



EDURANT[®] (Rilpivirine) Approved in Europe for Treatment-Naïve Adults with HIV-1 Infection with a Baseline Viral Load \leq 100,000 HIV-1 RNA Copies/mL

Beerse, Belgium, 28 November 2011 - Janssen International NV announced today that the European Commission (EC) has granted marketing authorisation for EDURANT[®] (rilpivirine) as a once daily treatment in combination with other antiretroviral agents (ARVs), for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in ARV treatment-naïve adult patients with a viral load \leq 100,000 HIV-1 RNA copies/mL. Rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) and has been shown to offer similar efficacy and a better tolerability profile with respect to central nervous system (CNS) side effects (including insomnia, depression and dizziness), rash, triglyceride elevations and severe vitamin D deficiency compared to the standard of care (efavirenz).^{1,2} Dosed at 25mg once daily, rilpivirine is the smallest ARV tablet currently available.³ The tablet must be taken with a meal, at the same time each day.⁴

"As people with HIV are living longer than ever before, there is now a greater necessity for therapies with improved tolerability and dosing simplification, which can be tailored and individualised depending on patient needs," said Jean-Michel Molina, MD, Professor of Infectious Diseases at University of Paris Diderot in Paris and ECHO/THRIVE study investigator. "The approval of rilpivirine is an advancement for patients as it offers previously untreated patients more treatment choice, as well as a different tolerability profile to the current standard of care, which may suit some patients better."

The marketing authorisation of rilpivirine is based on the 48-week analyses of ECHO and THRIVE, two randomised, double blind, active controlled, global Phase 3 clinical trials which evaluated the efficacy, safety and tolerability of rilpivirine compared to efavirenz in more than 1,350 treatment-naïve HIV-1 adult patients in over 20 countries.^{1,2}

In the overall population, 84.3% of patients in the rilpivirine arm achieved an undetectable viral load ($<$ 50 HIV-1 RNA copies/mL) at week 48 compared to 82.3% in the efavirenz arm.⁴ In the licensed indicated population (i.e. patients with a baseline viral load of \leq 100,000 HIV-1 RNA copies/mL), 90.2% of patients in the rilpivirine arm achieved an undetectable viral load at week 48 compared to 83.6% in the efavirenz arm and virologic failure (VF) was similar in both groups; 3.8% and 3.3% respectively (in the overall population VF was 9.0% and 4.8% respectively).⁴

Rilpivirine demonstrated some advantages over efavirenz with regards to tolerability.^{1,2} There were approximately half the incidence of grade 2-4 overall adverse events in the rilpivirine arm vs. the efavirenz arm (16% vs. 31%) including significantly lower incidence of rash, dizziness, abnormal dreams/nightmares, and lower incidence of grade 3-4 lipid abnormalities.⁵ In the rilpivirine arm, the most frequently reported adverse drug reactions (ADRs) (\geq 2%) that were at least of moderate intensity were depression (3.5%), insomnia (2.9%), headache (2.6%) and rash (2.2%).⁴

Strong HIV Franchise

EDURANT is the second NNRTI and third antiretroviral agent Janssen has launched in five years to treat people with HIV.

"EDURANT is the latest antiretroviral agent in the Janssen HIV portfolio. Through the portfolio, we can now offer treatment options for most people living with HIV at every stage of their disease," said Wim Parys, MD, Global Head, Infectious Diseases, Janssen. "The small pill size, once daily dosing and a good tolerability profile provides patients with another important treatment option for the long term management of HIV. The approval of EDURANT highlights our commitment to improve the lives of patients living with this chronic disease."

Rilpivirine is also part of Gilead Sciences' EVIPLERA[®], a complete once daily single-tablet regimen of emtricitabine 200mg/rilpivirine 25mg/tenofovir disoproxil 245mg, which also received marketing authorisation today from the European Commission for use in HIV-1 infection in ARV naïve patients with a viral load \leq 100,000 HIV-1 RNA copies/mL.

Rilpivirine was approved by the US Food and Drug Administration (FDA) in May 2011 and by the Canadian health authorities (Health Canada) in July 2011. Marketing authorisation applications have also been submitted in other countries including Russia, Japan and Switzerland.

To view the Multimedia News Release, which includes video content and backgrounders please click:

<http://www.multivu.com/mnr/52794-janssen>

About EDURANT (rilpivirine)

Rilpivirine is a NNRTI, which blocks reverse transcriptase, a key enzyme that the HIV virus uses to replicate. The marketing authorisation application for rilpivirine is based on the 48-week results of two pivotal Phase 3 double-blind, randomised studies known as ECHO (TMC278-TiDP6-C209) and THRIVE (TMC278-TiDP6-C215). The studies evaluated the efficacy, safety and tolerability of once daily rilpivirine, in combination with two N(t)RTIs, in treatment-naïve HIV-1-infected adults. Both achieved their primary objective of demonstrating non-inferiority of rilpivirine vs. efavirenz in the percentage of patients achieving an undetectable viral load (< 50 HIV-1 RNA copies/mL) at week 48.^{1,2}

The overall safety profile of EDURANT is based on the Phase 3 clinical trials.^{1,2} In the rilpivirine arm, the most frequently reported adverse drug reactions (ADRs) ($\geq 2\%$) that were at least of moderate intensity were depression (3.5%), insomnia (2.9%), headache (2.6%) and rash (2.2%).⁴ The most common AEs leading to discontinuation in the rilpivirine included psychiatric disorders (1%) and rash (0.1%).^{1,2}

Important Safety Information

Please see full Summary of Product Characteristics or visit <http://www.emea.europa.eu> for more details.

About Janssen

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology, immunology, neuroscience, infectious disease, and cardiovascular and metabolic diseases. Driven by our commitment to patients, Janssen develops innovative products, services and healthcare solutions to help people throughout the world. More information can be found at www.janssen-emea.com

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen International NV and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; trends toward health care cost containment; and increased scrutiny of the healthcare industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 2, 2011. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Janssen International NV nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.

References

1. Cohen C et al. Rilpivirine versus efavirenz with two background nucleoside or nucleotide reverse transcriptase inhibitors in treatment-naïve adults infected with HIV-1 (THRIVE): a Phase 3, randomised, non-inferiority trial. *The Lancet* 2011;378:229-237.
2. Molina J-M et al. Rilpivirine versus efavirenz with tenofovir and emtricitabine in treatment-naïve adults infected with HIV-1 (ECHO): a Phase 3 randomised double-blind active-controlled trial. *The Lancet* 2011;378:238-246.
3. Pillbox. US National Library of Medicine. <http://pillbox.nlm.nih.gov>. Accessed November 10, 2011.
4. EDURANT® (rilpivirine) Summary of Product Characteristics. Janssen-Cilag, November 2011.
5. C Cohen et al. Pooled 48-week efficacy and safety results from ECHO and THRIVE, two double-blind, randomised, Phase III trials comparing TMC278 versus efavirenz in treatment-naïve, HIV-1-infected patients. Presented at IAC 2010, Vienna.