Merck Announces Discontinuation of APECS Study Evaluating Verubecestat (MK-8931) for the Treatment of People with Prodromal Alzheimer’s Disease

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KENILWORTH, N.J. -- (BUSINESS WIRE) -- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that it will be stopping protocol 019, also known as the APECS study, a Phase 3 study evaluating verubecestat (MK-8931), an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), in people with prodromal Alzheimer’s disease (AD). The decision to stop the study follows a recommendation by the external Data Monitoring Committee (eDMC), which assessed overall benefit/risk during a recent interim safety analysis. The eDMC concluded that it was unlikely that positive benefit/risk could be established if the trial continued. Data from the APECS study will be presented at an upcoming medical meeting.

“We are disappointed with this outcome, especially given the lack of treatment options for patients suffering from Alzheimer’s disease,” said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. “We are grateful to the patients and caregivers who participated in this study, and despite this outcome, Merck remains committed to developing novel therapies for the treatment of Alzheimer’s and other neurodegenerative diseases.”

About the APECS Study
APECS is a randomized, placebo-controlled, parallel-group, double-blind Phase 3 clinical trial evaluating the efficacy and safety of verubecestat in people with prodromal AD. Subjects are randomized to receive placebo, or 12 mg or 40 mg verubecestat, once-daily. The primary efficacy outcome of the study is change from baseline in the Clinical Dementia Rating Scale-Sum of Boxes (CDR-SB) score following 104 weeks of treatment. For further information please see NCT01953601 at www.clinicaltrials.gov.

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 investing 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 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 advancements, 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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