News Release

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Janssen Submits Regulatory Application to European Medicines Agency for Rilpivirine Long Acting, to Be Used in Combination with Cabotegravir Long Acting, as the First Monthly Injectable Treatment for HIV

The marketing application is based on Phase 3 ATLAS and FLAIR pivotal trials in which the once-monthly injectable treatment regimen showed similar efficacy and safety to daily, three-drug oral treatment[1,2]

BEERSE, Belgium, 29 July, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the submission of a marketing authorisation application (MAA) to the European Medicines Agency (EMA) for the once-monthly, injectable rilpivirine long acting (LA), which will be used in combination with ViiV Healthcare's once-monthly, injectable cabotegravir LA to treat HIV-1. If approved, the two-drug regimen will be the first monthly LA injectable treatment for HIV infection in adults whose viral load is suppressed and who are not resistant to rilpivirine or cabotegravir.

"Providing long-acting injectable treatment to people living with HIV offers them the opportunity to live their lives without the need for daily pills," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee, Chief Scientific Officer, Johnson & Johnson. "Janssen has a rich history of innovation in HIV and we are passionate about continuing the fight. We aim for firsts, from single tablet two-drug regimens to a long-acting injection, to the pursuit of a preventive vaccine and cure. We look forward to continuing our work with ViiV Healthcare to bring the first long-acting injectable HIV treatment to patients across Europe."

The submission is based on the global 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 and demonstrated that the combination of cabotegravir LA and rilpivirine LA, injected monthly, was as effective as a standard of care, daily, oral, three-drug regimen in maintaining viral suppression throughout 48 weeks.[1,2]

The EMA filing follows the recent submission by ViiV Healthcare of a New Drug Application for the two-drug regimen of cabotegravir LA and rilpivirine LA to the U.S. Food and Drug Administration (FDA) in April 2019. In June, the FDA submission was granted a Priority Review designation with expected approval in December 2019. ViiV Healthcare and Janssen also plan to submit additional parallel regulatory applications for cabotegravir LA and rilpivirine LA to other agencies globally in the coming months.

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About ATLAS (NCT02951052)
ATLAS is a Phase 3, open-label, active-controlled, multi-center, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of a two-drug regimen of LA, 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.[1] 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.[1]

About FLAIR (NCT02938520)
FLAIR is a Phase 3, randomised, open-label, multi-center, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of a two-drug regimen of intramuscular, LA injectable rilpivirine and cabotegravir in virologically suppressed adults living with HIV, following 20 weeks of induction therapy with Triumeq® (abacavir / dolutegravir / lamivudine) compared to continuation of the oral dolutegravir-based treatment regimen.[2] 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).[2]

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 LA, prolonged-release formulation for intramuscular injection and also as a once-daily oral tablet for short-term use prior to LA injection.

About rilpivirine
Rilpivirine is a once daily non-nucleoside reverse transcriptase inhibitor (NNRTI) used for the treatment of HIV-1 infection in combination with other antiretroviral agents in antiretroviral treatment-naïve patients 12 years of age and older, with a viral load ≤100,000 HIV RNA copies/mL.[3] LA injectable rilpivirine is not approved by regulatory authorities anywhere in the world.

Rilpivirine was developed by Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Rilpivirine is approved in the EU as EDURANT®, a 25mg tablet taken once-a-day and is always taken with a meal.[3] The most common side effects of rilpivirine include: depression, headache, trouble sleeping (insomnia) and rash.[3]

Important safety information:
Please refer to the full Summary of Product Characteristics for full prescribing information for EDURANT® (rilpivirine):
https://www.medicines.org.uk/emc/product/4968/smpc

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/EMEA. Follow us at www.twitter.com/JanssenEMEA.

Janssen-Cilag International NV; Janssen Research & Development, LLC and Janssen Sciences Ireland UC 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 approval of a once-monthly long-acting injectable HIV treatment. 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 materialise, actual results could vary materially from the expectations and projections of Janssen Vaccines & Prevention B.V., 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," in the company's most recently filed Quarterly Report on Form 10-Q and in 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. Neither 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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1. Swindells S et al. (2019) LONG-ACTING CABOTEGRAVIR + RILPIVIRINE FOR MAINTENANCE THERAPY: ATLAS WEEK 48 RESULTS. Oral presentation, the Annual Conference on Retroviruses and Opportunistic Infections (CROI).
2. Orkin C et al. (2019) LONG-ACTING CABOTEGRAVIR + RILPIVIRINE FOR HIV MAINTENANCE: FLAIR WEEK 48 RESULTS. Oral Presentation at the Annual Conference on Retroviruses and Opportunistic Infections (CROI).
3. EDURANT® Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/4968/smpc Last access July 2019.