NEWS RELEASE

Merck Announces Week 96 Results from ONCEMRK, A Study Evaluating Once-Daily ISENTRESS® HD (raltegravir), in Combination with Other Antiretroviral Agents, for the Treatment of HIV-1 Infection in Appropriate Patients

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Once-Daily Version of Raltegravir Now Approved in U.S. and European Union

Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced the presentation of Week 96 results from the pivotal Phase 3 ONCEMRK study evaluating the efficacy and safety of ISENTRESS HD1, a 1200 mg once-daily dose of the company's integrase inhibitor, ISENTRESS® (raltegravir), administered orally as two 600 mg film-coated tablets, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg, who are treatment-naïve or whose virus has been suppressed on an initial regimen of ISENTRESS 400 mg given twice daily. Previously, the findings at Week 48 demonstrated that once-daily ISENTRESS HD met its primary efficacy endpoint of non-inferiority to twice-daily ISENTRESS, with a similar safety and tolerability profile. The Week 96 results reaffirm the comparable efficacy and safety of ISENTRESS HD. These study results were presented today during a late-breaking abstract session at the 9th International Conference on HIV Science (**IAS 2017**) being held in Paris, France, from July 23-26, 2017.

"The Week 96 results from the ONCEMRK trial reinforce the findings from the 48-week analysis and support the use of ISENTRESS HD, in combination with other antiretroviral agents, as a once-a-day treatment option for some people living with HIV," said Dr. Pedro Cahn, chief of the infectious disease unit at Juan A. Fernandez Hospital, Buenos Aires, Argentina, and lead study investigator.

ISENTRESS and ISENTRESS HD do 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 or ISENTRESS HD and other suspect agents if severe hypersensitivity, severe rash, or rash with systemic symptoms or liver aminotransferase elevations develop and monitor clinical status, including liver aminotransferases closely. For more information, see “Selected Safety Information” below.

Week 96 data from the ONCEMRK study showed that 81.5 percent of the 531 patients taking once-daily ISENTRESS HD 1200 mg (2 x 600 mg) achieved viral suppression of less than 40 copies/mL of HIV-1 RNA, compared to 80.1 percent of the 266 patients taking twice-daily ISENTRESS 400 mg, both in combination therapy with emtricitabine plus tenofovir disoproxil fumarate, with a treatment difference of 1.4 percent (95 percent confidence interval -4.4, 7.3). Increases in CD4+T-cell counts from baseline were comparable for the two treatment regimens, with an average increase of 261.6 cells/mm3 for once-daily ISENTRESS HD and 262.2 cells/mm3 for twice-daily ISENTRESS. Efficacy was consistent across a variety of patient populations, including those with high viral load at baseline (HIV-1 RNA >100,000 copies/mL).

Treatment-emergent viral mutations leading to any drug resistance were detected in less than 1 percent of patients in both treatment arms, with 4/531 (0.8 percent) in the once-daily ISENTRESS HD treatment arm, and 2/266 (0.8 percent) in the twice-daily ISENTRESS treatment arm through 96 weeks. The rate of discontinuation of therapy due to adverse events through 96 weeks was low (1.3 percent in patients receiving once-daily ISENTRESS HD and 2.3 percent in patients receiving twice-daily ISENTRESS).

In the United States, once-daily ISENTRESS HD was approved by the Food and Drug Administration (FDA) on May 26, 2017, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults, and pediatric patients weighing at least 40 kg, who are treatment-naïve or whose virus has been suppressed on an initial regimen of ISENTRESS 400 mg given twice daily. ISENTRESS HD is administered as a 1200 mg once-daily dose, given orally as two 600 mg film-coated tablets.

On July 13, 2017, the European Commission granted marketing authorization for once-daily ISENTRESS 600 mg in the European Union, to be administered as a once-daily 1200 mg oral dose given as two 600 mg tablets, in combination therapy with other antiretroviral medicinal products, for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg, who are treatment-naïve or whose virus has been suppressed on an initial regimen of ISENTRESS 400 mg twice daily. Regulatory reviews are underway for once-daily version of ISENTRESS in other countries and regions around the world, including Australia and Switzerland.

About ONCEMRK

The ONCEMRK study is a Phase 3 multicenter, double-blind, randomized, active comparator-controlled clinical trial designed to evaluate the efficacy and safety of once-daily ISENTRESS HD 1200 mg (given as two 600 mg oral tablets), compared to twice-daily ISENTRESS 400 mg, each in combination therapy with emtricitabine plus tenofovir disoproxil fumarate in previously untreated adults with HIV-1 infection with levels of HIV-1 RNA ≥ 1,000 copies/mL. The primary efficacy objective was the proportion of participants achieving less than 40 copies/mL of HIV-1 RNA at Week 48, with a planned total treatment duration of 96 weeks. The non-inferiority margin was 10 percentage points.

