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News Release

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Janssen Announces European Commission Authorisation of the First Complete Long-Acting Injectable HIV Treatment in Europe

Marketing Authorisation granted by European Commission for Janssen's REKAMBYS® (rilpivirine injection) to be used with ViiV Healthcare's VOCABRIA® (cabotegravir injection and tablets)

Long-acting, two-drug regimen can enable reduction of treatment days from 365 to 12 or six per year after initiation

The long-acting injectable regimen was preferred by majority of clinical trial patients who tried the treatment over their previous daily oral therapy[1]

BEERSE, BELGIUM, 21 December, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the authorisation of REKAMBYS® (rilpivirine injection) in combination with ViiV Healthcare's VOCABRIA® (cabotegravir injection and tablets) in the European Union for the treatment of HIV-1 infection in adults who are virologically suppressed.[2] This authorisation represents the first-time people living in Europe with HIV may be able to receive a long-acting injectable treatment that removes the need to take daily oral tablets.

"There has been significant progress in the way HIV is managed and perceived over the past 30 years. However, for many people living with or at risk of HIV, stigma and discrimination remains and often prevents them from speaking out or seeking treatment," said Professor Giovanni Guaraldi*, Associate Professor of Infectious Disease and Head of the Modena HIV Metabolic Clinic (MHMC), Italy. "This long-acting regimen could mean people living with HIV no longer need daily therapy, maintaining viral load suppression with just 12 or six injection days a year and eliminating a daily reminder of their condition. My hope is that, as medicines continue to improve, they will lead to further significant developments, particularly for some of those who still face discrimination."

Underscoring the need for a less frequent dosing regimen, the largest global HIV patient-reported outcomes study to-date conducted by ViiV Healthcare, Positive Perspectives Wave 2, found that when participants were asked about their treatment aspirations and attitudes

towards innovative medications, 55 percent (n=1306/2389) would prefer a long-acting regimen.[3] In addition, 58 percent (n=1394/2389) noted that taking daily HIV medication acts as a constant reminder of HIV in their lives, while up to 38 percent (n=906/2389) of participants reported anxiety around the fact that taking daily treatment could increase the chances of revealing their HIV status to others.[4]

"We are delighted with the European Commission's decision to approve this long-acting injectable treatment," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee, Chief Scientific Officer, Johnson & Johnson. "At Janssen, we are incredibly proud of this authorisation and the progress it marks in achieving our goal to address some of the biggest health threats of our time. We will continue building on our 25-year commitment to make HIV history and to change the course of the epidemic through our passionate pursuit of innovation, from long-term remission to effective prevention of HIV."

Marketing Authorisation is based on the pivotal Phase 3 ATLAS (Antiretroviral Therapy as Long-Acting Suppression), FLAIR (First Long-Acting Injectable Regimen) and ATLAS-2M studies, which included more than 1,200 participants from 16 countries.[1,5,6] The rilpivirine and cabotegravir injection combination is indicated for adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL), on a stable antiretroviral regimen, without present or past evidence of viral resistance to, or virological failure with, agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) classes.

Janssen's long-acting rilpivirine in combination with ViiV Healthcare's long-acting cabotegravir was co-developed as part of a collaboration with ViiV Healthcare and builds on Janssen's industry-leading portfolio that is centered on delivering innovative medicines for the HIV community.

**Professor Giovanni Guaraldi is a paid consultant for Janssen. He has not been compensated for any media work.*

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About ATLAS (NCT02951052)

ATLAS is a Phase 3, open-label, active-controlled, multi-centre, 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.[7] 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). Participants were required to be virally suppressed for six months or longer, on a first or second regimen, with no prior failure.[7]

About ATLAS-2M (NCT03299049)

The ATLAS-2M study is a Phase 3, randomised, open-label, active-controlled, multicentre, parallel-group, non-inferiority study designed to assess the non-inferior antiviral activity and safety of long-acting rilpivirine and cabotegravir administered every eight weeks compared to long-acting rilpivirine and cabotegravir administered every four weeks over a 48-week treatment period in 1,045 adults living with HIV-1.[8] Participants were required to be virologically suppressed for six months or greater, on first or second regimen, with no prior failure. The primary outcome measure for the study is the proportion of participants with HIV-1 RNA ≥50c/mL at Week 48 using the FDA Snapshot algorithm (Intent-to-Treat Exposed [ITT-E] population).[1,8]

ATLAS-2M is being conducted at research centres in Argentina, Australia, Canada, France, Germany, Italy, Mexico, Russia, South Africa, South Korea, Spain, Sweden and the United States.

For further information, please see https://clinicaltrials.gov/ct2/show/NCT03299049.

About FLAIR (NCT02938520)
FLAIR is a Phase 3, randomised, open-label, multi-centre, 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 ViiV Healthcare's Triumeq® (abacavir / dolutegravir / lamivudine) compared to continuation of the oral dolutegravir-based treatment regimen.[9] 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).[9]

About rilpivirine and rilpivirine long-acting
The oral formulation of rilpivirine is also licensed for the treatment of HIV-1 infection 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 copies/mL.[10]

Rilpivirine long-acting is a prolonged-release suspension for IM injection developed by Janssen Sciences Ireland Unlimited Company, one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) that works by interfering with an enzyme called reverse transcriptase, which in turn stops the virus from multiplying. The EC marketing authorisation marks the second for the long-acting regimen of rilpivirine and cabotegravir with once-monthly dosing licensed by Health Canada under the brand name CABENUVA® for the treatment of HIV-1 infection in adults who are virologically stable and suppressed.[11]

Administration and dosing of rilpivirine and cabotegravir
Rilpivirine injection used in combination with cabotegravir injection will be the first complete long-acting regimen dosed once-monthly or once every 2-months, for virologically suppressed people living with HIV-1. Rilpivirine and cabotegravir injections are administered as two intramuscular (IM) injections in the buttocks by a Healthcare Professional at the same appointment. Prior to the initiation of the injections, rilpivirine and cabotegravir oral tablets are taken for approximately one month (at least 28 days) to assess tolerability to the medicines.

About cabotegravir
Cabotegravir is an INI developed by ViiV Healthcare for the treatment of HIV-1 in virologically suppressed adults. It is being evaluated in combination with injectable rilpivirine as a long-acting formulation.[12]

Integrase strand transfer inhibitors (INSTIs), like cabotegravir, 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 infection.

Important Safety Information (ISI)
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

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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 for our latest news. Janssen-Cilag International NV, Janssen Research & Development, LLC and Janssen Sciences Ireland Unlimited Company are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

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. 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-Cilag International NV and Janssen Research & Development, LLC, 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 behaviour 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 29, 2019, 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.

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