Johnson&Johnson

Media contact:
Brooke Hillman
bhillman@its.jnj.com
267-337-0508

Investor contact:
Raychel Kruper
investor-relations@its.jnj.com

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

If approved, PREZCOBIX® would offer a new HIV-1 treatment option for pediatric patients aged 6 and older weighing at least 25 kg

Titusville, N.J. (June 4, 2024) – Johnson & Johnson today announced the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking to expand the indication of PREZCOBIX® (darunavir/cobicistat) to include the treatment of HIV-1 infection in younger children at least 6 years of age weighing at least 25 kg. A parallel line extension application and type 2 variation application have also been submitted to the European Medicines Agency (EMA) for expanded pediatric use in Europe, where the product is marketed as REZOLSTA®.

If the applications are approved, PREZCOBIX®/REZOLSTA® could be administered to adults and pediatric patients at least 6 years of age, weighing at least 25kg. A new co-formulated tablet containing a weight-adjusted pediatric dose (darunavir 675 mg/cobicistat 150 mg) has been developed to aid administration for younger children. The new pediatric tablets are scored to facilitate breaking for ease of swallowing.

“We are proud of this latest step in our years of work to ensure that some of the youngest people living with HIV have access to different treatment regimens that can work for them,” said Penny Heaton, M.D., Global Therapeutic Area Head, Infectious Diseases and Vaccines and Global Public Health R&D at Johnson & Johnson. “If approved, this medicine could offer healthcare providers a new treatment option that ensures weight-appropriate dosing to better meet the needs of young people living with HIV.”

The applications to the FDA and EMA are supported by data from a clinical study sponsored by Janssen Research & Development, LLC, that evaluated the pharmacokinetics of the new combination tablet and established that it is bioequivalent to darunavir and cobicistat when dosed as single agents (NCT04718805). The efficacy, safety and tolerability of cobicistat-boosted darunavir for the treatment of younger children with HIV-1 was established in a Phase 2/3 clinical trial conducted by Gilead Sciences (NCT02016924).

Based on these data, Janssen Products, LP, a division of Johnson & Johnson, is seeking an expanded indication to allow the use of PREZCOBIX®/REZOLSTA® in treatment-naïve and treatment-experienced pediatric patients aged 6 years and older, weighing at least 25 kg, and who have no viral resistance mutations associated with darunavir. These filings reflect Johnson & Johnson’s work toward expanding access to its treatment portfolio to support people of many ages living with HIV.

About PREZCOBIX®/REZOLSTA®

PREZCOBIX®/REZOLSTA® is a two-drug fixed-dose combination tablet containing darunavir, an HIV-1 protease inhibitor, and cobicistat, a CYP3A inhibitor that serves as a PK enhancer or “booster.” The booster enables once-daily dosing and optimal therapeutic levels of darunavir.

This product is currently indicated for the treatment of HIV-1 infection in treatment-naïve and treatment-experienced adults and adolescent patients weighing at least 40 kg with no darunavir resistance-associated mutations.

Darunavir as a single agent is marketed by Janssen Products, LP as PREZISTA® in the United States, and cobicistat, developed by Gilead Sciences, Inc., is marketed as TYBOST®. The fixed-dose combination PREZCOBIX®/REZOLSTA® is a collaboration between Janssen R&D Ireland and Gilead Sciences, Inc.

Please see full Prescribing Information for important safety information.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PREZCOBIX?

- **PREZCOBIX® may cause liver problems.** Some people taking PREZCOBIX® may develop liver problems which may be life-threatening. Your healthcare provider should do blood tests before and during your treatment with PREZCOBIX®. 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 the below 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

- **PREZCOBIX® 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. Call your healthcare provider right away if you develop a rash. Stop taking PREZCOBIX® and call your healthcare provider right away if you develop any skin changes with symptoms below:**
    - fever
    - tiredness
    - muscle or joint pain
    - blisters or skin lesions
    - mouth sores or ulcers
    - red or inflamed eyes, like “pink eye” (conjunctivitis)

- **PREZCOBIX®, when taken with certain other medicines can cause new or worse kidney problems, including kidney failure.** Your healthcare provider should check your kidneys before you start and while you are taking PREZCOBIX®.

See “What are the possible side effects of PREZCOBIX®?” for more information about side effects.

