



## **FDA Accepts New Drug Application For Priority Review Of Investigational HIV Treatment TMC125**

### **The Prescription Drug User Fee Act (PDUFA) user fee goal date will be January 18, 2008**

Yardley, PA (September 20, 2007) – Tibotec Pharmaceuticals Ltd. today announced that the New Drug Application (NDA) for TMC125 (etravirine), an investigational non-nucleoside reverse transcriptase inhibitor (NNRTI), has been accepted for priority review by the United States Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) user fee goal date for the NDA for TMC125, the date by which the FDA must announce its decision regarding the application, will be Friday, January 18, 2008.

The NDA for TMC125, the first NNRTI to show antiviral activity in patients with documented NNRTI resistance, is based on the 24-week efficacy and safety results of two ongoing Phase III randomized, double-blinded, placebo-controlled studies, known as DUET-1 and DUET-2. The DUET studies examined the use of TMC125 in combination with other antiretroviral agents in adult treatment-experienced HIV-1 patients. The safety and efficacy of TMC125 in combination with other anti-retroviral agents has not been established.

TMC125 is currently available through an expanded access program (EAP) in the United States, as well as a number of European countries, Australia and Canada. The EAP provides access to TMC125 to HIV-1 infected adults, at least 18 years old, who have limited treatment options either due to virological failure or intolerance to multiple ARV regimens. Patients must be three-class experienced, having received treatment from each of the three major oral classes of anti-HIV drugs (NRTIs, NNRTIs, and PIs), unable to use currently approved NNRTIs due to resistance and/or intolerance and have received at least two PI-based regimens.

Pending U.S. regulatory approval, Tibotec Therapeutics, a division of Ortho Biotech Products, L.P., will commercialize the product in the U.S. The trade name for the marketed product has not yet been determined.

#### About Tibotec Therapeutics

Tibotec Therapeutics, a division of Ortho Biotech Products, L.P., headquartered in Bridgewater, NJ, is dedicated to delivering innovative virology therapeutics that help health care professionals address serious unmet needs in people living with HIV.

#### About Tibotec Pharmaceuticals Ltd.

Tibotec Pharmaceuticals Ltd., based in Cork, Ireland, is a pharmaceutical research and development company. The Company's main research and development facilities are in Mechelen, Belgium, with offices in Yardley, PA. Tibotec is dedicated to the discovery and development of innovative HIV/AIDS drugs and anti-infectives for diseases of high unmet medical need.

Ortho Biotech Products, L. P. and Tibotec Pharmaceuticals Ltd. are subsidiaries of Johnson & Johnson.

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 Company's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, 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; and trends toward health care cost containment. 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 December 31, 2006. Copies of this Form 10-K, as well as subsequent filings, are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from the Company. The Company does not undertake to update any forward-looking statements as a result of new information or future events or developments.