Selected Safety Information about ISENTRESS HD (raltegravir) and ISENTRESS (raltegravir)

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.

Co-administration of ISENTRESS or ISENTRESS HD with drugs that induce uridine diphosphate glucuronosyltransferase (UGT) 1A1 may result in reduced plasma concentrations of raltegravir. Co-administration of ISENTRESS or ISENTRESS HD with drugs that inhibit UGT1A1 may increase plasma levels of raltegravir.

Co-administration of ISENTRESS or ISENTRESS HD and other drugs may alter the plasma concentration of raltegravir. The potential for drug-drug interactions must be considered prior to and during therapy. Co-administration or staggered administration of aluminum and/or magnesium hydroxide-containing antacids and ISENTRESS or ISENTRESS HD is not recommended. Co-administration of ISENTRESS HD with calcium carbonate antacids, tipranavir/ritonavir, or etravirine is also not recommended.

During co-administration with rifampin, the recommended dosage of ISENTRESS in adults is 800 mg twice daily. Rifampin, a strong inducer of UGT1A1, reduces plasma concentrations of ISENTRESS. There are no data to guide co-administration of ISENTRESS with rifampin in patients below 18 years of age.

Co-administration with rifampin is not recommended with ISENTRESS HD.

The impact of other strong inducers of drug metabolizing enzymes on raltegravir is unknown (e.g., Carbamazepine, Phenobarbital, and Phenytoin). Co-administration of ISENTRESS or ISENTRESS HD with other strong inducers is not recommended.

About ISENTRESS (raltegravir)

Approved in 2007, ISENTRESS was the first integrase inhibitor developed for the treatment of HIV-1 infection. ISENTRESS is one of the regimen options recommended by the Department of Health and Human Services – in combination with other antiretroviral agents – as a first-line therapy in treatment-naïve HIV-1 infected adults. ISENTRESS chewable tablets and oral suspension, each in combination therapy, are approved to treat pediatric patients aged at least four weeks of age, and weighing less than 20 kg.

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 112 countries for treatment of HIV-1 infection in adult patients. ISENTRESS, in combination therapy, for use in children and adolescents with HIV-1 aged two years and older has also been approved for use in 69 countries, and ISENTRESS oral suspension for infants at least four weeks of age is approved for use in 33 countries.

Selected Safety Information about ISENTRESS HD (raltegravir) and ISENTRESS (raltegravir) Continued

The most commonly reported (≥2 percent) drug-related clinical adverse reactions of moderate to severe intensity in treatment-naïve adult patients receiving ISENTRESS compared with efavirenz were headache (4 percent vs. 5 percent), insomnia (4 percent vs. 4 percent), nausea (3 percent vs. 4 percent), dizziness (2 percent vs. 6 percent), and fatigue (2 percent vs. 3 percent), respectively. The most commonly reported (≥2 percent) clinical adverse reactions of all intensities (Mild, Moderate, and Severe) in treatment-naïve adult patients receiving ISENTRESS HD compared with ISENTRESS through 48 weeks included abdominal pain, diarrhea, vomiting, and decreased appetite. Intensities were defined as follows: Mild (awareness of sign or symptom, but easily tolerated); 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 subjects treated with ISENTRESS or ISENTRESS HD. Myopathy and rhabdomyolysis have been reported with ISENTRESS. 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.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ISENTRESS or ISENTRESS HD during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263.

Women infected with HIV-1 should be instructed not to breastfeed if they are receiving ISENTRESS or ISENTRESS HD due to the potential for HIV transmission.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. 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. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

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

This news release of Merck & Co., Inc., Kenilworth, N.J., 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 2016 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) and ISENTRESS HD (raltegravir) at **http://www.merck.com/product/usa/pi_circulars/i/isentress/isentress_pi.pdf** , Patient Information for ISENTRESS and ISENTRESS HD (raltegravir) at **http://www.merck.com/product/usa/pi_circulars/i/isentress/isentress_ppi.pdf** . The Instructions for Use also are available at **http://www.merck.com/product/usa/pi_circulars/i/isentress/isentress_ifu.pdf**

1 ISENTRESS HD is marketed outside of the U.S. as ISENTRESS 600 mg

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