NEWS RELEASE

Merck's Investigational Once-Daily Formulation of ISENTRESS® (raltegravir) Meets Primary and Secondary Endpoints in Pivotal Phase 3 Study

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Results to be Presented at Future Medical Meeting, and Regulatory Submissions Planned for 2016

Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced top-line results from the company's Phase 3 pivotal trial, ONCEMRK. ONCEMRK is evaluating an investigational once-daily formulation of ISENTRESS® (raltegravir), known as raltegravir 600 mg (to be given as 2 x 600 mg once-daily), for previously untreated HIV-1 infected adults. The study met its primary efficacy endpoint: 1200 mg raltegravir (given as 2 x 600 mg once-daily) was statistically non-inferior to the marketed formulation approved dose of ISENTRESS 400 mg twice-daily, each in combination therapy with TRUVADA™, as assessed by the proportion of patients achieving HIV-1 RNA <40 copies/mL at Week 48. In addition, the secondary endpoints of tolerability and immunologic efficacy (as measured by change from baseline in CD4 cell counts at Week 48) were comparable. Later this year, Merck plans to present detailed findings of the study at an upcoming scientific conference, and to submit applications for licensure to the U.S. Food and Drug Administration and the European Medicines Agency for this investigational new formulation.

ISENTRESS is indicated twice-daily in combination with other antiretroviral agents for the treatment of HIV-1 infection in patients 4 weeks of age and older. The use of other active agents with ISENTRESS is associated with a greater likelihood of treatment response.

"Merck has never wavered in our commitment to develop meaningful therapeutic options for people with HIV-1 infection," said Dr. Eliav Barr, vice president clinical development, infectious diseases, Merck Research Laboratories.

"We are pleased that this study has met its primary endpoint and look forward to presenting the data at a future congress."

About ONCEMRK

The ongoing Phase 3 multicenter, double-blind, randomized, active comparator-controlled clinical trial is evaluating the efficacy and safety of raltegravir 1200 mg (given as 2 x 600 mg) once-daily compared to ISENTRESS 400 mg twice-daily each in combination therapy with TRUVADA™ in previously untreated HIV-1 infected adult patients. The primary efficacy objective is the proportion of patients achieving HIV RNA <40 copies/mL at Week 48. Secondary objectives included change from baseline in CD4 cell counts and tolerability at Week 48. The newly formulated 600 mg tablet for once-daily use (2 x 600 mg), in this study, is not currently approved for use and this formulation is not interchangeable with the currently marketed 400 mg tablet.

The planned total treatment duration for this study is 96 weeks.

For further information regarding ONCEMRK please visit **clinicaltrials.gov**., clinical trial registry number NCT02131233.

Important Selected Safety Information

ISENTRESS does not cure HIV-1 infection or AIDS.

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 systemic symptoms or liver aminotransferase elevations develops and monitor clinical status, including liver aminotransferases closely.

Immune reconstitution syndrome can occur, including the occurrence of autoimmune disorders with variable time to onset, which may necessitate further evaluation and treatment.

ISENTRESS chewable tablets contain phenylalanine, a component of aspartame, which may be harmful to patients with phenylketonuria.

Coadministration of ISENTRESS with drugs that are strong inducers of uridine diphosphate glucuronosyltransferase (UGT) 1A1 may result in reduced plasma concentrations of raltegravir. Coadministration of ISENTRESS (raltegravir) with drugs that inhibit UGT1A1 may increase plasma levels of raltegravir.

Coadministration of ISENTRESS and other drugs may alter the plasma concentration of raltegravir. The potential for

drug-drug interactions must be considered prior to and during therapy. Coadministration or staggered administration of aluminum and/or magnesium hydroxide-containing antacids and ISENTRESS is not recommended.

Rifampin, a strong inducer of UGT1A1, reduces plasma concentrations of ISENTRESS. Therefore, the dose of ISENTRESS for adults should be increased to 800 mg twice daily during coadministration with rifampin. There are no data to guide coadministration of ISENTRESS with rifampin in patients below 18 years of age.

The most commonly reported (≥2%) drug-related clinical adverse reactions of moderate to severe intensity in treatment-naïve adult patients receiving ISENTRESS compared with efavirenz were insomnia (4% vs 4%), headache (4% vs 5%), nausea (3% vs 4%), fatigue (2% vs 3%), and dizziness (2% vs 6%) respectively. In treatment-experienced adult patients receiving ISENTRESS, the most commonly reported (≥2%) drug-related clinical adverse reactions of moderate to severe intensity and at a higher incidence compared with placebo was headache (2% vs <1%). In both studies, intensities were defined as: Moderate (discomfort enough to cause interference with usual activity); or Severe (incapacitating with inability to work or do usual activity). In treatment-experienced pediatric patients 4 weeks through 18 years of age receiving ISENTRESS, the frequency, type and severity of drug-related adverse reactions were comparable to those observed in adults.

Grade 2-4 creatine kinase laboratory abnormalities were observed in subjects 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 and patients with a history of rhabdomyolysis, myopathy or increased serum creatine kinase.

Rash occurred more commonly in treatment-experienced subjects receiving regimens containing ISENTRESS + darunavir/ritonavir compared to subjects receiving ISENTRESS without darunavir/ritonavir or darunavir/ritonavir without ISENTRESS. However, rash that was considered drug related occurred at similar rates for all 3 groups. These rashes were mild to moderate in severity and did not limit therapy; there were no discontinuations due to rash.

ISENTRESS should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. There are no adequate and well-controlled studies in pregnant women. In addition, there have been no pharmacokinetic studies conducted in pregnant patients.

To monitor maternal-fetal outcomes of pregnant patients exposed to ISENTRESS, an Antiretroviral Pregnancy Registry has been established. Physicians are encouraged to register patients by calling 1-800-258-4263.

About ISENTRESS (raltegravir)

ISENTRESS is Merck's integrase inhibitor for the treatment of HIV-1 infection in adult and pediatric patients ages four weeks and older and weighing at least 3 kg as part of combination HIV therapy. 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.

ISENTRESS is approved as part of combination therapy in 115 countries for treatment of HIV-1 infection in adult patients. ISENTRESS, in combination therapy, for use in children and adolescents with HIV-1 ages two years and older has also been approved for use in 64 countries, and ISENTRESS oral suspension for infants at least four weeks of age is approved for use in 34 countries. Please refer to the Prescribing Information for ISENTRESS for information about dosage and administration for each formulation.

About Merck

Today's Merck is a global health care 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 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 health care through far-reaching policies, programs and partnerships. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co. Inc., Kenilworth, NJ, USA

This news release of Merck & Co., Inc., Kenilworth, NJ, USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately

predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company 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 the company's 2014 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 Prescribing Information for ISENTRESS (raltegravir) at **http://www.merck.com/product/usa/pi_circulars/i/isentress/isentress_pi.pdf**, Patient Information for ISENTRESS at **http://www.merck.com/product/usa/pi_circulars/i/isentress/isentress_ppi.pdf** and Instructions for Use of ISENTRESS (raltegravir) for Oral Suspension at **http://www.merck.com/product/usa/pi_circulars/i/isentress/isentress_ifu.pdf**

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