News Release

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U.S. FDA Approves Streamlined Process for Initiating HIV Therapy with CABENUVA (cabotegravir and rilpivirine), the First and Only Complete Long-Acting Injectable HIV Treatment

Adults living with HIV now have an option to start injectable regimen without the need for an oral lead-in period first

TITUSVILLE, N.J., March 24, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the U.S. Food and Drug Administration (FDA) has approved a label update for CABENUVA (cabotegravir and rilpivirine), giving healthcare professionals and people living with human immunodeficiency virus (HIV-1) in the U.S. the option to start this once-monthly or every-two-month injectable treatment without the need for the oral lead-in phase (daily cabotegravir and rilpivirine tablets, taken for one month prior to initiation of cabotegravir and rilpivirine injections).[1] Clinical data demonstrated the regimen displays a similar safety and efficacy profile both with and without an oral lead-in period.[2] CABENUVA was co-developed as part of a collaboration with ViiV Healthcare and builds on Janssen's decades-long commitment to combatting HIV.

"We have a proven track record of bringing innovative therapies to people living with HIV, and our commitment to ushering in new scientific advancements has not wavered," said James Merson, Ph.D., Global Therapeutic Area Head, Infectious Diseases, Janssen Research & Development, LLC. "With this expanded label milestone, Janssen is offering an additional pathway that simplifies the treatment landscape for people living with HIV in the U.S. who are prescribed CABENUVA therapy."

CABENUVA is the first and only complete long-acting HIV treatment regimen and is approved in the U.S. as a once-monthly or every-two-month treatment for HIV-1 in virologically suppressed adults (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.[1] It contains ViiV Healthcare's cabotegravir extended-release injectable suspension in a single-dose vial and rilpivirine extended-release injectable suspension in a single-dose vial, a product of Janssen Sciences Ireland Unlimited Company, one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

"At Janssen, we are proud to continue advancing options that support patients and help healthcare providers in finding personalized treatment plans that address unique individual needs and circumstances for people living with HIV," said Candice Long, President, Infectious Diseases & Vaccines, Janssen Therapeutics, a Division of Janssen Products, LP. "Providing a diverse portfolio of HIV therapies is critical to help meet these various treatment needs, and we believe CABENUVA is a meaningful option for the patients and providers we serve."

This U.S. FDA approval is based on the FLAIR (First Long-Acting Injectable Regimen) Week 124 results, which showed there were similar outcomes regarding maintenance of virologic suppression, safety, tolerability and pharmacokinetics in people starting cabotegravir and rilpivirine injections with or without the oral lead-in.[2]

Johnson & Johnson's Commitment to HIV
Johnson & Johnson has been committed to the fight against HIV for decades, playing a central role in bringing nine different treatments to people living with HIV, and continuing to drive innovation in HIV prevention and care. Johnson & Johnson also works with vulnerable communities on the frontlines of the HIV epidemic through initiatives such as Positively Fearless, DREAMS Thina Abantu Abasha, the MenStar Coalition and the New Horizons Collaborative.

To learn more, visit jnj.com/hiv.

About CABENUVA (cabotegravir and rilpivirine)
CABENUVA is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 c/ml) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

The complete regimen combines the integrase strand transfer inhibitor (INSTI) cabotegravir, developed by ViiV Healthcare, with rilpivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI) developed by Janssen. Rilpivirine is approved in the U.S. as a 25 mg tablet taken once a day to treat HIV-1 in combination with other antiretroviral agents in antiretroviral treatment-naïve patients 12 years of age and older and weighing at least 35 kg with a viral load ≤100,000 HIV RNA c/ml.

INSTIs inhibit HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic disease. Rilpivirine is an NNRTI that works by interfering with an enzyme called reverse transcriptase, which stops the virus from multiplying.

The once-monthly version of the rilpivirine and cabotegravir injectable treatment has been approved by the European Commission, Health Canada, the Australia Therapeutic Goods

Administration and the Swiss Agency for Therapeutic Products. The every-two-months version has also been approved by the European Commission, Health Canada, and the Swiss Agency for Therapeutic Products. The option to initiate treatment without oral therapy lead-in was approved by the European Commission in 2021. Regulatory reviews continue with additional submissions planned throughout 2022.

