



## ASX ANNOUNCEMENT

### **First Patient Enrolled in XanaMIA trial**

Sydney, 15 July 2021. Actinogen Medical ASX: ACW ('Actinogen' or 'the Company') is pleased to announce that the first patient has been enrolled in Part A of its two-part XanaMIA trial, which targets patients with Mild Cognitive Impairment (MCI) due to Alzheimer's Disease (AD). This follows Actinogen receiving ethics approval from the Bellberry Human Research Ethics Committee to commence the XanaMIA Part A study, as announced on 2 June 2021.

#### **Dr Steven Gourlay, Actinogen CEO and MD, commented:**

*"The commencement of the XanaMIA Part A trial marks a significant milestone in the progression of Actinogen's program to treat patients with Alzheimer's Disease. This trial will add to the considerable safety and efficacy dataset the Company has accumulated on Xanamem® and will explore the minimally effective dose to be studied in future trials. I look forward to working with the team to investigate the potential benefits of Xanamem in improving cognition and treating this devastating disease."*

Part A is being conducted at 4 outpatient sites in Australia and will enroll 105 older healthy volunteers, aged 50-80 years old, in a dose-ranging study to confirm the minimum effective dose. The study will determine the safety and efficacy of a 5mg and 10mg Xanamem dose on cognition (ability to remember and think), over 6 weeks. The trial will utilise an iPad testing method with the sensitive endpoints of the Cogstate Neurological Test Battery, incorporating the Digit Symbol Substitution Test - a previously FDA-approved endpoint for cognition.

The results from Part A will inform the dose(s) to be used in the Part B study, which will assess the efficacy of Xanamem in patients with biomarker-positive Alzheimer's Disease. Part B will measure the effects of Xanamem on biomarkers indicative of the underlying disease processes in addition to those on cognition.

#### **ENDS**

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***Announcement authorised by the Board of Directors of Actinogen Medical***

#### **About Actinogen Medical**

Actinogen Medical (ASX:ACW) is an ASX-listed biotechnology company developing novel therapies for neurological diseases associated with dysregulated brain cortisol. The Company is currently developing its lead compound, Xanamem™, as a promising new therapy for Alzheimer's Disease, Fragile X syndrome, and other potential neurological diseases. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is significantly 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 – the stress hormone – through the inhibition of the 11 $\beta$ -HSD1 enzyme in the brain. There is a strong association between persistent stress and the production of excess cortisol that leads to detrimental changes in the brain, affecting memory, cognitive function and behaviour and neuropsychological symptoms.

The Company has studied 11 $\beta$ -HSD1 inhibition by Xanamem in more than 200 volunteers and patients, finding a statistically significant improvement in cognition over placebo in healthy, older volunteers. A series of Phase II studies in multiple indications will be conducted to further confirm and characterise Xanamem's efficacy and safety.

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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