



News Release

FOR IMMEDIATE RELEASE

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Merck Reports Initial Results of Phase III Study of ISENTRESS[®] (raltegravir) Investigational Once-Daily Dosing in Treatment-Naïve Adult Patients Infected with HIV-1

WHITEHOUSE STATION, N.J., Nov. 29, 2010 – Merck today reported initial results from the Phase III study investigating the efficacy and safety of a treatment regimen including ISENTRESS[®] (raltegravir) Tablets once daily in treatment-naïve adult patients infected with HIV-1. ISENTRESS is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve and treatment-experienced adults. In the study, although the treatment regimen that included ISENTRESS once daily enabled more than 80 percent of patients to achieve viral suppression, ISENTRESS once daily did not demonstrate non-inferiority to the treatment regimen that included ISENTRESS twice daily. Merck said that based on the initial results, and following the recommendation of an independent Data Monitoring Committee, Merck will end the study. Merck is notifying clinical investigators of this decision this week and is recommending that patients enrolled in the once-daily dosing arm of the study be switched to ISENTRESS twice daily, the FDA-approved dose. Results from this study will be submitted for presentation at an appropriate scientific meeting in 2011.

This Phase III study evaluated the safety and efficacy of an investigational once-daily dose of raltegravir (800 mg once daily) versus the approved twice-daily dose (400 mg twice daily), each given in combination with a once-daily fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate¹, in adult treatment-naïve HIV-1-infected patients. In this study, 775 patients were randomized, and 770 patients received study drug and are included in the current analyses. After 48 weeks in the study, 83.2 percent (n=318/382) of patients receiving the regimen including ISENTRESS once daily achieved undetectable viral levels (HIV-RNA <50 copies/mL), compared to 88.9 percent (n=343/386) of patients receiving the regimen including ISENTRESS twice daily. The treatment difference between the 800 mg once daily group and 400 mg twice daily group was -5.7 percent, with an associated 95 percent confidence interval (CI) of (-10.7 percent, -0.83 percent). The difference did not meet the pre-defined statistical criteria for non-inferiority.

The overall treatment difference observed between the once-daily and twice-daily groups was primarily due to results in patients with high viral load. Among patients with more than 100,000 copies/mL of HIV-RNA, 74.3 percent (n=113/152) of those in the once-daily group achieved viral suppression compared to 84.2 percent (n=128/152) of those in the twice-daily group. The safety and tolerability

ISENTRESS[®] is a registered trademark of Merck & Co., Inc., Whitehouse Station, N.J., USA.

profiles of the two regimens were similar in the study, and were consistent with current labeling for ISENTRESS.

About ISENTRESS

ISENTRESS is Merck's integrase inhibitor for the treatment of HIV-1 infection in treatment-naïve and treatment-experienced adult patients. ISENTRESS currently is the only approved integrase inhibitor for the treatment of HIV-1. The label for ISENTRESS is based on analyses of plasma HIV-1 RNA levels through 96 weeks in three double-blind controlled clinical studies of ISENTRESS. Two of these studies were conducted in clinically advanced, three-class antiretroviral (ARV) [non-nucleoside reverse transcriptase inhibitor (NNRTI), nucleoside reverse transcriptase inhibitor (NRTI), protease inhibitor (PI)] treatment-experienced adults and one was conducted in treatment-naïve adults. The safety and efficacy of ISENTRESS have not been established in pediatric patients. The use of other active agents with ISENTRESS is associated with a greater likelihood of treatment response.

ISENTRESS is the first medicine to be approved in a class of antiretroviral drugs called integrase inhibitors. ISENTRESS works by inhibiting the insertion of HIV-1 DNA into human DNA by the integrase enzyme and has demonstrated rapid antiviral activity. Inhibiting integrase from performing this essential function limits the ability of the virus to replicate and infect new cells. Other HIV-1 drugs in use inhibit two other enzymes critical to the HIV-1 replication process – protease and reverse transcriptase – but ISENTRESS is the only approved drug that inhibits the integrase enzyme. ISENTRESS is now approved in more than 90 countries worldwide. Merck is continuing to move forward with filings in additional countries around the world for use of ISENTRESS in both treatment-experienced and treatment-naïve HIV-infected patients.

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 ARV therapy, which may necessitate further evaluation and treatment.

Creatine kinase elevations were observed in subjects who received ISENTRESS. Myopathy and rhabdomyolysis have been reported. 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.

The most commonly reported drug-related adverse event (AE) of moderate to severe intensity that occurred in greater than or equal to 2 percent of patients and at a higher incidence than efavirenz in treatment-naïve patients receiving ISENTRESS was insomnia (4 percent versus 3 percent, respectively).

The most commonly reported (greater than or equal to 2 percent in either treatment group) drug-related clinical AE of moderate or severe intensity in treatment-experienced patients receiving ISENTRESS and at a higher rate compared to placebo was headache (2 percent vs. less than 1 percent) for ISENTRESS plus optimized background therapy (OBT) and placebo plus OBT, respectively.

In treatment-experienced patients, rash occurred more often in patients taking ISENTRESS and darunavir together than with either drug separately. Rashes were mild to moderate in severity and did not limit therapy. There were no discontinuations due to rash.

Dosing and administration

ISENTRESS is a single 400 mg tablet taken twice daily without regard to food. The dose of ISENTRESS should be increased during coadministration with rifampin to 800 mg twice daily.

Drug interactions

Coadministration with strong inducers of uridine diphosphate glucuronosyltransferase (UGT) 1A1 may reduce plasma concentrations of ISENTRESS. Rifampin, a strong inducer of (UGT) 1A1 reduces plasma concentrations of ISENTRESS. Based on the results of drug interaction studies and the clinical trials data, no dose adjustment of ISENTRESS is required when coadministered with other ARV agents. Also, preclinical studies show that ISENTRESS is not metabolized by cytochrome P450 enzymes.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com.

Merck Forward Looking Statement

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. The forward-looking statements may include statements regarding product development, product potential, the company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the impact of pharmaceutical industry regulation and health care legislation; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the United States and internationally and the exposure to litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2009 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

Before prescribing ISENTRESS® (raltegravir) Tablets, please read the attached full prescribing information, which also is available at http://www.merck.com/product/usa/pi_circulars/i/isentress/isentress_pi.pdf, and the attached patient information, which also is available at http://www.merck.com/product/usa/pi_circulars/i/isentress/isentress_ppi.pdf.

¹ The once-daily fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate is marketed as TRUVADA, a registered trademark of Gilead Sciences, Inc. Please see the TRUVADA product insert for information on this product.