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Actinogen Xanamia Phase Ib Part A Trial Meets Endpoints

ACTINOGEN MEDICAL

Actinogen says its 107 healthy, cognitively normal, older adult phase Ib study of Xanamem for cognition met its primary safety, pharmacodynamic and efficacy endpoints.

Actinogen said the dose-ranging trial of adults aged 50 years to 80 years received 10mg or 5mg doses of Xanamem or placebo for six weeks and assessed cognitive abilities.

The company said that the study confirmed “Xanamem’s ability to rapidly enhance attention and working memory, confirming prior findings with a 20mg dose” and the results were “consistent with a prior positron emission tomography (PET) dose-ranging study that indicated dose levels of 10mg daily or lower [were] likely to be effective”.

Actinogen said the efficacy endpoint was defined as clinically significant “effect size” of Xanamem treatment on cognitive ability versus placebo, measured with validated tests of attention and working memory using the Cogstate cognition test.

The company said that daily Xanamem doses of 10mg and 5mg showed “a good safety profile and full pharmaco-dynamic activity supportive of continued development”.

Actinogen chief medical officer Prof Paul Rolan said the results “consolidate demonstration of the positive effects of Xanamem on cognition, with excellent safety”.

Prof Rolan said the results were “a major boost to our Alzheimer’s disease program and open the door to Xanamem’s evaluation in other chronic neurological and psychiatric diseases where poor cognition is a significant complaint”.

Actinogen managing-director Dr Steven Gourlay said the company was “excited to see the positive clinical data for these lower Xanamem dose levels”.

“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.

“Our future clinical trials will evaluate if Xanamem can make a significant improvement in the lives of patients and their families living with serious neurological and psychiatric conditions,” Dr Gourlay said.

Actinogen said the trial’s efficacy objective was to estimate “effect size”, especially for attention tests and confirm clinically significant effects, with the formal primary efficacy endpoint one or more cognitive domains showing an “effect size” of more than 0.3.

The company said that the primary efficacy endpoint was met at the end of treatment with 5mg, where the identification test of visual attention had a statistically significant effect size of 0.32 ($p < 0.05$).

Actinogen said it would review the results as it finalized the design of its next trial.

Actinogen fell 0.1 cents or 1.05 percent to 9.4 cents with 8.5 million shares traded.