



FOR IMMEDIATE RELEASE

Media Contacts: Amy Rose
(908) 423-3786

Investor Contact: Graeme Bell
(908) 423-5185

Lynn Kenney
(908) 423-4188

FDA Approves ISENTRESS™ (raltegravir) Tablets, First-in-Class Oral HIV-1 Integrase Inhibitor

WHITEHOUSE STATION, N.J., October 12, 2007 -- Merck & Co., Inc., announced today that the U.S. Food and Drug Administration (FDA) granted ISENTRESS™ (raltegravir) tablets accelerated approval 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.

This indication is based on analyses of plasma HIV-1 RNA levels up through 24 weeks in two controlled studies of ISENTRESS [pronounced i-sen-tris]. These studies were conducted in clinically advanced, three-class antiretroviral [nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs)] treatment-experienced adults. The use of other active agents with ISENTRESS is associated with a greater likelihood of treatment response. The safety and efficacy of ISENTRESS have not been established in treatment-naïve adult patients or pediatric patients. There are no study results demonstrating the effect of ISENTRESS on clinical progression of HIV-1 infection. Longer term data will be required before the FDA can consider traditional approval for ISENTRESS.

ISENTRESS is the first medicine to be approved in a new class of antiretroviral drugs called integrase inhibitors. ISENTRESS works by inhibiting the insertion of HIV DNA into human DNA by the integrase enzyme. Inhibiting integrase from performing this essential function limits the ability of the virus to replicate and infect new cells. There are drugs in use that inhibit two other enzymes critical to the HIV replication process – protease and reverse transcriptase – but ISENTRESS is the only drug approved that inhibits the integrase enzyme.

The FDA's decision was based on a 24-week analysis of clinical trials in which ISENTRESS in combination with optimized background therapy (OBT) in treatment-experienced patients, provided significant reductions in HIV RNA viral load and increases in CD4 cell counts.

"The development of ISENTRESS is a significant milestone in the history of HIV/AIDS therapy because we now have a drug that's potent against another key enzyme essential for viral replication,"

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said Joseph J. Eron Jr., M.D., professor of medicine, Division of Infectious Diseases, UNC Chapel Hill School of Medicine. "It's important for physicians to know that ISENTRESS should always be used in combination with other active agents."

Data from two ongoing Phase III multi-center, 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 ISENTRESS 400 mg dosed twice daily in combination with OBT was significantly 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.

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 ISENTRESS 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. In addition, after 24 weeks of therapy, 62.6 percent of patients (179 out of 286) receiving ISENTRESS 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 ISENTRESS plus OBT and for those receiving placebo plus OBT, respectively.

Important safety information about ISENTRESS

ISENTRESS does not cure HIV or AIDS and does not prevent passing HIV to others. Healthcare providers should know that immune reconstitution syndrome has been reported in patients treated with antiretroviral therapy, which may necessitate further evaluation and treatment.

The most commonly reported adverse experiences of any severity (mild, moderate or severe) regardless of drug relationship were diarrhea (16.6 percent vs. 19.5 percent), nausea (9.9 percent vs. 14.2 percent), headache (9.7 percent vs. 11.7 percent) and fever (4.9 percent vs. 10.3 percent) for ISENTRESS plus OBT and placebo plus OBT, respectively.

Creatine kinase elevations were observed in subjects who received ISENTRESS. Myopathy and rhabdomyolysis have been reported; however, the relationship of ISENTRESS to these events is not known. ISENTRESS should be used with caution in patients at increased risk of myopathy or rhabdomyolysis, such as patients receiving concomitant medication known to cause these conditions.

Safety and tolerability profile of ISENTRESS

Results from pooled safety analyses from three separate studies in treatment-experienced patients taking 400 mg of ISENTRESS dosed twice daily plus OBT or placebo plus OBT showed that after 24 weeks of therapy the rates of discontinuation of therapy due to adverse experiences were 2.0 percent in patients receiving ISENTRESS plus OBT and 1.4 percent in patients receiving placebo plus OBT. In addition, drug-related clinical adverse events of moderate to severe intensity occurring in greater than or equal to 2.0 percent of patients were diarrhea (3.7 percent vs. 4.6 percent), nausea (2.2 percent vs. 3.2 percent) and headache (2.4 percent vs. 1.4 percent) for ISENTRESS plus OBT and placebo plus OBT, respectively.

Drug interactions

Based on the results of drug interaction studies and the clinical trials data, no dose adjustment of ISENTRESS is required when coadministered with other antiretroviral agents. Also, preclinical studies show that ISENTRESS is not metabolized by cytochrome P450 enzymes. Caution should be used when coadministering ISENTRESS with strong inducers of uridine diphosphate glucuronosyltransferase (UGT) 1A1 (e.g., rifampin) due to reduced plasma concentrations of ISENTRESS.

About ISENTRESS

ISENTRESS is a single 400 mg tablet taken twice daily without regard to food. ISENTRESS does not require boosting with ritonavir.

Merck has worked closely with the HIV community regarding the price of ISENTRESS. The wholesale acquisition cost (WAC) of ISENTRESS will be \$27 per day, comparable to the price of several available ritonavir-boosted protease inhibitors.

To help patients in the United States who cannot afford treatment with ISENTRESS, the SUPPORT™ program is available. The SUPPORT program is a patient assistance program to help patients who have been prescribed ISENTRESS by providing personalized support and patient advocacy regarding individual reimbursement issues. In addition, Merck also participates in the Partnership for Prescription Assistance program, a single point of access to more than 475 public and private patient assistance programs. ISENTRESS will be available in pharmacies in approximately two weeks. For more information on ISENTRESS, visit www.isentress.com.

Expanded access program

ISENTRESS is currently available worldwide to qualified patients through an expanded access clinical research program, EARMRK. This global program provides early access to ISENTRESS for patients failing current therapy whose HIV is resistant to drugs in three existing classes (NRTIs, NNRTIs, PIs) of antiretroviral medications. Information about the program can be found at www.benchmrk.com.

Merck HIV research

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

Prevalence of HIV/AIDS

In 2006, over one million Americans were living with HIV/AIDS and it is estimated that approximately 40,000 new cases of HIV/AIDS are diagnosed each year in the United States. Worldwide, an estimated 40 million people are infected with HIV/AIDS, and more than four million new infections occurred in 2006.

"As the AIDS crisis continues, new drugs like ISENTRESS are needed, which target the virus in unique ways," said Ben Cheng, deputy director, Forum for Collaborative HIV Research. "The HIV Advocacy Community is really excited and encouraged by this new treatment."

SUPPORT™ is a trademark of Merck & Co., Inc.

About Merck

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck currently discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit www.merck.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 risk factors and cautionary statements in Item 1A 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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Full prescribing information and patient product information for ISENTRESS™ is attached.