EDURANT® (rilpivirine) Receives Positive Opinion from the Committee for Medicinal Products for Human Use (CHMP) for Use in Treatment-Naïve Adults with HIV-1

- Third HIV medication submitted by Tibotec -

Titusville, NJ, September 23, 2011 - Tibotec Pharmaceuticals (Tibotec), one of the Janssen Pharmaceutical Companies, announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the approval of EDURANT® (rilpivirine), a 25 mg tablet, 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 antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml. EDURANT is a medicinal product in the non-nucleoside reverse transcriptase inhibitor (NNRTI) class.

The CHMP positive opinion is a critical step in the approval process and will be considered by the European Commission, which has authority to approve medicines for use throughout the European Union. EDURANT was approved by the U.S. Food and Drug Administration (FDA) in May 2011 (see below for the U.S. indication and safety information) and by the Canadian Health authorities (Health Canada) in July 2011. Applications for approval have also been submitted in other countries, including Switzerland and Australia.

The positive opinion is based on 48-week analyses of ECHO and THRIVE, two phase 3 clinical trials which evaluated the efficacy, safety and tolerability of EDURANT in treatment-naïve HIV-1 adult patients in over 20 countries. The 48-week analyses of both ECHO and THRIVE were published in the 16th July 2011 edition of the *Lancet*[1, 2].

"We are committed to developing new and innovative treatment options for HIV; EDURANT will offer a further option for patients who are starting HIV combination therapy for the first time," says Wim Parys, MD, Global Head, Infectious Diseases, Janssen. "We are encouraged by this positive opinion from the CHMP and will work closely with regulatory authorities to make EDURANT available to HIV patients in Europe."

EDURANT is also combined with Gilead's TRUVADA® (emtricitabine 200mg/tenofovir disoproxil fumarate 300mg) in a once-daily single-tablet regimen, which was submitted under a separate Marketing Authorisation Application (MAA) and is currently under assessment by the EMA. The fixed dose combination of EDURANT and TRUVADA was approved by the U.S. FDA in August 2011.

Parys added: "We are pleased to partner with Gilead, one of the leading companies in the fight against HIV/AIDS, which shares our dedication to improving treatment options for people living with HIV."

About EDURANT (rilpivirine)
EDURANT is an NNRTI, which blocks reverse transcriptase, a key enzyme that the HIV virus uses to replicate. The EMA regulatory application for EDURANT is based on the 48-week results of two pivotal Phase 3 double-blind, randomized studies known as ECHO (TMC278-C209) and THRIVE (TMC278-TiDP6-C215).[2] The studies evaluated the efficacy, safety and tolerability of once-daily EDURANT, in combination with two NRTIs, in treatment-naïve HIV-1-infected adults, and both achieved their primary objective of demonstrating non-inferiority of EDURANT vs. efavirenz in the percentage of patients achieving an undetectable viral load (less than 50 copies/mL) at week 48.[2]

U.S. Indication
EDURANT is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment naïve adult patients.

This indication is based on Week 48 safety and efficacy analyses from two randomized, double-blinded, active controlled, Phase 3 trials in treatment-naïve patients and Week 96 safety and efficacy analyses from a Phase 2b trial in treatment-naïve patients.

The following points should be considered when initiating therapy with EDURANT:

- More EDURANT treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure compared to subjects with HIV-1 RNA less than 100,000 copies/mL at the start of therapy.
- The observed virologic failure rate in EDURANT treated subjects conferred a higher rate of overall treatment resistance

and cross-resistance to the NNRTI class compared to efavirenz.
- More subjects treated with EDURANT developed lamivudine/emtricitabine associated resistance compared to efavirenz.

U.S. Important Safety Information
Contraindications

- " Coadministration of EDURANT™ with the following drugs is contraindicated because significant decreases in rilpivirine plasma concentrations may occur due to CYP3A enzyme induction or gastric pH increase, which may result in loss of virologic response and possible resistance and cross-resistance: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, proton pump inhibitors such as esomeprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole, systemic dexamethasone, and products containing St. John's wort (*Hypericum perforatum*)

Warnings and Precautions

- Depressive Disorders: Severe depressive disorders, defined as depressed mood, depression, dysphoria, major depression, mood altered, negative thoughts, suicide attempt, and suicidal ideation, have been reported with EDURANT™. Immediate medical evaluation is recommended for severe depressive symptoms
- Fat Redistribution: Redistribution and/or accumulation of body fat have been observed in patients receiving antiretroviral (ARV) therapy. The causal relationship, mechanism, and long-term consequences of these events have not been established
- Immune Reconstitution Syndrome has been reported in patients treated with combination ARV therapy, including EDURANT™

Drug Interactions

- EDURANT™ should be used with caution when coadministered with drugs that may reduce the exposure of rilpivirine, such as antacids and H2-receptor antagonists
- EDURANT™ should be used with caution when coadministered with a drug with a known risk of Torsade de Pointes
- EDURANT™ should not be used in combination with NNRTIs

This is not a complete list of potential drug interactions.

Please see full Prescribing Information for more details.

Use in Specific Populations

- Hepatic Impairment: EDURANT™ should be used with caution in patients with severe hepatic impairment (Child-Pugh Class C) as pharmacokinetics of EDURANT™ have not been evaluated in these patients
- " Pregnancy Category B: EDURANT™ should be used during pregnancy only if the potential benefit justifies the potential risk. No adequate and well-controlled studies have been conducted in pregnant women

Adverse Reactions

- The most common adverse drug reactions reported (incidence >2%) of at least moderate intensity (≥ Grade 2) in patients taking EDURANT™ through 48 weeks were depressive disorders (4%), insomnia (3%), headache (3%), and rash (3%)

Please see full Prescribing Information for more details, available at:
http://www.edurant-info.com/sites/default/files/EDURANT-PI.pdf.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

About Tibotec
Tibotec Pharmaceuticals, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, is a global pharmaceutical and research development company. The Company's main research and development facilities are in Beerse, Belgium with offices in Titusville, NJ and Cork, Ireland. Tibotec is dedicated to the discovery and development of innovative HIV/AIDS and hepatitis C drugs, and anti-infectives for diseases of high unmet medical need.

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. 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 Tibotec Pharmaceuticals, any of the other Janssen Pharmaceutical Companies 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. The Janssen Pharmaceutical Companies and Johnson & Johnson do not undertake to update any forward-looking statements as a result of new information or future events or developments.

References

1. Molina J-M et al. Rilpivirine versus efavirenz with tenofovir and emtricitabine in treatment-naive adults infected with HIV-1 (ECHO): a phase 3 randomised double-blind active-controlled trial. Lancet. 2011; 378: 238-246.
2. Cohen C et al. Rilpivirine versus efavirenz with two background nucleoside or nucleotide reverse transcriptase inhibitors in treatment-naive adults infected with HIV-1 (THRIVE): a phase 3, randomised, non-inferiority trial. Lancet. 2011; 378: 229-237.