

#### NEWS RELEASE

## Jan7Merck and the ADAP Crisis Task Force Announce New Agreement to Improve Access and Care for People with HIV

### 12/21/2011

Initiatives Include an Increased Discount on Merck's ISENTRESS® (raltegravir) Tabletsto Eligible ADAPs to Further Increase Access to the HIV Medicine

Today, Merck (NYSE: MRK), known as MSD outside the United States and Canada, and the ADAP Crisis Task Force (ACTF) announced a number of new initiatives to help struggling state AIDS Drug Assistance Programs (ADAPs) continue to provide access to medicines to people living with HIV. This is the third major response from Merck and ACTF in the last four years, as the financial crisis for these critical state programs continues.

Merck has agreed to:

-- Again lower the price of ISENTRESS® (raltegravir) to eligible ADAPs, effective Jan. 1, 2012. The new price will be "frozen" and will be available as part of the existing Merck special pricing program through Dec. 31, 2013. Merck was the first company to freeze the price of an antiretroviral (ARV) therapy to ADAPs in 2003.

In addition, Merck and ACTF have agreed to the following initiatives:

-- Increasing support for the Welvista ADAP Program. After its initial year in 2010 and evaluation of current needs, Merck is increasing it operations funding and medication donations for the Welvista ADAP Program. The program helps address the medication needs of ADAP clients who are currently on state ADAP waiting lists by expediting

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access to HIV medicines through a simplified application process.

-- Working to optimize the use of comprehensive health insurance options available to persons with HIV. Between 2009 and 2010, the use of private insurance by ADAPs tripled to more than 110,000 persons. The National Alliance of State and Territorial AIDS Directors (NASTAD) reported about 40 ADAPs used ADAP funds to purchase health insurance or pay insurance premiums, co-payments and/or deductibles for individuals eligible for ADAP (provided the insurance has comparable formulary benefits to that of the ADAP). Merck and NASTAD will seek solutions that overcome barriers to more widespread use of such approaches, such as expanding enrollments in Medicare Part D, private insurance and pre-existing condition insurance plans (PCIPs).

ISENTRESS is indicated in combination with other antiretroviral (ARV) agents for the treatment of HIV-1 infection in adult patients. The label for ISENTRESS is based on analyses of plasma HIV-1 RNA levels through 96 weeks in three double-blind controlled Phase III clinical studies of ISENTRESS. Two of these studies were conducted in clinically advanced, three-class 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 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 pediatric patients.

Merck and the ACTF maintain a mutual commitment to partner together to assess the situation and to find solutions that will provide relief to sustain ADAPs. The first ADAP response from Merck and the ACTF was announced in August 2008, and the second response was announced in May 2010. At the time of the latest response, it was both parties' expectation that those actions – including a special pricing program for ADAPs and price freeze for ARV medicines – would be sufficient until 2014. It is believed that, in 2014, the U.S. government's newly-expanded Medicaid program and subsidized private health insurance program, mandated by the Patient Protection and Affordable Care Act (PPACA), will provide sufficient, sustainable care to the majority of people served by ADAPs.

It has become clear within the last year that previous agreements coupled with current federal and state funding were not enough to sustain ADAPs until 2014. Merck's latest response was a result of discussions between Merck and the ACTF over the last few months, and reflects the continuing fiscal circumstances in the states and the unmet needs of people with HIV.

"On behalf of the nearly two hundred thousand clients that ADAPs serve, we applaud Merck for its continued commitment to HIV," said Dwayne Haught, spokesperson for the ACTF and manager of the Texas ADAP. "Merck's history of HIV research and development, responsible pricing and related efforts are consistent with its track record of working to help ensure access to treatments for the people most in need. We commend Merck for responding once again to the unprecedented fiscal need faced by state ADAPs by providing additional support to help provide

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people living with HIV access to HIV medicines."

"With our company's legacy in HIV over the last 25 years, we consider it our obligation to continue to work with the ADAPs on solutions that provide crucial support for uninsured and underserved people living with HIV," said Chirfi Guindo, vice president and general manager, Merck HIV Franchise. "It is imperative to act now, given the ongoing ADAP funding crisis. We applaud President Obama's recent announcements of enhanced federal support for ADAPs and state HIV programs, and look forward to working together on sustainable solutions through improvements in the health care delivery system."

