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Actinogen Xanamem Alzheimer's Biomarker Effect

Actinogen says a 72-patient phase IIa Alzheimer's disease biomarker study shows Xanamem has "a therapeutic effect in patients with a biomarker-positive blood profile".

Actinogen said that the 72-patient, double-blind, pre-specified, biomarker study used blood biomarker samples from the prior phase IIa placebo-controlled 'Xanadu' study of 185 patients diagnosed with mild Alzheimer's disease who were treated with Xanamem 10mg or placebo once daily for 12 weeks.

In 2019, the company fell as much as 70.8 percent on news that its 186-patient, phase II Xanadu trial of Xanamem for Alzheimer's disease "did not achieve statistical significance" (BD: May 7, 2019).

At that time, Actinogen said that despite missing primary and secondary efficacy endpoints the "results provide great encouragement to pursue higher dose and longer duration studies, consistent with ongoing Xanamem safety and target occupancy studies".

Today, Actinogen said that the endpoints of its biomarker study were to measure Xanamem effects in patients with biomarker-positive Alzheimer's and establish short-term effects of Xanamem on the levels of blood biomarkers.

The company said the study found that the Alzheimer's disease diagnostic biomarker, phosphorylated tau (pTau) blood levels were above the median value of 6.74 picograms per milliliter (pg/ml) in 34 patients, or 10.2pg/ml in nine patients who had a "clinically significant therapeutic benefit" from Xanamem.

Actinogen said that there was an average effect size of 0.6 to 0.8 points on the cognition and function clinical dementia rating-sum of boxes (CDR-SB) scale, which compared to 0.45 reported for the anti-amyloid antibody lecanemab.

The company said that it used Cohen's "d" statistic of effect size for treatment compared to placebo ($p = 0.09$), representing a 60 percent reduction in progression compared with placebo treatment, and that based on CDR-SB scores, twice as many patients in the Xanamem group were stable or improved compared with those in the placebo group.

Actinogen said that the findings confirmed that CDR-SB was a suitable endpoint for measuring Xanamem's therapeutic effect in trials of biomarker-positive Alzheimer's patients over a period as short as 12 weeks.

The company said that it had a "clear and uncontroversial" regulatory pathway with CDR-SB following the trial, which would be its primary endpoint in a planned phase IIb study and the findings "significantly de-risk and improve [Alzheimer's disease] program efficiency".

Actinogen chief medical officer Prof Paul Rolan said "these clinical results provide further validation of our Alzheimer's disease program and are a significant step forward in the development of Xanamem as a new treatment for Alzheimer's disease with a novel, amyloid-independent mechanism of action".

Actinogen managing-director Dr Steven Gourlay said the company was "very pleased to see such positive clinical data for patients with biomarker-positive, mild Alzheimer's disease.

"The results extend findings of therapeutic effects on cognition in two prior trials of cognitively normal, older volunteers to patients with early Alzheimer's disease," Dr Gourlay said.

"The data also validates the dose range planned for our upcoming trials in Alzheimer's disease and depression," Dr Gourlay said.

"Xanamem has the potential to be a novel daily oral therapy for Alzheimer's disease and other conditions that could be safely used alone or in combination with other therapies," Dr Gourlay said.

Actinogen climbed 2.4 cents or 25 percent to 12 cents with 37.2 million shares traded.