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Janssen Receives Positive CHMP Opinion Recommending EDURANT®▼ (rilpivirine) for the Treatment of Adolescents Aged 12 to <18 Years with HIV-1 infection

Beerse, Belgium, 26 October 2015 – Janssen-Cilag International NV (Janssen) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending a change to the terms of the marketing authorisation for EDURANT® (rilpivirine) in the European Union, to extend the indication to adolescent patients aged 12 to <18 years with human immunodeficiency virus-1 (HIV-1) infection, starting treatment for the first time and with a viral load ≤ 100,000 HIV-1 ribonucleic acid (RNA) copies/ml at start of treatment.[1]

Rilpivirine is already approved in Europe for the treatment of HIV-1 infection in combination with other antiretroviral agents in antiretroviral treatment-naïve adult patients with a viral load ≤100,000 HIV RNA copies/mL. If approved by the European Commission, rilpivirine will become available for the first time for the treatment of adolescents with HIV-1, ages 12 to <18 years. It is estimated that one in seven of all new HIV infections occur in adolescence and young adulthood.[2]

"In some regions, adolescents are an age group for whom HIV-related diseases are on the rise,[2] as young people can be overlooked or face barriers when accessing health services. We are happy to be closer to improving the health needs of this vulnerable patient group," said Christiane Moecklinghoff, M.D Ph.D., Medical Director, Virology, Janssen EMEA. "We look forward to the European Commission's decision and the opportunity to offer an additional treatment option to adolescent patients."

The CHMP adopted the opinion based on a review of 48-week data from a Phase 2 multi-centre study, which looked at the pharmacokinetics, safety/tolerability and efficacy of rilpivirine 25 mg once daily in combination with a background regimen of antiretroviral treatment* in HIV-1 infected adolescents aged 12 to <18 years and starting treatment for the first time.[1]

Updated results from the study were most recently presented at the International AIDS Society Conference in Vancouver this year (IAS 2015) and showed that at week 48, 26/36 (72%) patients overall† achieved virologic response (HIV-1 RNA < 50 copies/mL).[3] Adverse events considered at least possibly related to rilpivirine occurred in 13 (36% [CI: 21% - 54%]) patients, mainly (excluding investigations) somnolence (n=5, 14% [CI: 5% - 30%]) and nausea (n=2, 6% [CI: 1% - 19%]).[3] Overall, the data support the use of rilpivirine combined with other antiretrovirals in adolescent patients aged 12 to <18 years with HIV-1 infection, starting treatment for the first time and who have a viral load ≤ 100,000 HIV-1 RNA copies/mL at start of treatment, with pharmacokinetic results similar to those observed in adults.[3]

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About HIV in adolescents
As of 2012, it is estimated that 35 million people are currently living with HIV globally, including 2.1 million adolescents, many of whom were born with the virus.[2,4] While the number of HIV-related deaths among adults is decreasing, deaths among adolescents is increasing, especially in HIV epidemic areas.[5,6] In 2012, UNAIDS and WHO estimate that 2.2 million people were living with HIV in the WHO European Region, including 1.3 million in eastern Europe and central Asia.[7]

*Containing two nucleoside reverse transcriptase inhibitors (NRTIs) (zidovudine [AZT]/lamivudine [3TC] or abacavir [ABC]/3TC)

† 22/28 (79%) with baseline viral load (BLVL) ≤100,000 copies/mL and 4/8 (50%) with BLVL >100,000 copies/mL

About rilpivirine
Rilpivirine is a once daily non-nucleoside reverse transcriptase inhibitor (NNRTI) used for the treatment of human immunodeficiency virus (HIV-1) infection in combination with other antiretroviral agents in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV RNA copies/mL. Rilpivirine first received initial marketing authorisation in Europe in 2011.[8]

For complete EU summary of product characteristics, please visit: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002264/human_med_001513.jsp&mid=WC0b01ac058001d124.

For complete UK summary of product characteristics,[9] please visit: www.medicines.org.uk/emc/medicine/25490.

About Janssen
At Janssen, we are dedicated to addressing some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen-Cilag International NV is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

More information about Janssen can be found at: www.janssen-emea.com.

About our commitment to global public health
Our initiatives in support of global public health complement the groundbreaking science of the Janssen Pharmaceutical companies of Johnson & Johnson with innovative strategies that improve access to medicines, foster collaborations, and support public health solutions to sustainably advance health care worldwide. Current areas of focus include multidrug-resistant tuberculosis (MDR-TB); human immunodeficiency virus (HIV); elephantiasis and river blindness; intestinal worms; and use of mobile technologies (mHealth) to improve health outcomes.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. 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/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and description 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 28, 2014, including in Exhibit 99 thereto, 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 or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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