



# Biotech Daily

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## Actinogen: 'Xanamem Fails Alzheimer's Endpoints', Falls 71%

Actinogen 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".

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".

The company said that the randomized, placebo-controlled study at 25 sites in Australia, the US, and the UK investigated the effect of 12 weeks of daily oral dosing of Xanamem in patients with mild dementia due to Alzheimer's disease.

In 2014, Actinogen acquired the University of Edinburgh spin-out company Corticrine for its compound, UE2343, which had completed a phase I, single, ascending-dose study in healthy volunteers and was "well tolerated in humans with no serious adverse events" (BD: Aug 27, 2014).

The company said that UE2343, later renamed Xanamem, reduced cortisol production though inhibiting the 11beta-hydroxysteroid dehydrogenase type 1 (11b-HSD1), enzyme in the human brain (BD: Jun 30, 2018).

Today, Actinogen said that reducing the stress hormone cortisol could have an effect on the development of Alzheimer's disease.

The company said that the 10mg Xanamem dose did not demonstrate efficacy in improving cognition in Alzheimer's and the primary and secondary endpoint measures did not demonstrate statistical differences between Xanamem and placebo.

Actinogen did not specify the data differences between the Xanamem and placebo groups, or any other detailed results.

Actinogen chief executive officer Bill Ketelbey said the results were “encouraging” and that “while 10mg Xanamem was not shown to be a clinically effective dose in Alzheimer’s disease, the safety and pharmacodynamic effects observed show potential that higher doses and a longer treatment duration of Xanamem may be efficacious”.

In 2015, Actinogen said that a phase I dose-ranging trial showed that Xanamem was safe and well-tolerated from 10mg to 35mg (BD: May 12, 2015).

Today, the company said it would study the effects of 20mg and 30mg doses of Xanamem on cortisol production in the brain and expected initial results from the Xanamem higher dose safety studies by the end of June 2019 and it was confident in the relationship between raised cortisol and cognitive impairment.

“The inhibition of cortisol production in the brain with Xanamem represents a compelling approach to treating cognitive impairment in Alzheimer’s and other neurological diseases, such as bipolar disorder and schizophrenia,” Actinogen said.

In 2017, the company said it received US, UK and Australian approvals and treated the first patient in the trial (BD: Jan 22, Feb 10, Mar 8, May 16, 2017).

Actinogen fell as much as 70.8 percent to 1.4 cents before closing down 3.3 cents or 68.75 percent at 1.5 cents with 322.7 million shares traded.