



Lilly Announces Topline Results for Solanezumab from the Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) Study

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Study with novel trial design did not meet primary endpoint

INDIANAPOLIS, Feb. 10, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the analysis performed by Washington University School of Medicine in the Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) Study showed that solanezumab did not meet the primary endpoint. Additional analyses of secondary endpoints and biomarkers are ongoing by Washington University and Lilly. Results will be presented at the Advances in Alzheimer's and Parkinson's Therapies (AAT-AD/PD™) Focus Meeting in April of 2020. At this time, Lilly does not plan to pursue a submission for solanezumab in people with dominantly inherited Alzheimer's disease (DIAD), also known as autosomal dominant Alzheimer's disease, based on the result of the primary endpoint. This outcome does not impact the ongoing solanezumab Anti-Amyloid Treatment in Asymptomatic Alzheimer's (A4) Study.

"We are grateful to the courageous participants, their families, and clinical investigators for their dedication to the study. We look forward to the opportunity to analyze the data so that we may continue to propel the science forward and bring hope to these patients," said Daniel Skovronsky, M.D., Ph.D., Lilly's chief scientific officer and president of Lilly Research Labs. "Lilly is committed to finding treatments for patients and remains excited about the potential of our medicines under development in the area of Alzheimer's."

The DIAN-TU platform trial is a Phase 2/3 randomized, double-blind, placebo-controlled study. The goal is to test potential disease-modifying therapies in individuals at risk for or with dominantly inherited Alzheimer's disease, which is caused by rare gene mutations. It began as a two-year biomarker target engagement study and evolved into a Phase 2/3 registration study with a primary cognitive outcome measure and a minimum of four years of treatment.

The primary efficacy analysis included 50 solanezumab and 40 placebo participants. The minimum four-year treatment period was completed by 36 solanezumab and 32 placebo participants. The initial study dose was 400mg every four weeks. A late amendment to the study increased the dose resulting in approximately 25 percent of the total doses being administered at the 1600mg level.

The DIAN-TU Study, which was established in 2010 and funded by Lilly, Roche and Genentech, National Institutes of Health, and other donors, is the first disease prevention trial to test investigational Alzheimer's disease compounds with different mechanisms of action from two pharmaceutical companies. The collaboration between Lilly, Washington University, Roche and Genentech combined research, resources, and expertise for a common goal of serving patients and their loved ones battling this devastating disease.

"Our first attempt to slow Alzheimer's before symptoms manifest is the result of the heroic commitment of patients and families at risk for dominantly inherited Alzheimer's, leading global academic researchers, the NIH, the Alzheimer's Association, philanthropic supporters, the DIAN-TU Pharma Consortium, government and regulatory colleagues, and pharmaceutical companies whose drugs are being tested," said principal investigator [Randall J. Bateman](#), M.D., the Charles F. and Joanne Knight Distinguished Professor of Neurology and the director of DIAN-TU. "It wouldn't have been possible without all stakeholders coming together for the cause to stop Alzheimer's disease."

For more than 30 years, Lilly has been committed to bringing innovative Alzheimer's disease therapies and diagnostics to patients and continues to lead the field in research, which also includes identifying biomarkers to support early detection of the disease.

About Solanezumab

Solanezumab is an investigational anti-amyloid monoclonal antibody being studied in preclinical Alzheimer's disease in the Anti-Amyloid Treatment in Asymptomatic Alzheimer's (A4) Study. The A4 Study is a clinical trial testing solanezumab in older individuals who have evidence of amyloid in their brains, but do not show symptoms of memory impairment.

About the Primary Endpoint: DIAN-Multivariate Cognitive Endpoint (DIAN-MCE)

The DIAN-Multivariate Cognitive Endpoint (DIAN-MCE) includes the Wechsler Memory Scale-Revised Logical Memory Delayed Recall, Cogstate International Shopping List Test, Wechsler Adult Intelligence Scale-Revised Digit Symbol Substitution Test, and the Mini Mental State Examination.

About Eli Lilly and Company

Lilly is a global health care leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at lilly.com and lilly.com/newsroom. P-LLY

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about solanezumab as a potential treatment for patients with people with dominantly inherited Alzheimer's disease, and reflects Lilly's current beliefs. As with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug development and commercialization. Among other things, there is no guarantee that future study results will be consistent with study findings to date. For further discussion of these and other risks and uncertainties, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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