"These actions come at a time when federal funding for ADAPs remains relatively flat compared to enrollment growth, and state funding continues to fluctuate, making it difficult for the ADAP programs to provide access and care to all the clients they need to serve," said Lynda Dee, spokesperson for the Fair Pricing Coalition. "The Fair Pricing Coalition commends Merck for its long-standing commitment to providing access to treatment and welcomes Merck's new initiatives to help with the current ADAP funding crises."

#### Important Selected Safety Information

Severe, potentially life-threatening and fatal skin reactions have been reported. This includes cases of Stevens-Johnson syndrome, hypersensitivity reaction and toxic epidermal necrolysis. Immediately discontinue treatment with ISENTRESS and other suspect agents if severe hypersensitivity, severe rash, or rash with systematic symptoms or liver aminotransferase elevations develops and monitor clinical status, including liver aminotransferases closely.

Healthcare providers should know that during the initial phase of treatment, immune reconstitution syndrome can occur, which may necessitate further evaluation and treatment. Monitor for immune reconstitution syndrome.

The most common adverse reactions of moderate to severe intensity 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. 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).

Grade 2-4 creatine kinase laboratory abnormalities were observed in patients treated with ISENTRESS. Myopathy and rhabdomyolysis have been reported. Use with caution in patients at increased risk of myopathy or rhabdomyolysis, such as patients receiving concomitant medications known to cause these conditions.

#### About ISENTRESS

ISENTRESS is Merck's integrase inhibitor for the treatment of HIV-1 infection in treatment-naïve and treatment-

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experienced adult patients as part of combination therapy. ISENTRESS is currently 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 medicine that inhibits the integrase enzyme. ISENTRESS is now approved in combination therapy in more than 45 countries for use in treatment-naïve adult patients with HIV-1 and in more than 90 countries for use in treatment-experienced adult patients with HIV-1. Merck is continuing to move forward with filings in additional countries around the world.

Merck's patient assistance programs in the U.S.

The SUPPORT<sup>™</sup> Program is a two-part program that consists of: (1) free reimbursement support services; and (2) a patient assistance program for eligible individuals who have been prescribed one or more Merck HIV medicines. One part of this free program provides personalized support and patient advocacy regarding individual reimbursement issues. In addition, the SUPPORT<sup>™</sup> Program also offers a patient assistance program, which may provide Merck HIV medicines free of charge to eligible patients which may be delivered directly to the patient's home. Information about the SUPPORT Program can be obtained by calling 1-800-850-3430 or at **www.merckhelps.com**.

About the ADAP Crisis Task Force (ACTF) and National Alliance of State and Territorial AIDS Directors (NASTAD)

The ADAP Crisis Task Force (ACTF) was formed in December 2002 by NASTAD and a group of state AIDS/ADAP directors concerned about the fiscal crisis facing ADAPs nationwide. The ACTF works in partnership with pharmaceutical manufacturers of antiretroviral and other HIV-related medications to reduce drug costs and improve access to medications for clients in the nation's ADAPs. It is estimated that ACTF agreements with companies have saved ADAPs approximately \$1.2 billion since 2003. NASTAD provides logistical support for the ACTF.

Founded in 1992, NASTAD is a nonprofit national association of state and territorial health department HIV/AIDS and viral hepatitis program directors who have responsibility for administering HIV/AIDS and viral hepatitis health care, prevention, education and supportive services programs funded by state and federal governments. For more information, visit **www.NASTAD.org.** 

#### About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the

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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** and connect with us on Twitter, Facebook and YouTube.

#### 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).

# Please see accompanying prescribing information for ISENTRESS® (raltegravir) Tablets at http://www.merck.com/product/usa/pi\_circulars/i/isentress/isentress\_pi.pdf, and patient information for ISENTRESS® (raltegravir) Tablets at http://www.merck.com/product/usa/pi\_circulars/i/isentress\_ppi.pdf

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