Delayed-Start Method Used With Solanezumab to Treat Alzheimer’s Disease

Eli Lilly announced results suggesting the treatment effect of solanezumab was preserved within a pre-specified amount in patients with mild Alzheimer’s disease who received it 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 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.

Key results included:
- Treatment differences in cognition and function between early-start and delayed-start groups at the end of the placebo-controlled period (i.e., 80 weeks since randomization) were preserved at the primary time point of 108 weeks (i.e., 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 (i.e., 80 weeks since randomization) were also preserved at an additional time point of 132 weeks (i.e., 52 weeks after the start of Expedition-EXT) within a pre-defined margin. This difference at 132 weeks was statistically significant.


Generic Version of Namenda® Approved

Upsher-Smith Laboratories, Inc., announced it received U.S. Food and Drug Administration approval of an abbreviated new drug application for Memantine Hydrochloride Tablets in 5 and 10 mg strengths. Memantine Hydrochloride Tablets are equivalent to Namenda®, which is indicated for the treatment of moderate to severe dementia of the Alzheimer’s type.