INDIANAPOLIS (July 22, 2015) /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced results suggesting the treatment effect of solanezumab was preserved within a pre-specified amount in patients with mild Alzheimer’s disease who received solanezumab earlier in the disease compared to patients who began treatment at a later point. These results were from a pre-specified secondary analysis of the Phase 3 EXPEDITION, EXPEDITION2 and EXPEDITION-EXT studies, and were presented today at the Alzheimer’s Association International Conference® 2015 (AAIC®) in Washington, D.C.¹ ² These results support the use of the “delayed-start” method for assessing the potential effects of a treatment on the underlying disease progression of Alzheimer’s disease.¹ Results from this study are expected to be published online today in Alzheimer’s & Dementia: Translational Research & Clinical Interventions.

“We are particularly excited about these data because this is the first time the delayed-start methodology has been implemented for an Alzheimer’s disease clinical trial,” said Hong Liu-Seifert, Ph.D., study research advisor at Eli Lilly and Company. “This new analytical method enabled us to assess if solanezumab had an effect that is consistent with slowing progression of disease by modifying the underlying disease progression, which, up until now, has not been studied. These results support the trial design and delayed-start analysis plan of EXPEDITION3, which is expected to have the last patient visit in October 2016.”

The objective of the delayed-start analysis was to assess a possible disease-modifying effect of solanezumab in patients with mild Alzheimer’s disease. These results were obtained from a pre-specified secondary analysis of the Phase 3 EXPEDITION, EXPEDITION2 and EXPEDITION-
EXT studies. EXPEDITION and EXPEDITION2 had identical study protocols, which included an 18-month randomized, double-blind, placebo-controlled period, after which a two-year delayed-start period occurred (EXPEDITION-EXT), where the placebo-treated patients from the placebo-controlled period began treatment with solanezumab. Results from EXPEDITION and EXPEDITION2 were pooled and only patients with mild dementia at the beginning of the study were included in this analysis. During the delayed-start period, the original treatment assignment remained blinded to patients and sites. When considering the placebo-controlled period and delayed-start period together, all patients were randomized to the same active treatment (solanezumab) but starting at different times, resulting in two treatment regimens: early-start and delayed-start. The primary analysis was at 108 weeks after the beginning of the placebo-controlled period (28 weeks after the beginning of the delayed-start period) among the subgroup of patients with mild Alzheimer's disease at baseline. To assess whether the benefits of early treatment can be matched by later treatment (that is, whether delayed-start patients can “catch up” with early-start patients), a noninferiority test was conducted.\(^1\)

**Key Results Highlights:**\(^1\)
- Treatment differences in cognition and function between early-start and delayed-start groups at the end of the placebo-controlled period (80 weeks since randomization) were preserved at the primary time point of 108 weeks (28 weeks after the start of EXPEDITION-EXT) within a pre-defined margin. This difference at 108 weeks remained statistically significant.
- Treatment differences in cognition and function between early-start and delayed-start groups at the end of the placebo-controlled period (80 weeks since randomization) were also preserved at an additional time point of 132 weeks (52 weeks after the start of EXPEDITION-EXT) within a pre-defined margin. This difference at 132 weeks was statistically significant.

**Analysis Methods**\(^1\)
A total of 1,322 subjects with mild Alzheimer’s disease were randomized to either the delayed-start (n=663) or to the early-start (n=659) groups. Of the 1,024 subjects who completed the placebo-controlled period (pooled EXPEDITION and EXPEDITION2), 95.2 percent (n=975) entered the delayed-start period (EXPEDITION-EXT), and 58.2 percent of delayed-start (n=286) and 61.0 percent of early-start patients (n=295) completed two years in the delayed-start period. Researchers tested the hypothesis of a potential disease-modifying effect of solanezumab using a delayed-start analysis, which applied a noninferiority test framework to determine if the delayed-start patients caught up with the early-start patients.
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. There are currently an estimated 44 million people living with dementia worldwide. The number of people affected by dementia is expected to be more than 75 million in 2030 and 135 million in 2050. Estimates vary, but experts suggest that as many as 5.3 million Americans may have Alzheimer’s disease.

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 certain forward-looking statements about solanezumab, an anti-amyloid monoclonal antibody in clinical testing for treatment of Alzheimer’s disease. This release reflects Lilly's current beliefs; however, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that solanezumab will be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly’s filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.