



## ASX ANNOUNCEMENT

### Actinogen announces designs for Phase 2 trials in Alzheimer's Disease and Depression

**Sydney, 14 June 2022 Actinogen Medical ASX: ACW ("ACW" or "the Company")** announces that it has finalised the designs for its planned Phase 2 trials in Alzheimer's Disease and Major Depressive Disorder.

**The Alzheimer's Disease (AD) XanaMIA Part B Phase 2 trial** will be a six-month dose-ranging, placebo-controlled trial in approximately 300 patients with early stages of AD, including patients with Mild Cognitive Impairment (MCI) as well as patients with mild AD, where some functional impairment (difficulty completing activities of daily living) is present over and above the purely cognitive difficulties experienced by MCI patients.

Effects of 5mg and 10mg Xanamem<sup>®</sup> dose levels on cognition will be measured by the same Cogstate Cognitive Test Battery (CTB) used in the recent XanaMIA Part A trial, supplemented by a variety of other tests of memory, attention and executive function. Results are expected in 2024.

**The Major Depressive Disorder (MDD) Phase 2 trial** will be a six-week proof-of-concept, placebo-controlled trial in approximately 120 patients with persistent MDD and cognitive difficulties despite a standard course of anti-depressant therapy. Xanamem 10 mg daily or placebo will be added to the existing anti-depressant therapy and effects on both depression and cognition will be assessed. Results are expected in late 2023 or 2024.

These Phase 2 trials follow on from the Company's positive XanaMIA Part A trial results announced on 27 April 2022 that confirmed Xanamem's ability to rapidly enhance attention and working memory in healthy, cognitively normal older adults while also confirming its promising safety profile.

**Actinogen's CEO, Dr Steven Gourlay, said:**

*"The results from our recent XanaMIA trial are exciting and highly confirmatory. We are now initiating two robust Phase 2 trials in patients with Alzheimer's Disease and Depression. Xanamem has the potential to be an effective low-dose daily oral therapy for these and many conditions where it may be used alone or in combination with other treatments."*

**ENDS**

<sup>®</sup> Xanamem is a registered trademark of Actinogen Medical Limited.

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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 and neuropsychiatric 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, attention, reasoning, awareness and decision-making.

Actinogen is currently developing its lead compound, Xanamem, as a promising new therapy for Alzheimer's Disease and Depression and hopes to study Fragile X Syndrome and other neurological and psychiatric diseases in the future. Reducing cortisol inside brain cells could have a positive impact in these and many other diseases. 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 is to block the production of cortisol inside cells through the inhibition of the 11 $\beta$ -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, and Xanamem has shown the ability to enhance cognition in healthy, older volunteers. Cognitive impairment is also a feature in Depression and many other diseases. Cortisol itself is also associated with depressive symptoms and when targeted via other mechanisms has shown some promise in prior clinical trials.

The Company has studied 11 $\beta$ -HSD1 inhibition by Xanamem in more than 300 volunteers and patients, so far finding a statistically significant improvement in working memory and attention, compared with placebo, in healthy, older volunteers in two consecutive trials. Previously, high levels of target engagement in the brain with doses as low as 5 mg daily have been demonstrated in a human PET imaging study. A series of Phase 2 studies in multiple diseases is being conducted to further confirm and characterize 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<sup>®</sup> is a trademark of Actinogen Medical.

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