March 15, 2016

Lilly Announces Change to Primary Endpoint of EXPEDITION3 Study

INDIANAPOLIS, March 15, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced a change to the primary endpoint for the EXPEDITION3 clinical trial, a Phase 3 study of solanezumab in people with mild Alzheimer's dementia.

The original study design included co-primary endpoints of cognition and function—measured by ADAS-Cog$_{14}$ (Alzheimer's Disease Assessment Scale-Cognitive subscale) and ADCS-iADL (Alzheimer's Disease Cooperative Study-Instrumental Activities of Daily Living), respectively. Emerging scientific evidence supports the idea that cognitive decline precedes and predicts functional decline in Alzheimer's disease, particularly in earlier stages of the disease.[1,2,3] Thus, Lilly has decided to amend the EXPEDITION3 trial to include a single primary endpoint of cognition (ADAS-Cog$_{14}$). Functional outcomes will be measured during the trial in the same manner as previously designed, using both the ADCS-iADL and the FAQ (Functional Assessment Questionnaire). These two functional outcomes will now be considered key secondary endpoints for the EXPEDITION3 study.

It is important to note that the endpoint change affects the study's data analysis plan, but it does not affect anything related to the actual conduct of the trial. Lilly will continue to remain blinded to study data until after the database lock occurs in the fourth quarter of 2016.

Lilly understands that regulators globally will continue to view both cognitive and functional endpoints as necessary for clinical trials in people with mild Alzheimer's dementia, and regulatory guidance has been to include these as co-primary endpoints. Lilly is submitting the EXPEDITION3 amendment to all appropriate regulatory authorities.

About Solanezumab
Solanezumab is Lilly's Phase 3 monoclonal antibody being studied as a potential therapy for people with mild Alzheimer's dementia, prodromal Alzheimer's dementia and preclinical Alzheimer's disease. Solanezumab binds to soluble monomeric forms of amyloid beta after it is produced, allowing it to be cleared from the brain before it clumps together to form amyloid plaques.

About EXPEDITION3
EXPEDITION3 is a Phase 3 trial of solanezumab. Participant enrollment completed in 2015 and last patient visit is expected in October 2016. Top-line results will be reported after completion of database lock and analysis. EXPEDITION3 is the first Phase 3 trial to evaluate only people with mild Alzheimer's dementia.

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.[4] There are currently an estimated 47 million people living with dementia worldwide.[5] The number of people affected by dementia is expected to be nearly 75 million in 2030 and nearly 132 million in 2050.[4] Estimates vary, but experts suggest that as many as 5.3 million Americans may have Alzheimer's disease.[4]

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. **(P-LLY)**

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about the EXPEDITION3 trial and solanezumab, an anti-amyloid monoclonal antibody in clinical testing for treatment of 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 is no guarantee that the EXPEDITION3 trial will meet its primary or secondary endpoints as revised or that regulators will approve solanezumab based on meeting the revised primary endpoint. If solanezumab is approved, there is no guarantee it will be commercially successful. 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]Zadhone L., et al. Cognitive Declines Precede and Predict Functional Declines in Aging and Alzheimer's Disease. PLOS One. September 2013. PLOS One. DOI: 10.1371/journal.pone.0073645.

[2] Liu-Seifert H., et al. Cognitive Impairment Precedes and Predicts Functional Impairment in Mild Alzheimer's Disease. Journal of Alzheimer's Disease. 47 (2015) 205-214 DOI 10.3233/JAD-142508.

[3] Liu-Seifert H., et al. Cognitive and Functional Decline and Their Relationship in Patients with Mild Alzheimer's Dementia. Journal of Alzheimer's Disease. 43 (2015) 949-955 DOI 10.3233/JAD-140792.

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

[5] Alzheimer's Disease International and World Health Organization Dementia Statistics. Available at: http://www.alz.co.uk/research/statistics. Accessed February 5, 2016.

Refer to: Media - Nicole Hebert; hebert_nicole@lilly.com; 317.701.9984
Investors - Phil Johnson; johnson_philip_l@lilly.com; 317.748.5122

Logo - http://photos.prnewswire.com/prnh/20031219/LLYLOGO

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/lilly-announces-change-to-primary-endpoint-of-expedition3-study-300235846.html

SOURCE Eli Lilly and Company