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Actinogen Plans Three Phase II Cognition Trials For 2022

ACTINOGEN MEDICAL

Actinogen's newly appointed chief executive officer Dr Steven Gourlay has wasted no time in reviewing Xanamem's data for cognition and planning three trials.

Dr Gourlay told Biotech Daily today that the company expected to have three separate phase II Australian trials running in 2022: for cognition in elderly subjects; for Fragile X in boys aged 12 to 18 years; and the third an "undisclosed but exciting" trial for "cognition plus".

In 2014, Actinogen acquired UE2343 from Edinburgh University for Alzheimer's disease, appointing Pfizer's Dr Bill Ketelbey as its chief executive officer to run the program (BD: Aug 27, Dec 1, 15, 2014).

In 2017, the company began the 186-patient, phase II Xanadu trial of 10mg Xanamem for Alzheimer's disease, but in 2019 told the ASX that the trial "did not achieve statistical significance" (BD: Jan 22, 2017; May 7, 2019).

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

Also in 2019, Actinogen began the Xanahes trial of 20mg Xanamem or placebo for 12 weeks (intended to be followed by a second cohort receiving 30mg Xanamem, which was abandoned following the success of the first cohort) to evaluate the safety of higher doses and cognitive efficacy (BD: May 29, 2019).

In October 2019, the company claimed success in the Xanahes trial of healthy elderly subjects, with “statistically significant” improvement in cognition and reduction in serum cortisol following treatment with Xanamem 20mg daily (BD: Oct 1, 2019).

In February, Actinogen said it had been granted US Food and Drug Administration rare paediatric disease designation for Xanamem for Fragile X syndrome and would receive a priority review voucher if approved by the FDA, which could be used for different indications and could be sold, with average voucher sale prices of more than $US100 million ($A131.7 million) (BD: Feb 5, 2021).

Dr Ketelbey resigned on February 5 and Dr Gourlay was appointed chief executive officer on March 15, 2021.

Today, Dr Gourlay said that part 1 of the phase II Xanamia trial would enrol about 100 healthy elderly subjects for a dose-ranging study comparing 5mg and 10mg Xanamem with placebo to confirm cognition, including a digit substitution test.

Dr Gourlay said the extension of the previous study was expected to begin “mid-year and report early next year”.

Dr Gourlay said that part 2 of the trial would investigate Xanamem for mild cognitive impairment in Alzheimer’s patients, starting after part 1 concluded AND with results expected in 2023.

Dr Gourlay said that, subject to further discussions with the FDA, the second phase II trial of Xanamen would be in 30 to 40 boys aged 12 to 18 years with Fragile X syndrome.

He said that the company was aiming to begin the trial “this year and report in 2023”.

Dr Gourlay said there were no approved drugs for Fragile X and the trial would include a mix of caregiver and clinician observations as well objective measures such as eye-tracking.

He said the phase II trial was hoped “to lead to a modest sized phase III trial in the orphan disease”.

Dr Gourlay said the third trial was “undisclosed but exciting … and would start this year or early next year” with endpoints described as “cognition plus”.

He said that all three trials were fully-funded with the cash currently held by the company.

Actinogen was up 0.2 cents or four percent to 5.2 cents with 23.4 million shares traded.