

FOR IMMEDIATE RELEASE

Health Canada Approves ISENTRESS™ (raltegravir) Only drug to inhibit Integrase Enzyme

Montreal, QC, November 30th, 2007 - Merck Frosst announced today that Health Canada granted a Notice of Compliance with Conditions (NOC/c) to ISENTRESS™ (raltegravir) for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents.¹ It has been issued marketing authorization with conditions, pending the results of studies to verify its clinical benefit. Patients should be advised of the nature of this authorization.

A Notice of Compliance with Conditions reflects the promising nature of the clinical evidence in patients with this serious disease and the need for further follow up to verify the clinical benefits. The NOC/c is based on an analysis of clinical trials in which raltegravir, in combination with other antiretroviral agents, was shown to be effective at reducing viral load and increasing CD4 cell counts, the two most widely recognized measures of efficacy against HIV/AIDS infection.^{1,5}

Now available in Canada, raltegravir is the first medicine to be approved in a new class of antiretroviral drugs called integrase inhibitors.^{1,2} Raltegravir works by inhibiting the insertion of HIV DNA into human DNA by the integrase enzyme.¹ Inhibiting integrase from performing this essential function limits the ability of the virus to replicate and infect new cells.³ There are drugs in use that inhibit two other enzymes critical to the HIV replication process – protease and reverse transcriptase – but raltegravir is the only drug approved that inhibits the integrase enzyme.^{4,2} Raltegravir is administered as a single 400 mg tablet taken twice daily with or without food with other HIV medications. Raltegravir does not require boosting with ritonavir, which can be associated with adverse side effects.

Resistance to current therapies is one of the leading challenges to treating HIV. "ISENTRESS™ will definitively play an important role in the management of patients who have developed resistance against first line therapies and furthermore will be welcomed by physicians and patients because it is effective, well tolerated and has few side effects," said Dr. Mark Wainberg, Director, McGill AIDS Centre and Professor of Medicine and Microbiology at McGill University. "ISENTRESS™ can make a difference in the lives of many patients who can no longer be adequately treated by traditional therapies."

Clinical Data support

Data from two Phase III multi-centre, double-blind, randomized, placebo-controlled studies (BENCHMRK-1 and BENCHMRK-2) in 699 treatment-experienced adult patients with documented resistance to at least one drug in each of three classes (NRTIs, NNRTIs and PIs) of antiretroviral therapies showed that raltegravir 400 mg dosed twice daily in combination with optimized background therapy (OBT) was significantly ($p < 0.001$) more effective at both reducing levels of HIV viral RNA and increasing CD4 cell counts in these patients living with HIV, when compared to a regimen of placebo plus OBT.¹

Pooled analyses from the two Phase III studies showed that after 24 weeks of therapy, 75.5 percent of patients (216 out of 286) receiving raltegravir in combination with OBT achieved HIV

viral RNA load reduction to below 400 copies/mL compared to 39.3 percent of patients (59 out of 150) receiving placebo plus OBT.¹ In addition, after 24 weeks of therapy, 62.6 percent of patients (179 out of 286) receiving raltegravir plus OBT achieved viral load reduction to below 50 copies/mL compared to 33.3 percent of patients (50 out of 150) receiving placebo plus OBT. After 24 weeks of therapy, increases in CD4 cell counts from baseline were 89 and 35 cells/mm³ for patients receiving raltegravir plus OBT and for those receiving placebo plus OBT, respectively.¹ These efficacy results were supported by the 48 week analysis of a randomized, double-blind, controlled, dose-ranging trial in antiretroviral treatment-experienced HIV-1 infected patients.¹

"Raltegravir is an important new advance in the treatment of HIV/AIDS, because it is the first therapy in a new class of drugs that attacks the virus in a completely different way, said Dr. François Bertrand, Executive Director, Medical at Merck Frosst. "This approval builds on our long standing commitment to research in HIV/AIDS, with the goal of making truly differentiated therapies available to patients in need. This is another tangible example of Merck's overall commitment to discover and market new medications which address truly unmet medical needs."

Tolerability profile of raltegravir

The safety assessment of raltegravir in treatment-experienced patients is based on the pooled safety data from three randomized clinical studies in treatment-experienced patients taking 400 mg of raltegravir dosed twice daily plus OBT or placebo plus OBT. The most commonly reported adverse experiences (>10% in either group) of all intensities and regardless of causality were diarrhea in 16.6% and 19.5%, nausea in 9.9% and 14.2%, headache in 9.7% and 11.7%, pyrexia in 4.9% and 10.3% of patients, respectively.¹

Access program

ISENTRESS™ was provided to more than 400 Canadians through a special access program by Health Canada.

Our Commitment to HIV research

We are committed to developing innovative therapies that offer advances in the treatment of infectious diseases – including HIV. The Company's efforts to develop investigational treatments for HIV/AIDS have been under way for more than 20 years and continue today. We began our HIV integrase inhibitor research in 1993 and were the first to demonstrate inhibition of HIV integrase *in vitro* and *in vivo*.

Raltegravir is one part of our history in HIV research, which includes the development of CRIVAN® (indinavir sulfate), a PI; STOCRIN®⁺ (efavirenz), an NNRTI; and research currently underway on additional treatment options.

About Merck Frosst

At Merck Frosst, patients come first. Merck Frosst Canada Ltd. is a research-driven pharmaceutical company discovering, developing and marketing a broad range of innovative medicines and vaccines to improve human health. Merck Frosst is one of the top 20 R&D investors in Canada, with an investment of \$114 million in 2006. More information about Merck Frosst is available at <http://www.merckfrosst.com>

Forward-looking statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements

regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the cautionary statements in Item 1 of Merck's Form 10-K for the year ended Dec. 31, 2006, and in its periodic reports on Form 10-Q and Form 8-K, which the Company incorporates by reference.

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† In Canada STOCRIN® is marketed as SUSTIVA by BMS

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Thursday at 2:35 pm and Friday at 10 am
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