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Lilly to End Contract with the University of California, San Diego for A4 Alzheimer's Study

Study continues; company will begin discussions to transition management of the Anti-amyloid Treatment in Asymptomatic Alzheimer's disease (A4) secondary prevention clinical trial to a new organization

INDIANAPOLIS, Aug. 4, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE:LLY) today notified the University of California, San Diego (UCSD) of its intent to end its contract with the university for the management of the Anti-amyloid Treatment in Asymptomatic Alzheimer's disease (A4) study. The A4 study is a novel clinical trial testing solanezumab in the preclinical stage of Alzheimer's disease in older individuals who have evidence of amyloid in their brains on a PET scan, but do not show symptoms of memory impairment. A4 has been managed by the Alzheimer's Disease Cooperative Study (ADCS) at UCSD. Lilly, the National Institutes of Health (NIH) and multiple philanthropic organizations fund the study.

Dr. Paul Aisen, who had been director of ADCS, and many members of the ADCS staff left UCSD this summer to join the University of Southern California. Both universities are now engaged in legal proceedings related to this matter. During this period, Lilly has been carefully evaluating the best course to ensure the successful continuation and eventual completion of the A4 study.

From the outset of this unfortunate dispute, Lilly has publicly stated that the company's objectives are to maintain the safety of the A4 participants, ensure scientific and data integrity for the study and maintain our obligations as the regulatory sponsor.

After a thorough evaluation of the on-going situation, Lilly has determined that it is in the best interest of the A4 study and its participants to end UCSD's management of the study. The A4 study will continue uninterrupted as the company initiates discussions with the University of Southern California about transitioning management and oversight of the study, while the company will simultaneously work with UCSD on a transition plan.

"Lilly continues to be committed to the continuation and completion of this landmark study," said Phyllis Ferrell, Alzheimer's Platform Leader for Lilly. "We are extremely grateful for the ongoing efforts of the A4 study participants, study investigators and the NIH. We wish to thank UCSD for its work to date and cooperation as the A4 study transitions. Lilly has many ongoing collaborations with researchers at UCSD and within the UC system more broadly, and nothing in our decision concerning the A4 study should be read to reflect any diminished enthusiasm in working with UCSD on these other important projects."

About solanezumab
Solanezumab is Lilly's Phase 3 monoclonal antibody being studied as a potential therapy for patients with mild Alzheimer's disease. Solanezumab binds to soluble monomeric forms of amyloid-beta after it is produced, allowing it to be cleared before it clumps together to form beta-amyloid plaques.

About Alzheimer's disease
Alzheimer's disease is a fatal illness that causes progressive decline in memory and other aspects of cognition. It is the most common form of dementia, accounting for 60 to 80 percent of dementia cases.[1] There are currently an estimated 44 million people living with dementia worldwide.[2] The number of people affected by dementia is expected to be more than 75 million in 2030 and 135 million in 2050.[2] Estimates vary, but experts suggest that as many as 5.3 million Americans may have Alzheimer's disease.[1]

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to 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 www.lilly.com and newsroom.lilly.com/social-channels.

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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 Alzheimer's disease and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with the results to date or that solanezumab will achieve its primary study endpoints or receive regulatory approvals. For further discussion of these and other risks and uncertainties, see Lilly's most recent 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.

[1] Alzheimer's Association. 2015 Alzheimer's Disease Facts and Figures. *Alzheimer's & Dementia* 2015;11(3)332+.

[2] Alzheimer's Disease International and World Health Organization Dementia Statistics. Available at: http://www.alz.co.uk/research/statistics. Accessed May 27, 2015.

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