Tibotec Pharmaceuticals Seeks European Marketing Authorization for Investigational Once-Daily HIV Treatment TMC278

Cork, Ireland 3 September, 2010 - Tibotec Pharmaceuticals today announced its submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for TMC278 (rilpivirine, as hydrochloride), an investigational non-nucleoside reverse transcriptase inhibitor (NNRTI) for the treatment of HIV. The proposed indication would make TMC278 available for once-daily use with other antiretroviral agents in treatment-naïve HIV-1-infected adults.

It is estimated that 33.4 million people are living with HIV worldwide,[1] 2.3 million of which are in Europe.[2] Research shows that antiretrovirals have helped to extend life expectancy for people living with HIV.[3] However, new treatments are needed which suppress the replication of the virus while also minimizing the occurrence of unwanted side effects.[4]

The TMC278 filing is based on an extensive global clinical development programme involving more than 1,350 patients[5] in over 20 countries. If approved, TMC278 would help to expand the treatment options for people living with HIV.

"Thanks to advances in treatment, people with HIV are living longer than ever before, which is made possible by continuous research for new and improved treatments," said Eric Lefebvre, Medical Director at Tibotec. "The EMA regulatory submission for TMC278 represents an important part of our ongoing commitment to HIV and to helping patients receive the treatment and care they need."

Pending EMA approval, Tibotec will commercialize TMC278 in the European Union. Tibotec has also submitted new drug applications in the US and Canada, and regulatory submissions for TMC278 in other countries are expected in the coming months. Tibotec has entered into a license and collaboration agreement with Gilead Sciences, Inc. (Nasdaq: GILD) for the development and commercialization of a once-daily fixed-dose combination of TMC278 and Gilead's Truvada® (emtricitabine and tenofovir disoproxil (as fumarate)).

About TMC278
TMC278 is an investigational NNRTI, which blocks the reverse transcriptase, a key enzyme the HIV virus uses to replicate. The regulatory application for TMC278 is based on the 48-week results of two pivotal Phase 3 double-blind, randomized studies recently presented at the International AIDS Congress, known as ECHO (TMC278-TiDP6-C209) and THRIVE (TMC278-TiDP6-C215).[5] The studies evaluated the efficacy, safety and tolerability of once-daily TMC278, in combination with two NRTIs, in treatment-naïve HIV-1-infected adults, and both reached their primary objective of demonstrating non-inferiority of TMC278 vs. efavirenz in the percentage of patients achieving an undetectable viral load (less than 50 copies/mL) at week 48 (with a maximum allowable difference of 12 percent).[5] The studies showed that TMC278 demonstrated significant improvements in tolerability, with lower rates of discontinuations due to adverse events including dizziness, abnormal dreams and nightmares, and rashes.[5]

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

About Tibotec, a division of Janssen-Cilag
Tibotec, a division of Janssen-Cilag, brings innovative products for HIV/AIDS to patients in Europe, the Middle East and Africa focusing on patients' and healthcare providers' specific needs in this disease domain. The company will also commercialise medicines to combat other viral diseases in the future.

About Janssen-Cilag
Janssen-Cilag is a leader in traditional and biological medicines in areas such as gastroenterology, women's health, mental health and neurology as well as for pain, oncology, haematology and nephrology.

Tibotec Pharmaceuticals and Janssen-Cilag are subsidiaries of the Johnson & Johnson family of companies.

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