provider if you did not receive the correct dosage form. Your child's healthcare provider will prescribe EDURANT® or EDURANT® PED based on your child's weight
- EDURANT® PED tablets for oral suspension must be dispersed in drinking water. **Do not** crush, chew, or swallow whole EDURANT® PED tablets for oral suspension.
- If you take an H2-receptor antagonist (such as famotidine, cimetidine, nizatidine, or ranitidine), you should take these medicines at least 12 hours before or at least 4 hours after you take EDURANT® or EDURANT® PED.
- If you take antacids, or other products that contain aluminum, calcium carbonate, or magnesium hydroxide, you should take these medicines at least 2 hours before or at least 4 hours after you take EDURANT® or EDURANT® PED.
- **Do not** miss a dose of EDURANT® or EDURANT® PED.
- If you miss a dose of EDURANT® or EDURANT® PED within 12 hours of the time you usually take it, take your dose of EDURANT® or EDURANT® PED with a meal as soon as possible. Then, take your next dose of EDURANT® or EDURANT® PED at the regularly scheduled time. If you miss a dose of EDURANT® or EDURANT® PED by more than 12 hours of the time you usually take it, wait and then take the next dose of EDURANT® or EDURANT® PED at the regularly scheduled time.
- **Do not** take more than your prescribed dose to make up for a missed dose or take less than your prescribed dose.
- If you take too much EDURANT® or EDURANT® PED, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your supply of EDURANT® or EDURANT® PED starts to run low, get more from your healthcare provider or pharmacy. It is important not to run out of EDURANT® or EDURANT® PED. The amount of HIV in your blood may increase if the medicine is stopped even for a short time.
- When your healthcare provider prescribes use of EDURANT® with oral VOCABRIA (cabotegravir):
    - Take EDURANT® and oral VOCABRIA (cabotegravir) 1 time a day at about the same time each day with a meal.
    - You will receive treatment with EDURANT® tablets in combination with VOCABRIA tablets for one month (at least 28 days) before you receive the long-acting medicine called CABENUVA (cabotegravir; rilpivirine extended-release injectable suspensions) for the first time. This will allow your healthcare provider to assess how well you tolerate these medicines.
    - Your final dose of EDURANT® and VOCABRIA tablets should be taken on the same day you receive your first CABENUVA injections.
    - If you miss or plan to miss a scheduled monthly or every 2 months injection of CABENUVA by more than 7 days, call your healthcare provider right away to discuss your treatment options.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF EDURANT® and EDURANT® PED?

EDURANT® and EDURANT® PED can cause serious side effects including:

- **Severe skin rash and allergic reactions.** Call your healthcare provider right away if you develop a rash with EDURANT® or EDURANT® PED. In some cases, rash and allergic reaction may need to be treated in a hospital. **Stop taking EDURANT® or EDURANT® PED and get medical help right away if you develop a rash with any of the following signs or symptoms:**
    - fever
    - tiredness
    - difficulty breathing or swallowing
    - skin blisters
    - swelling of the face, lips, mouth, tongue or throat
    - generally ill feeling
    - muscle or joint aches
    - blisters or mouth sores
    - redness or swelling of the eyes (conjunctivitis)

- **Liver problems.** People with a history of hepatitis B or C virus infection or who have certain liver function test changes may have an increased risk of developing new or worsening changes in certain liver tests during treatment with EDURANT® or EDURANT® PED. Liver problems have also happened in people without a history of problems or other risk factors. Your healthcare provider may need to do tests to check your liver function before and during treatment with EDURANT® or EDURANT® PED. **Call your healthcare provider right away if you develop any of the following signs or symptoms of liver problems:**

    - your skin or the white part of your eyes turns yellow (jaundice)
    - loss of appetite
    - light-colored stools (bowel movements)
    - dark or “tea-colored” urine
    - pain, aching, or tenderness on the right side of the stomach area
    - nausea or vomiting

- **Depression or mood changes. Tell your healthcare provider right away if you have any of the following symptoms**

    - feeling sad or hopeless
    - feeling anxious or restless
    - have thoughts of hurting yourself (suicide) or have tried to hurt yourself

- **Changes in your immune system (Immune Reconstitution Syndrome)** 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. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.

The most common side effects of EDURANT® or EDURANT® PED include depression, headache, trouble sleeping (insomnia), and rash.
These are not all the possible side effects with EDURANT® or EDURANT® PED.
Call your doctor for medical advice about side effects. **You may report side effects to the FDA at 1-800-FDA-1088.**

How should I store EDURANT® or EDURANT® PED?

- Store EDURANT® or EDURANT® PED at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep EDURANT® tablets in the original bottle to protect from light.
- Keep EDURANT® PED tablets in the original package to protect from moisture.

Keep EDURANT® or EDURANT® PED and all medicines out of the reach of children.

Please read the full Prescribing Information for EDURANT® and EDURANT® PED and **discuss any questions you have with your healthcare provider.**

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at https://www.jnj.com.

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CAUTIONS CONCERNING FORWARD-LOOKING STATEMENTS

This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995 regarding rilpivirine and other treatments for HIV. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson’s Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including in the sections captioned “Cautionary Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” and in Johnson & Johnson’s subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. *None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.*

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