What is PREZCOBIX®?

PREZCOBIX® is a prescription medicine that is used with other HIV-1 medicines to treat HIV-1 infection in adults and in children who weigh at least 88 pounds (40 kg).

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). PREZCOBIX® contains the prescription medicines darunavir and cobicistat.

It is not known if PREZCOBIX® is safe and effective in children weighing less than 88 pounds (40 kg).

Do not take PREZCOBIX® with any medicine that contains:

- alfuzosin
- carbamazepine
- colchicine, if you have liver or kidney problems
- dronedarone
- elbasvir and grazoprevir
- ergot-containing medicines:
    - dihydroergotamine
    - ergotamine
    - methylergonovine
- ivabradine
- lomitapide
- lovastatin
- lurasidone
- midazolam, when taken by mouth
- naloxegol
- phenobarbital

- phenytoin
- pimozide
- ranolazine
- rifampin
- sildenafil, when used for the treatment of pulmonary arterial hypertension (PAH)
- simvastatin
- St. John's wort (Hypericum perforatum)
- Triazolam

Serious problems can happen if you take any of these medicines with PREZCOBIX®. This is not a complete list of medicines. Therefore, tell your healthcare provider about **all** medicines you take.

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

- have liver problems, including hepatitis B or hepatitis C
- have kidney problems
- are allergic to sulfa (sulfonamide)
- have diabetes
- have hemophilia
- are pregnant or plan to become pregnant.
    - It is not known if PREZCOBIX® will harm your unborn baby.
    - PREZCOBIX® should not be used during pregnancy because the PREZCOBIX® levels in your blood may be lower during pregnancy and may not control your HIV-1.
    - Tell your healthcare provider right away if you become pregnant during treatment with PREZCOBIX®.
    - Your healthcare provider will prescribe different medicines if you become pregnant during treatment with PREZCOBIX®.
    - **Hormonal forms of birth control, such as injections, vaginal rings or implants, contraceptive patches, and some birth control pills may not work during treatment with PREZCOBIX®.** Talk to your healthcare provider about forms of birth control that may be used during treatment with PREZCOBIX®.
    - **Pregnancy Exposure Registry:** There is a pregnancy exposure registry for people who take HIV-1 medicines during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take PREZCOBIX®.
    - 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 PREZCOBIX® 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 medicines, topical creams, vitamins, and herbal supplements. Some medicines interact with PREZCOBIX®. **Keep a list of your medicines to show your healthcare provider and pharmacist.**
    - You can ask your healthcare provider or pharmacist for a list of medicines that interact with PREZCOBIX®.
    - **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take PREZCOBIX® with other medicines.

How should I take PREZCOBIX®?

- Take PREZCOBIX® exactly as your healthcare provider tells you.
    - Do not change your dose or stop taking PREZCOBIX® without talking to your healthcare provider.
    - Take PREZCOBIX® 1 time a day with food.
    - Do not miss a dose of PREZCOBIX®.
    - If you take too much PREZCOBIX®, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of PREZCOBIX®?

PREZCOBIX® may cause serious side effects, including:

- See **"What is the most important information I should know about PREZCOBIX®?"**

- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including PREZCOBIX® can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or urinate often while taking PREZCOBIX®.
- **Changes in body fat** can happen in people who take HIV-1 medications. The changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 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 new symptoms after starting your HIV-1 medicine.
- **Increased bleeding for hemophiliacs.** Some people with hemophilia have increased bleeding with protease inhibitors including PREZCOBIX®. The most common side effects of darunavir, one of the medicines in PREZCOBIX®, include:
    - diarrhea
    - nausea
    - rash
    - headache
    - stomach-area (abdominal) pain
    - vomiting

These are not all of the possible side effects of PREZCOBIX®. Call your doctor for medical advice about side effects.

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.

Please see full Product Information for more details.

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.

Learn more at https://www.janssen.com/johnson-johnson-innovative-medicine and follow us at https://twitter.com/JNJInnovMed and https://twitter.com/JNJNews. Janssen R&D Ireland, Janssen Research & Development, LLC, and Janssen Products, LP are Johnson & Johnson companies.

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 R&D Ireland, Janssen Products, LP, Janssen Research & Development, LLC 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 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 Janssen R&D Ireland, Janssen Products, LP, Janssen Research & Development, LLC nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.