News Release

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Janssen Submits Supplemental New Drug Application to U.S. FDA Seeking Expanded Pediatric Indication for HIV-1 Therapy EDURANT®

Parallel application also submitted to European Medicines Agency

If approved, EDURANT® (rilpivirine) in combination with other antiretroviral therapies would offer a new HIV-1 treatment option for younger children

TITUSVILLE, N.J., July 28, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking to expand the indication of EDURANT® (rilpivirine) to include the treatment of HIV-1 infection in children weighing 10 kg or more. A parallel Marketing Authorization application has also been submitted to the European Medicines Agency (EMA) in support of a type II variation and line extension for expanded pediatric use in Europe. These applications reflect Janssen's longstanding commitment to address the needs of adults, adolescents and children affected by the global HIV epidemic.

If the new applications are approved, EDURANT®, a product of Janssen Sciences Ireland Unlimited Company, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, could be administered to younger pediatric patients via standard 25 mg tablets or new 2.5 mg tablets for oral dispersion that were developed to aid administration and weight-adjusted dosing for children.

"We've been working to fight HIV for decades and are proud to have helped bring forward nine medicines for people living with HIV," said Penny Heaton, M.D., Global Therapeutic Area Head, Infectious Diseases and Vaccines, Janssen Research & Development, LLC.

"These filings are the latest example of our longstanding work to make different treatment options available to meet the diverse needs of people living with HIV."

The expanded pediatric applications are supported by data from the Phase 2 PAINT (NCT00799864) and PICTURE (NCT04012931) studies, which showed that EDURANT®, in combination with other antiretroviral therapies, effectively maintains or suppresses the virus in treatment-experienced and treatment-naive pediatric patients, respectively. Given these data, Janssen is seeking an expanded indication to allow use in treatment-naïve children (with HIV-1 RNA ≤100,000 copies/mL) and treatment-experienced virologically suppressed children (with HIV-1 RNA <50 copies/mL) weighing 10 kg or more.

The expansion of the EDURANT® indication would mark the latest step forward in Janssen's efforts to make its HIV medicines available to young people living with HIV. In 2022, the FDA approved the world's first long-acting injectable HIV-1 treatment option for adolescents 12 years of age and older. This regimen consists of Janssen's long-acting rilpivirine and ViiV Healthcare's long-acting cabotegravir and requires as few as six treatments per year.

Johnson & Johnson's Commitment to HIV
In addition to driving innovation in HIV care, Johnson & Johnson also works with vulnerable communities on the global frontlines of the HIV epidemic, and has supported collaborative initiatives like Positively Fearless, the DREAMS Partnership and the MenStar Coalition. We also support the New Horizons Collaborative, which is working to address the unmet needs of HIV treatment-experienced children, adolescents and young adults in sub-Saharan Africa.

To learn more about Johnson & Johnson's commitment to combating HIV, please visit jnj.com/HIV.

About EDURANT®
EDURANT is a human immunodeficiency virus type 1 (HIV-1) specific, nonnucleoside reverse transcriptase inhibitor (NNRTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients 12 years of age and older and weighing at least 35 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 greater 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.

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.

Please see full Prescribing Information for important safety information.

Important Safety Information

Who should not take EDURANT®?

Do not take EDURANT® if you also take:

- anti-seizure medicines:
  - carbamazepine
  - oxcarbazepine

    - phenobarbital
    - phenytoin
- anti-tuberculosis (anti-TB) medicines:
    - rifampin
    - rifapentine
- proton pump inhibitor (PPI) medicine for certain stomach or intestinal problems:
    - esomeprazole
    - lansoprazole
    - omeprazole
    - pantoprazole sodium
    - rabeprazole
- more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate
- St. John's wort (*Hypericum perforatum*)

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

Before taking EDURANT®, 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® will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with EDURANT®
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take EDURANT®**
    - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
    - It is not known if EDURANT® passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby during EDURANT® treatment.

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®. 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®.

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® with other medicines.

How should I take EDURANT®?

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

- If you take an H_2-receptor antagonist (famotidine, cimetidine, nizatidine, or ranitidine), you should take these medicines at least 12 hours before or at least 4 hours after you take EDURANT®.
- 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®.
- If you miss a dose of EDURANT® within 12 hours of the time you usually take it, take your dose of EDURANT® with a meal as soon as possible. Then, take your next dose of EDURANT® at the regularly scheduled time. If you miss a dose of EDURANT® by more than 12 hours of the time you usually take it, wait and then take the next dose of EDURANT® at the regularly scheduled time.
- Do not take more than your prescribed dose to make up for a missed dose.
- If you take too much EDURANT®, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your supply of EDURANT® starts to run low, get more from your healthcare provider or pharmacy. It is important not to run out of EDURANT®. 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) once a day at approximately the same time with a meal.
    - You will receive treatment with EDURANT® tablets in combination with oral VOCABRIA (cabotegravir) 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 oral VOCABRIA 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®?

EDURANT® can cause serious side effects including:

- **Severe skin rash and allergic reactions.** Skin rash is a common side effect of EDURANT®. Skin rash can be serious. Call your healthcare provider right away if you get a rash. In some cases, rash and allergic reaction may need to be treated in a hospital.

Stop taking EDURANT® 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 liver problems during treatment with EDURANT®. Liver problems have also happened during treatment with EDURANT® in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with EDURANT®. **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)
- Light-colored stools (bowel movements)
- Loss of appetite
- 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® include depression, headache, trouble sleeping (insomnia), and rash.

This is not a complete list of all side effects. If you experience these or other symptoms, contact your healthcare provider right away.

You are encouraged to report side effects of prescription drugs to the FDA. 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 read the full Product Information for EDURANT® and discuss any questions you have with your healthcare provider.

About the Janssen Pharmaceutical Companies of Johnson & Johnson
At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at http://www.janssen.com and follow us at http://www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS. Janssen Sciences Ireland Unlimited Company and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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 Janssen Sciences Ireland Unlimited Company, Janssen Research & Development, LLC, the Janssen Pharmaceutical Companies and/or 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 January 1, 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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