



## STATEMENT

---

### **Merck Statement on New Access Initiative to Provide ISENTRESS<sup>®</sup> (raltegravir) Tablets to Patients in Low-Income Countries and Sub-Saharan Africa**

WHITEHOUSE STATION, N.J., June 9, 2011 – For more than 25 years, Merck has been at the forefront of the HIV/AIDS epidemic by researching and developing breakthrough medicines, helping to ensure broad access to our antiretroviral therapies and participating in partnerships that help address healthcare challenges around the world. Merck is committed to HIV research and development, and our current efforts include ongoing basic research on HIV neutralizing antibodies, programs to develop novel HIV prevention technologies, new HIV antiretroviral medicines and new drugs targeting HIV latency.

Through our long-standing efforts to address the threat of HIV/AIDS to global health, Merck has learned valuable lessons about barriers to treatment access – barriers that extend beyond the price of medicines.

Drawing on these learnings and building on past efforts to facilitate access in under-resourced communities overseas, Merck is implementing a new, sustainable business model to bring ISENTRESS<sup>®</sup> (raltegravir) Tablets to patients in the poorest countries and those hardest hit by HIV/AIDS (all Low-Income and all sub-Saharan African countries). This model includes:

- A commitment to maintain a local presence and investment in sub-Saharan Africa  
Merck will actively engage with local healthcare professionals, non-governmental organizations (NGOs) and the HIV/AIDS community to better understand their specific challenges. In particular, we will support medical education programs to help ensure the appropriate use of our medicines.

Merck will continue to support clinical research to further study the best use of our HIV medicines, specifically in these resource-limited settings.

- A new approach for reducing the price of ISENTRESS to improve affordability for all Low-Income and all sub-Saharan African countries  
Merck has worked with generic suppliers to establish a reliable, low-cost supply chain covering these territories for ISENTRESS that maintains the same quality standards we demand for all of Merck's medicines. This will allow us to implement a new, reduced access price for ISENTRESS in July 2011 in all sub-Saharan African and all Low-Income countries.

In addition, Merck has granted two non-exclusive voluntary licenses for ISENTRESS covering these territories to generic manufacturers in India that have a track record of delivering quality medicines.

Merck will continue to partner with qualified generic manufacturers on a case-by-case basis to increase the low-cost supply chain and ensure quality manufacturing of ISENTRESS for use in these countries.

Outside these countries, Merck is committed to facilitating access to ISENTRESS in middle-income countries through the implementation of a differential pricing policy mainly based on country income and disease burden, and through the development of country-specific models.

Merck's engagement in HIV/AIDS globally is part of our broader commitment to addressing the health needs of the developing world and making access to health a guiding principle of the way we conduct business.

We are proud of our long-standing history of bringing critical medicines to patients in need. We look forward to continued partnerships with the global HIV and public health communities as we work together to address the challenges of the HIV/AIDS epidemic.

### **About ISENTRESS**

ISENTRESS is indicated in combination with other antiretroviral (ARV) agents for the treatment of HIV-1 infection in treatment-naïve and treatment-experienced adults. 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 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. 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 common adverse reactions of moderate to severe intensity<sup>1</sup> (greater than or equal to two percent) that occurred at a higher rate than the comparator were insomnia in treatment-naïve patients and headache in treatment-experienced patients.

<sup>1</sup>Intensities were defined as follows: Moderate (discomfort enough to cause interference with usual activity); or Severe (incapacitating with inability to work or do usual activity).

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](http://www.merck.com).

## **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. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined 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 possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; 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 U.S. 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 2010 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](http://www.sec.gov)).

###

Before prescribing ISENTRESS (raltegravir) Tablets, please read the attached prescribing information, which also is available at: [http://www.merck.com/product/usa/pi\\_circulars/i/isentress/isentress\\_pi.pdf](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](http://www.merck.com/product/usa/pi_circulars/i/isentress/isentress_ppi.pdf).

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

---