Drug for Mild AD Enters Next Wave of Study

Following discussions with regulators in the United States, Europe, and Canada, Eli Lilly and Company plans to conduct an additional Phase III study of solanezumab in patients with mild Alzheimer’s disease (AD). Additional details, including study design and length, are still being determined. Lilly expects to initiate this study no later than the third quarter of 2013. Solanezumab is a Phase III, monoclonal antibody that 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.

Lilly will continue to analyze and discuss the data from the two, Phase III, double-blind, placebo-controlled solanezumab EXPEDITION studies with regulators globally to determine the regulatory paths forward in different regions. Independent analyses of the Phase III solanezumab EXPEDITION data were conducted by the Alzheimer’s Disease Cooperative Study and presented at the annual meeting of the American Neurological Association and at the Clinical Trial on Alzheimer’s Disease.

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The EXPEDITION trials consisted of two Phase III, double-blind, placebo-controlled solanezumab trials in patients with mild-to-moderate AD in 16 countries. In both of the study protocols, mild AD was defined as a baseline Mini-Mental Status Examination (MMSE) score of 20 to 26, and moderate AD was defined as a baseline MMSE score of 16 to 19.

The designs of EXPEDITION1 and EXPEDITION2 were the same. Patients 55 and older were eligible to enroll in these studies; EXPEDITION1 enrolled 1,012 patients and EXPEDITION2 enrolled 1,040 patients. Patients received either 400 mg of solanezumab infused intravenously or placebo every 4 weeks for approximately 18 months. Both EXPEDITION trials allowed patients to remain on stable standard of care (defined as their existing treatment regimen) during these studies. More than 85% of the patients in these trials were taking an acetylcholinesterase inhibitor and/or memantine (Namenda®).

Although primary endpoints, both cognitive and functional, were not met in the two EXPEDITION trials, a pre-specified secondary analysis of pooled data in patients with mild AD showed a statistically significant slowing of cognitive decline. This finding represented a 34% reduction in decline. Over the 18 months of the EXPEDITION studies, the difference between patients treated with solanezumab versus placebo increased at a relatively constant rate over time.

An ongoing, open-label extension study, EXPEDITION-EXT, is fully enrolled and will continue as planned.


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Osteoporosis Treatment Shown to Increase Bone Mineral Density

Results of Unigene Laboratories, Inc.’s Phase II clinical trial evaluating an experimental oral parathyroid hormone (PTH) analog for the treatment of osteoporosis in postmenopausal women has been published online in Bone.

The study of oral PTH for the treatment of osteoporosis in 97 postmenopausal women was a multicenter, double-blind, randomized, repeat-dose placebo-controlled trial that included an open-label comparator arm of the Forsteo® injectable formulation. The primary objective of the Phase II study was to assess the change in bone mineral density (BMD) at the lumbar spine, a clinically validated predictor of fracture risk.

The study demonstrated once-daily treatment with 5 mg of orally delivered PTH resulted in a significant and clinically relevant mean increase in BMD at the lumbar spine of 2.2% (p < 0.001) at Week 24 compared to baseline. Secondary endpoints evaluated biochemical markers of bone formation and resorption, as well as the safety, tolerability, and pharmacokinetics of the oral formulation.


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