



ASX ANNOUNCEMENT

XanaMIA Part A trial achieves target enrolment

Sydney 29 November 2021. Actinogen Medical ASX:ACW (“ACW” or “the Company”) is pleased to announce that target enrolment has been reached in the XanaMIA Part A trial of 105 participants and that results are expected in Q2 CY2022.

The Part A XanaMIA trial is assessing the efficacy of 5mg and 10mg Xanamem doses compared to placebo in older healthy patients (aged 50 to 80 years old), over six weeks, to confirm the minimum effective dose needed to improve cognition (ability to think and remember things). The target dose range was determined by the results of a dose-ranging positron emission tomography (PET) study of Xanamem's inhibition of its target in the brain. Trial enrolment in under five months was achieved by a dedicated team of investigators and support staff working within the limitations of COVID-19 restrictions.

This study uses the Cogstate Neuropsychological Test Battery, which previously showed improvements in cognition at a higher dose, supplemented by the Digit Symbol Substitution Test (iDSST) which has been recognised in the past by regulatory bodies such as the FDA as an appropriate endpoint for a cognitive marketing claim.

Dr Steven Gourlay, the Company's CEO and Managing Director said, "The completion of XanaMIA Part A enrolment is a significant milestone in the Company's program to evaluate its lead molecule, Xanamem, for Alzheimer's Disease, Fragile X Syndrome and Depression. We look forward to the XanaMIA trial's confirmation of the effects of Xanamem on working memory and other measures of cognitive ability in Q2 CY2022."

ENDS

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Announcement authorised by the Board of Directors of Actinogen Medical

About Actinogen Medical

Actinogen Medical (ACW) is an ASX-listed, biotechnology company developing a novel therapy for neurological diseases associated with dysregulated brain cortisol. There is a strong association between cortisol and detrimental changes in the brain, affecting cognitive function, harm to brain cells and long-term cognitive health.

Cognitive function means how a person understands, remembers and thinks clearly. Cognitive functions include memory, reasoning, awareness and decision-making, and to a large extent, influence our personality.

We are currently developing our lead compound, Xanamem®, as a promising new therapy for Alzheimer's Disease, Fragile X Syndrome, and other neurological diseases where reducing cortisol inside brain cells could have a positive impact. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

About Xanamem®

Xanamem's novel mechanism of action works by blocking the production of intracellular cortisol through the inhibition of the 11β-HSD1 enzyme in the brain. Xanamem is designed to get into the brain after it is absorbed in the intestines upon swallowing its capsule.

Chronically elevated cortisol is associated with cognitive decline in Alzheimer's Disease, potentially linked to cognitive impairment and anxiety in Fragile X Syndrome, and cognitive impairment in other diseases.

The Company has studied 11β-HSD1 inhibition by Xanamem in more than 250 volunteers and patients, so far finding a statistically significant improvement in cognition over placebo in healthy, older volunteers. A series of Phase 2 studies in multiple diseases is being conducted to further confirm and characterise Xanamem's therapeutic potential.

Xanamem is an investigational product and is not approved for use outside of a clinical trial by the FDA or by any global regulatory authority. Xanamem® is a trademark of Actinogen Medical.

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