Merck to Present New Data from Clinical Trials Evaluating ISENTRETT® HD (raltegravir) and Investigational HIV Therapies Doravirine and MK-8591 at IAS 2017

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KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that new data from the company’s HIV portfolio and pipeline are scheduled to be presented at the 9th IAS Conference on HIV Science (IAS 2017). Presentations include late-breaker abstracts from two Phase 3 pivotal clinical trials – Week 96 data from ONCEMRK, a study evaluating once-daily ISENTRETT® HD (raltegravir) in combination with other antiretroviral agents in previously untreated adult patients with HIV-1 infection, and Week 48 data from DRIVE-AHEAD, a study evaluating doravirine (MK-1439), an investigational non-nucleoside reverse transcriptase inhibitor (NNRTI) as part of a fixed dose regimen containing doravirine (DOR), lamivudine (3TC), and tenofovir disoproxil fumarate (TDF) compared to a regimen containing efavirenz (EFV), emtricitabine (FTC), and TDF in previously untreated adult patients with HIV-1 infection. In addition, a late-breaker abstract will be presented of a Phase 1 study of MK-8591, Merck’s investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) in adult patients with HIV-1 infection. IAS 2017 is taking place in Paris, France, from July 23-26, 2017.

“Merck has never wavered in our commitment to addressing the treatment needs of people living with HIV, and the data to be presented at IAS 2017 on our portfolio and our pipeline reflect that commitment,” said Dr. George Hanna, associate vice president, clinical research, Merck Research Laboratories.

In the United States, once-daily ISENTRETT 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-naive or whose virus has been suppressed on an initial regimen of ISENTRETT 400 mg given twice daily. ISENTRETT HD is administered as a 1200 mg once-daily dose, given orally as two 600 mg film-coated tablets. On May 18, 2017, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending approval of the once-daily dose of ISENTRETT (ISENTRETT 600 mg as it will be known outside the United States) in combination with other antiretroviral medicinal products, for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg. The recommendation is under review by the European Commission for marketing authorization in the European Union with a decision on approval expected in the second half of 2017.

Select Late-Breaker Abstracts at IAS 2017:

- **Abstract # TULBPEB20**: Raltegravir (RAL) 1200 mg once daily (QD) versus RAL 400 mg twice daily (BID), in combination with tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), in previously untreated HIV-1 infection through week 96
  - Late-breaker poster, Tuesday, July 25, 12:30 – 14:30 CET, Poster Exhibition

- **Abstract # TUPDB0202LB**: Single doses as low as 0.5 mg of the novel NRTTI MK-8591 suppress HIV for at least seven days
  - Late-breaker poster discussion, Tuesday, July 25, 13:00 – 14:00 CET, Havana Amphitheater

- **Abstract # TUAB0104LB**: Fixed dose combination of doravirine/lamivudine/TDF is non-inferior to efavirenz/emtricitabine/TDF in treatment-naive adults with HIV-1 infection: week 48 results of the Phase 3 DRIVE-AHEAD study
  - Late-breaker oral presentation, Antiretroviral Therapy – ART: Season Two, Tuesday, July 25, 14:30 – 16:00 CET, Le Grand Amphithéâtre

About Doravirine

Doravirine (MK-1439) is an investigational NNRTI being evaluated by Merck for the treatment of HIV-1 infection. Doravirine is being evaluated in several ongoing studies as a once-daily fixed dose combination with 3TC and TDF or individually for use in combination with other antiretroviral agents. Phase 3 studies include DRIVE-AHEAD, a trial comparing DOR/3TC/TDF to EFV/FTC/TDF in previously untreated adult patients; DRIVE-FORWARD, a trial comparing doravirine (DOR) to once-daily ritonavir-boosted darunavir (DRV+r), each administered in combination with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) or abacavir/lamivudine (ABC/3TC), in previously untreated adult patients; and DRIVE-SHIFT, a trial evaluating a
switch to DOR/3TC/TDF in people who are currently virologically suppressed on another antiretroviral regimen. Other ongoing Phase 2 studies include an evaluation of DOR/3TC/TDF in previously untreated patients with transmitted resistance to NNRTIs and in people switching from efavirenz due to intolerance.

**About MK-8591**

MK-8591 (formerly known as Efda) is Merck's investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) currently being evaluated in early stage clinical trials for the treatment of HIV infection. It inhibits HIV reverse transcriptase through multiple mechanisms that are different from any approved anti-HIV medicines, including traditional nucleoside reverse transcriptase inhibitors (NRTIs). MK-8591 is being evaluated for its potential to be administered as part of a daily or an extended duration dosing regimen.

**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-naive 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.

IENTRESS 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.

IENTRESS 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)**

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 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.

IENTRESS 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.

The most commonly reported (>2 percent) drug-related clinical adverse reactions of moderate to severe intensity in treatment-naive 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-naive 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).


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