

#### **ASX ANNOUNCEMENT**

# Actinogen receives Ethics Committee approval for XanaMIA study

Sydney, 2 June 2021. Actinogen Medical ASX: ACW ('ACW' or 'the Company') is pleased to announce the progression of its clinical development program to treat patients with Alzheimer's Disease (AD). Actinogen has received approval from the Bellberry Human Research Ethics Committee (HREC) to commence the first part of the XanaMIA study, designed to study improvements in cognitive ability in older volunteers, and patients with Mild Cognitive Impairment (MCI), the first clinical stage of AD.

HREC approval allows the enrolment of the first patients, expected in July 2021. The XanaMIA study is planned to be conducted in two parts:

- XanaMIA Part A: Study is to be conducted at four clinics in Australia and enroll approximately 100 healthy volunteers aged 50 years and over in a dose-ranging study of 5mg and 10mg Xanamem® doses, to confirm the minimum effective dose. Part A utilises the Cogstate Neurological Test Battery, supplemented by the previously FDA-approved Digit Symbol Substitution Test.
- XanaMIA Part B: Study will assess the efficacy of Xanamem using the minimum effective dose selected from XanaMIA Part A. This will be conducted in a cohort of patients with MCI due to biomarkerpositive, early-stage Alzheimer's Disease.

#### **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 $^{TM}$  is a trademark of Actinogen Medical.

#### Disclaimer

This announcement and attachments may contain certain forward-looking statements that are based on subjective estimates and assumptions and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements involve known and unknown risks, uncertainties, and other factors (such as significant business, economic and competitive uncertainties and contingencies, and regulatory and clinical development risks and uncertainties) which may cause the actual results or the performance of Actinogen Medical to be materially different from the results or performance expressed or implied by such forward looking statements. Past performance is not a reliable indicator of future performance. There can be no assurance that any forward-looking statements will be realised. Actinogen Medical does not make any representation or give any warranty as to the likelihood of achievement or reasonableness of any forward-looking statements.

Actinogen Medical encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group.