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Actinogen: ‘Xanamem Improves Cognition In Healthy Volunteers’

Actinogen leapt as much as 467 percent on news that its 42-patient Xanahes study shows “statistically significant ... cognitive improvement” in healthy, elderly subjects.

Actinogen said the placebo-controlled study investigated the safety of 20mg Xanamem, dosed in healthy elderly subjects daily for 12-weeks.

The company said the results showed “a good safety profile with no serious adverse events observed” and a “statistically significant reduction in serum cortisol following treatment with Xanamem 20mg daily” ($p < 0.001$).

In May, the company said its 186-patient, phase II Xanadu trial of Xanamem for Alzheimer’s disease “did not achieve statistical significance”, and further study of the effects of higher doses of Xanamem on cortisol production in the brain would be undertaken (BD: May 7, 2019).

Today, Actinogen said there was a “significant improvement in cognition in trial participants dosed with Xanamem ... compared to placebo”.

Actinogen chief executive officer Dr Bill Ketelbey told Biotech Daily that 30 subjects had received Xanamem and 12 had been administered a placebo.

The company said that the “breakthrough results” reinforced the hypothesis that lowering persistently-raised cortisol levels in the brain could positively enhance cognition.

Actinogen said the trial used the Cogstate cognitive test battery which showed cognitive improvement in three of the six domains investigated after 12 weeks of treatment.

The company said the cognitive test measured cognitive improvement with a “quantitative measure” of effect size, with a result greater than 0.8 indicating a “large treatment effect” and greater than 0.5 representing a “medium treatment effect”.

Actinogen said that “these results demonstrate an encouraging clinical efficacy signal in cognitive domains that are core to cognitive evaluation across many diseases”.

The company said that the results at week-12 had recorded a measure of 0.83 in the “one back test” evaluating working memory which had increased from 0.64 at week-2, to 0.78 at week-4 and 0.64 at week-8 ($p < 0.01$).

Actinogen said that in the visual attention identification test the average change was from 0.19 at week-2 to 0.67 at week-12 ($p = 0.05$).

The company said that the psychomotor function detection test demonstrated a non-statistically significant change from 0.47 at week-2 to 0.76 at week-12 ($p = 0.09$).

Actinogen said that the improved cognition in the Xanahes trial supported “Xanamem’s potential for the treatment of Alzheimer’s disease and other conditions associated with cognitive impairment, including mood disorders like bipolar disorder, and schizophrenia”.

Dr Ketelbey said that the data from Xanahes and the other ongoing studies provided a “much clearer picture of Xanamem’s pharmacology, potential efficacy, safety, and mechanism of action; all of which will aid substantially in planning the future clinical development and commercialization strategy for the drug”.

Xanahes trial lead investigator Prof Michael Woodward from Melbourne’s Austin Health said with many past failures in the development of Alzheimer’s drugs, the Xanahes results “renewed hope for a treatment breakthrough for this devastating disease”.

The company said that cognition enhancement in the Xanahes trial “supports Xanamem’s potential for the treatment of Alzheimer’s disease and other conditions associated with cognitive impairment, including mood disorders like bipolar disorder, and schizophrenia”.

Dr Ketelbey said that “these are the results we have been looking for”.

“They are hugely important for the development of Xanamem and for the potential for Xanamem to treat Alzheimer’s disease and other conditions associated with cognitive impairment,” Dr Ketelbey said.

Actinogen was up 4.2 cents or 466.7 percent to 5.1 cents with 454.6 million shares traded.