IMPORTANT SAFETY INFORMATION

CABENUVA is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per ml) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

CONTRAINDICATIONS

- Do not use CABENUVA in patients with previous hypersensitivity reaction to cabotegravir or rilpivirine
- Do not use CABENUVA in patients receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, systemic dexamethasone (>1 dose), and St John's wort

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions:

- Hypersensitivity reactions, including cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), have been reported during postmarketing experience with rilpivirine-containing regimens. While some skin reactions were accompanied by constitutional symptoms such as fever, other skin reactions were associated with organ dysfunctions, including elevations in hepatic serum biochemistries
- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with CABENUVA
- Discontinue CABENUVA immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated. Prescribe the oral lead-in prior to administration of CABENUVA to help identify patients who may be at risk of a hypersensitivity reaction

Post-Injection Reactions:

- Serious post-injection reactions (reported in less than 1% of subjects) were reported within minutes after the injection of rilpivirine, including dyspnea, bronchospasm, agitation, abdominal cramping, rash/urticaria, dizziness, flushing, sweating, oral numbness, changes in blood pressure, and pain (e.g., back and chest). These events may have been associated with inadvertent (partial) intravenous administration and began to resolve within a few minutes after the injection
- Carefully follow the Instructions for Use when preparing and administering CABENUVA. The suspensions should be injected slowly via intramuscular injection and avoid accidental intravenous administration. Observe patients briefly (approximately 10 minutes) after the injection. If a post-injection reaction occurs, monitor and treat as clinically indicated

Hepatotoxicity:

- Hepatotoxicity has been reported in patients receiving cabotegravir or rilpivirine with or without known pre-existing hepatic disease or identifiable risk factors

- Patients with underlying liver disease or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations
- Monitoring of liver chemistries is recommended and treatment with CABENUVA should be discontinued if hepatotoxicity is suspected

Depressive Disorders:
- Depressive disorders (including depressed mood, depression, major depression, mood altered, mood swings, dysphoria, negative thoughts, suicidal ideation or attempt) have been reported with CABENUVA or the individual products
- Promptly evaluate patients with depressive symptoms

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:
- The concomitant use of CABENUVA and other drugs may result in known or potentially significant drug interactions (see Contraindications and Drug Interactions)
- Rilpivirine doses 3 and 12 times higher than the recommended oral dosage can prolong the QTc interval
- CABENUVA should be used with caution in combination with drugs with a known risk of Torsade de Pointes

Long-Acting Properties and Potential Associated Risks with CABENUVA:
- Residual concentrations of cabotegravir and rilpivirine may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer). Select appropriate patients who agree to the required monthly or every-2-month injection dosing schedule because non-adherence could lead to loss of virologic response and development of resistance
- To minimize the potential risk of developing viral resistance, it is essential to initiate an alternative, fully suppressive antiretroviral regimen no later than 1 month after the final injection doses of CABENUVA when dosed monthly and no later than 2 months after the final injections of CABENUVA when dosed every 2 months. If virologic failure is suspected, switch the patient to an alternative regimen as soon as possible

ADVERSE REACTIONS
- The most common adverse reactions (incidence ≥2%, all grades) with CABENUVA were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash

DRUG INTERACTIONS
- Refer to the applicable full Prescribing Information for important drug interactions with CABENUVA, VOCABRIA, or EDURANT
- Because CABENUVA is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended
- Drugs that are strong inducers of UGT1A1 or 1A9 are expected to decrease the plasma concentrations of cabotegravir. Drugs that induce or inhibit CYP3A may affect the plasma concentrations of rilpivirine
- CABENUVA should be used with caution in combination with drugs with a known risk of Torsade de Pointes

USE IN SPECIFIC POPULATIONS
- **Pregnancy:** There are insufficient human data on the use of CABENUVA during pregnancy to adequately assess a drug-associated risk for birth defects and miscarriage. Discuss the benefit-risk of using CABENUVA during pregnancy and

conception and consider that cabotegravir and rilpivirine are detected in systemic circulation for up to 12 months or longer after discontinuing injections of CABENUVA. An Antiretroviral Pregnancy Registry has been established
- **Lactation:** The CDC recommends that HIV-1-infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection. Breastfeeding is also not recommended due to the potential for developing viral resistance in HIV-positive infants, adverse reactions in a breastfed infant, and detectable cabotegravir and rilpivirine concentrations in systemic circulation for up to 12 months or longer after discontinuing injections of CABENUVA

Please see full Prescribing Information.

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 http://www.janssen.com and follow us at http://www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS.

Janssen Sciences Ireland Unlimited Company; Janssen Therapeutics, a Division of Janssen Products, LP; and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

To learn more about Janssen's commitment to the prevention and treatment of HIV, please visit jnj.com/HIV.

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 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 Unlimited Company, 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 January 2, 2022, 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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REFERENCES

1. Cabenuva (cabotegravir, rilpivirine) Prescribing Information. US Approval March 2022.
2. D'Amico R, Orkin C, Morell EB, et al. Safety and efficacy of cabotegravir + rilpivirine long-acting with and without oral lead-in: FLAIR Week 124 results. Presented at HIV Glasgow 2020.