News Release

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Janssen Announces Submission of New Drug Application to U.S. FDA For the First Monthly, Injectable, Two-Drug Regimen of Rilpivirine and Cabotegravir for Treatment of HIV

If approved, the rilpivirine and cabotegravir regimen would be the first-ever long-acting injectable treatment for adults living with HIV

CORK, IRELAND, April 29, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson have announced that a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) has been submitted by ViiV Healthcare for the investigational once-monthly, injectable, two-drug regimen of Janssen's rilpivirine and ViiV's cabotegravir for the treatment of HIV in adults whose viral load is suppressed and who are not resistant to cabotegravir or rilpivirine.

The submission is based on the ATLAS (Antiretroviral Therapy as Long-Acting Suppression) and FLAIR (First Long-Acting Injectable Regimen) pivotal Phase 3 studies that included more than 1,100 patients from 16 countries. These studies demonstrated that the combination of rilpivirine and cabotegravir, injected monthly, was as effective as a standard of care, daily, oral three-drug regimen in maintaining viral suppression throughout the 48-week study period. These results were presented in March at the 2019 Conference on Retroviruses and Opportunistic Infections.

"We believe this once-monthly injectable regimen has the potential to offer many people living with HIV a treatment option that does not require taking pills every day," said Brian Woodfall, M.D., Global Head, Development, Infectious Diseases, Janssen Biopharma, Inc. "In our quest to change the trajectory of health for humanity, we will continue to innovate in the field of HIV. We look forward to working with ViiV and the FDA on the steps needed to get the first long-acting injectable HIV treatment to patients."

This novel regimen is being co-developed as part of a collaboration between Janssen and ViiV Healthcare. The two companies plan to submit regulatory applications for the two-drug regimen of rilpivirine and cabotegravir to the European Medicines Agency, Health Canada and other global agencies in the coming months.

As part of the regulatory submission package to the FDA, a second NDA was submitted for an oral tablet formulation of cabotegravir that would be taken once-daily as an oral lead-in with the already-approved oral tablet formulation of rilpivirine (marketed by Janssen as EDURANT®).

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About ATLAS (NCT02951052)
ATLAS is a Phase 3, open-label, active-controlled, multicenter, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of a two-drug regimen of long-acting, injectable rilpivirine and cabotegravir dosed every four weeks compared to continuation of current oral anti-retroviral therapy (ART) of two nucleoside reverse transcriptase inhibitors (NRTIs) plus an integrase strand transfer inhibitor (INI), non-nucleoside reverse transcriptase inhibitor (NNRTI), or protease inhibitor (PI) among virally suppressed individuals. The primary endpoint for ATLAS is the proportion of participants with plasma HIV-1 RNA ≥50 c/mL per the FDA Snapshot algorithm at Week 48 (Missing, Switch, or Discontinuation = Failure, Intent-to-Treat Exposed [ITT-E] population). Subjects were required to be virally suppressed for six months or longer, on a first or second regimen, with no prior failure.

About FLAIR (NCT02938520)
FLAIR is a Phase 3, randomized, open-label, multicenter, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of a two-drug regimen of intramuscular, long-acting, injectable rilpivirine and cabotegravir in virologically suppressed adults living with HIV, following 20 weeks of induction therapy with Triumeq® compared to continuation of the oral dolutegravir-based treatment regimen. The primary endpoint for FLAIR is the proportion of participants with plasma HIV-1 RNA ≥50 c/mL per the FDA Snapshot algorithm at Week 48 (Missing, Switch, or Discontinuation = Failure, Intent-to-Treat Exposed [ITT-E] population).

About EDURANT® (Rilpivirine)
- EDURANT® (rilpivirine) is a prescription medicine that is used with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) in people 12 years of age and older and who weigh at least 77 lbs (35 kg):
  - Have **never** taken HIV medicines before, **and**
  - Have an amount of HIV in their blood (called "viral load") that is no more than 100,000 copies/mL

- EDURANT® is not recommended for patients less than 12 years of age or who weigh less than 77 lbs (35 kg)

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 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.

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.

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.

  If you get a rash with any of the following symptoms, **stop taking EDURANT® and get medical help right away**:
  - fever
  - skin blisters
  - mouth sores
  - redness or swelling of the eyes (conjunctivitis)
  - swelling of the face, lips, mouth, tongue, or throat
  - trouble breathing or swallowing
  - pain on the right side of the stomach (abdominal) area
  - dark-colored urine "tea colored"
- **Change in liver enzymes.** 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®.
- **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 body fat** can happen in people who take HIV medicine. These changes may include 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 problems are not known.
- **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. Do not stop taking EDURANT® or any other medications without first talking to your healthcare

provider.

You are encouraged to report 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 see accompanying full Product Information for more details.

Full US prescribing information including is available at:
http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/EDURANT-pi.pdf

For the EU Summary of Product Characteristics, please visit:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002264/WC500118874.pdf

About rilpivirine long-acting
Rilpivirine long-acting is an investigational, injectable, prolonged-release suspension for intramuscular injection being developed by Janssen Sciences Ireland UC and is not approved by regulatory authorities anywhere in the world.

About cabotegravir
Cabotegravir is an investigational integrase inhibitor (INI) and is not approved by regulatory authorities anywhere in the world. Cabotegravir is being developed by ViiV Healthcare for the treatment and prevention of HIV and is currently being evaluated as a long-acting, prolonged-release formulation for intramuscular injection and also as a once-daily oral tablet for short-term use prior to long-acting injection.

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, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com and follow us at www.twitter.com/JanssenGlobal. Janssen Biopharma Inc., and Janssen Sciences Ireland UC are members of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Notice to Investors 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 development of potential preventive and treatment regimens 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 UC, any of the other 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 December 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent 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.