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First New NNRTI in Nearly a Decade to Benefit Canadians with HIV/AIDS

~ INTELENCE (etravirine) for HIV combination therapy is the first new NNRTI to work for patients who have developed NNRTI-resistance ~*

TORONTO, ON, April 1, 2008 – Canadians living with HIV/AIDS now have a new prescription treatment option, with the recent approval of INTELENCE* (etravirine, also known as TMC125) from Tibotec, a division of Janssen-Ortho Inc. INTELENCE is the newest member of the family of AIDS-fighting drugs known as non-nucleoside reverse transcriptase inhibitors (NNRTI), and is the first new NNRTI to be introduced in nearly 10 years. Prior to approval, INTELENCE was granted priority review status by Health Canada. Health Canada applies priority status to New Drug Submission (NDS) for a serious, life-threatening or severely debilitating disease or condition for which a new drug demonstrates the potential to address an unmet medical need.¹

“It is important for me to share the benefits that a new therapy can bring to the lives of HIV/AIDS patients who are often faced with complicating side effects and deteriorating health,” says Yves Brunet, a Canadian living with HIV/AIDS. “Since my diagnosis in 1986, I have developed various resistances to drug regimens. The last time this happened, my physician added a drug which is now called INTELENCE to my treatment regimen and it has greatly improved my health and sense of well-being.”

INTELENCE is the first NNRTI to show antiviral activity (viral load (VL) decreases) in treatment-experienced adult patients with HIV who have failed prior therapies.^{2,3} “The approval of INTELENCE is an important development, as it is common for patients, like me, to build resistance to existing HIV medicines,” says Yves. “It is comforting to know that there are still options available.”

INTELENCE, in combination with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in treatment-experienced adult patients who have failed prior therapy and have HIV-1 strains resistant to multiple antiretroviral agents, including NNRTIs.

As part of a combination therapy, INTELENCE must be taken with other anti-HIV medicines in patients who have already taken anti-HIV medicine that did not control their HIV infection. When used with other anti-HIV medicines, INTELENCE works to reduce a patient’s VL and increase the number of white blood cells known as CD4 cells that help fight off other infections. Reducing the amount of HIV and increasing the CD4-cell count may improve a patient’s immune system, leading to improved health.⁴

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FIRST NEW NNRTI IN NEARLY A DECADE TO BENEFIT CANADIANS WITH HIV/AIDS/2

The NNRTI Class

NNRTIs block reverse transcriptase, a key enzyme the HIV virus uses to replicate. NNRTI drug resistance occurs when HIV develops mutations that partially or completely stop the NNRTI from binding to the reverse transcriptase enzyme, causing the drug to lose effectiveness.

DUET-1 and -2 Study Design^{2,3}

The approval of INTELENCE is based on the 24-week analysis of HIV viral load and CD4+ cell counts from the pooled analysis of the Phase 3 DUET-1 and -2 studies. The DUET-1 and -2 studies, identical in design but conducted in different regions, assessed the 24-week efficacy and safety of INTELENCE in combination with a background regimen (BR), which included PREZISTA* (darunavir), in treatment-experienced adult HIV-1 patients with documented evidence of NNRTI and protease inhibitor (PI) resistance. They were large randomized, controlled studies with a primary endpoint of VL less than 50 copies/mL (known as undetectable viral load). IAS-USA treatment guidelines define VL less than 50 copies/mL as the goal of therapy for treatment-experienced patients when two or more potent drugs are used in the treatment regimen.

Patients with HIV-1 who were eligible for the DUET studies had a VL of greater than 5,000 copies/mL, while on a stable antiretroviral therapy regimen for at least eight weeks and had evidence of at least one NNRTI resistance-associated mutation, either at screening or from prior resistance tests, as well as evidence of three or more primary PI mutations at screening.

In treatment-experienced patients with NNRTI-resistance, treatment with INTELENCE achieved greater VL reductions at week 24 than did placebo. The most commonly reported adverse drug reactions with INTELENCE identified from the pooled DUET 1 and 2 trials were rash (all types), diarrhea and nausea.⁵

INTELENCE does not cure HIV infection or AIDS, and does not prevent passing HIV to others.

About HIV/AIDS

Canada's first diagnosed AIDS case occurred in 1982, and the first death due to the disease occurred in 1983. Since then, 21,000 Canadians infected with HIV/AIDS have died;⁶ however, the number of positive AIDS diagnoses reported in 2006 have decreased from 498 in 2000 to 255.⁷ Given this decline, it's important to reflect just how far treatment advancements have come in managing the disease.

Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs) were introduced in 1987 as the first type of antiretroviral drug available to treat HIV infection. NRTIs interfere with the action of reverse transcriptase (an HIV protein) which the virus needs to make new copies of itself.⁸ From 1988 to the early 1990's, drug advancements focused on treating various HIV/AIDS complications, such as infections and weight loss.⁹ Significant breakthroughs occurred in the late 1990s, with the introduction of a new class of treatments called protease inhibitors (PI). PIs inhibit HIV-1 protease thereby preventing the formation of mature infectious virus particles.¹⁰

FIRST NEW NNRTI IN NEARLY A DECADE TO BENEFIT CANADIANS WITH HIV/AIDS /3

Approved in 1997, was the first of another class of antiretroviral drugs known as Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs), which stop HIV from replicating within cells by inhibiting the reverse transcriptase protein.¹¹

TIBOTEC – DIVISION OF JANSSEN-ORTHO INC.

Tibotec, a division of Janssen-Ortho Inc., is dedicated to delivering innovative virology therapeutics that improve Canadian patients' survival and quality of life and that address serious unmet healthcare needs.

- 30 -

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¹www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/priorit/prioridr_2006_e.html

²Lazzarin A, Campbell T, Clotet B, Johnson M, Katlama C, Moll A et al. Efficacy and safety of TMC125 (etravirine) in treatment-experienced HIV-1-infected patients in DUET-2: 24-week results from a randomised, double-blind, placebo-controlled trial. *Lancet* 2007; 370(9581):39-48.

³Madruca JV, Cahn P, Grinsztejn B, Haubrich R, Lalezari J, Mills A et al. Efficacy and safety of TMC125 (etravirine) in treatment-experienced HIV-1-infected patients in DUET-1: 24-week results from a randomised, double-blind, placebo-controlled trial. *Lancet* 2007; 370:29-38.

⁴Patient Information INTELENCE™, Tibotec Pharmaceuticals Ltd.

⁵INTELENCE Product Monograph, Janssen-Ortho Inc., 2008

⁶Public Health Agency of Canada "A Brief History of HIV/AIDS in Canada." www.phac-aspc.gc.ca/aids-sida/ingo/1_e.html. Her Majesty the Queen in Right of Canada, represented by the Minister of Health (2007). Sited on October 25, 2007.

⁷Public Health Agency of Canada, "HIV and AIDS in Canada: Surveillance Report to December 31, 2006." <http://www.phac-aspc.gc.ca/aids-sida/publication/survreport/pdf/survrep1206.pdf>. Her Majesty the Queen in Right of Canada, represented by the Minister of Health (2007). Sited on October 24, 2007.

⁸<http://www.avert.org/introtrt.htm>, sited on March 11, 2008.

⁹U.S. Food and Drug Administration, <http://www.fda.gov/oashi/aids/miles.html>, sited on October 24, 2007.

¹⁰U.S. Food and Drug Administration, <http://www.fda.gov/oashi/aids/miles95.html>, sited on October 24, 2007.

¹¹<http://www.avert.org/introtrt.htm>, sited on March 11, 2008.