



TMC278 Pivotal Phase 3 Clinical Trials Achieve Primary Objective

Data on investigational, once-daily TMC278, the third antiretroviral compound developed by Tibotec Pharmaceuticals, presented at International AIDS Conference

VIENNA, July 22 /PRNewswire/ -- Tibotec Pharmaceuticals announced today results from two pivotal Phase 3, double-blind, randomized clinical trials comparing the efficacy, safety and tolerability of its investigational non-nucleoside reverse transcriptase inhibitor (NNRTI) TMC278 (rilpivirine) versus efavirenz (EFV), each administered once daily with a nucleoside/nucleotide background regimen in treatment-naive, HIV-1-infected adults. These global trials, known as ECHO and THRIVE, reached their primary objective, which was to demonstrate non-inferiority of TMC278 vs. EFV in the proportion of patients achieving an undetectable viral load (less than 50 copies/mL) at week 48 (with a maximum allowable difference of 12 percent). A pooled analysis of ECHO and THRIVE was presented today at the XVIII International AIDS Conference in Vienna, Austria.

ECHO and THRIVE pooled results showed that 84.3 percent of patients (n=686) in the TMC278 group reached an undetectable viral load, compared with 82.3 percent of patients (n=682) in the EFV group. The difference between the treatment groups was not significant. Patients received TMC278 (25 mg) or EFV (600 mg), each administered once daily in combination with a nucleoside/nucleotide background regimen. The virologic failure rate was 9 percent in the TMC278 group and 4.8 percent in the EFV group.

TMC278 is an investigational product, and the safety and efficacy has not yet been established. Tibotec plans to submit these results to the U.S. Food and Drug Administration (FDA) to support approval of TMC278 for use in treatment-naive adult patients.

"I'm very excited by the findings of these Phase 3 results for TMC278," said Calvin J. Cohen, M.D., M.Sc., lead clinical investigator and Research Director at Community Research Initiative of New England and Harvard Vanguard Medical Associates. "These studies provide valuable information on the safety and tolerability of TMC278 and, specifically, its metabolic and CNS side effect profiles."

Adverse events (AEs) leading to discontinuation in the TMC278 group were 3.4 percent compared to 7.6 percent in the EFV group, and Grade 2-4 AEs at least possibly related to treatment were 15.9 percent in the TMC278 group versus 31.1 percent in the EFV group. Grade 2-4 AEs of interest by organ class reported among patients in the TMC278 group versus the EFV group were psychiatric (14.9 percent vs. 22.7 percent), neurological (17.1 percent vs. 37.8 percent) and rash-all types (3.1 percent vs. 13.6 percent). Grade 3/4 lipid abnormalities were also reported among patients in the TMC278 group versus the EFV group for increases in total cholesterol (0.1 percent vs. 2.5 percent), LDL-cholesterol (0.7 percent vs. 4.1 percent) and triglycerides (0.3 percent vs. 2.2 percent).

About ECHO and THRIVE

ECHO (TMC278-TiDP6-C209) and THRIVE (TMC278-TiDP6-C215) are pivotal Phase 3, double-blind, randomized studies that evaluated the efficacy, safety and tolerability of TMC278 in 1,368 treatment-naive, HIV-1-infected adults. ECHO (Efficacy Comparison in treatment-naive HIV-infected subjects Of TMC278 and EFV) evaluated TMC278 (25 mg) once daily, versus EFV (600 mg) once daily, combined with a fixed background regimen consisting of emtricitabine + tenofovir disoproxil fumarate. THRIVE (TMC278 against HIV, in a once daily Regimen Versus Efavirenz) evaluated TMC278 (25 mg) once daily versus EFV (600 mg) once daily, combined with an investigator-selected background regimen consisting of two N[t]RTIs (abacavir + lamivudine or emtricitabine + tenofovir disoproxil fumarate or zidovudine + lamivudine).

Each study is being conducted at more than 100 sites, in more than 20 countries. The studies will last for a total of 104 weeks, which includes a four-week screening period, a 96-week treatment period and a four-week follow-up period.

Tibotec Pharmaceuticals plans to file the 48-week findings from ECHO and THRIVE with the FDA when seeking marketing authorization for TMC278. Pending approval, Tibotec Therapeutics will commercialize TMC278 in the United States. Tibotec has also 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 200 mg/tenofovir disoproxil fumarate 300 mg).

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 Therapeutics

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

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

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