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Merck Announces EPOCH Study of Verubecestat for the Treatment of People with Mild to Moderate Alzheimer's Disease to Stop for Lack of Efficacy

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APECS Study in People with Prodromal Alzheimer's Disease to Continue

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 017, also known as the EPOCH study, a Phase 2/3 study evaluating verubecestat, an investigational small molecule inhibitor of the beta-site amyloid precursor protein cleaving enzyme 1 (BACE1), in people with mild-to-moderate Alzheimer's disease (AD). Merck is stopping the study following the recommendation of the external Data Monitoring Committee (eDMC), which assessed overall benefit/risk during a recent interim safety analysis, and determined that there was "virtually no chance of finding a positive clinical effect." The eDMC noted that safety signals observed in the study "are not sufficient to warrant stopping study 017," and recommended that protocol 019, also known as APECS, which is evaluating verubecestat in people with prodromal Alzheimer's disease, continue unchanged. Results from protocol 019 are expected in February 2019. Results from EPOCH will be analyzed and presented at an upcoming scientific meeting.

"Alzheimer's disease is one of the most pressing and daunting medical issues of our time, with inherent, substantial challenges to developing an effective disease-modifying therapy for people with mild-to-moderate disease. Studies such as EPOCH are critical, and we are indebted to the patients in this study and their caregivers," said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. "While we are disappointed that a benefit was not observed in this study, our work continues with APECS, which is studying verubecestat in people with less advanced disease."

The efficacy and safety of verubecestat was being evaluated in two pivotal Phase 3 clinical trials: Protocol 017, or EPOCH, in mild-to-moderate AD, and Protocol 019, or APECS, in prodromal AD. Patients with mild to moderate AD exhibit detectable and worsening impairment of cognitive and functional abilities. Patients with prodromal AD have objective memory problems but relatively normal functioning in activities of daily living.

About the EPOCH Study

EPOCH is a Phase 2/3 randomized, placebo-controlled, parallel-group, double-blind study evaluating the efficacy and safety of two oral doses of verubecestat (12 mg and 40 mg) administered once-daily versus placebo in patients with mild-to-moderate AD currently using standard of care treatment. The primary efficacy outcomes of the study are the change from baseline in the Alzheimer's Disease Assessment Scale Cognitive Subscale (ADAS-Cog) score, as well as the change from baseline in the Alzheimer's Disease Cooperative Study – Activities of Daily Living (ADCS-ADL) score, following 78 weeks of treatment. For more information about the EPOCH study, visit NCT01739348 at www.clinicaltrials.gov.

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. In February 2017, Merck announced that the study was fully enrolled. For further information please see NCT01953601 at www.clinicaltrials.gov.

About Merck

For over a century, Merck has been 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, 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 2015 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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