

ASX ANNOUNCEMENT

First participant dosed in important new Xanamem study: XanaHES

- **XanaHES** is a Phase I dose escalation safety study of Xanamem involving healthy elderly adult volunteers
- The study is designed to expand the safety data-set for Xanamem within two cohorts of higher doses
- **XanaHES** is one of nine fully funded new studies initiated by Actinogen Medical, designed to enhance the Xanamem data-set
- Initial results from the first cohort of **XanaHES** are expected in Q2 2019, around the same time as **XanADu**, the Company's Alzheimer's disease study
- Results of all the new studies will be used to inform and support the ongoing development of Xanamem

Sydney 11 February 2019. Actinogen Medical (ASX: ACW) is pleased to announce dosing of the first participant in **XanaHES**, a Phase I dose escalation safety study of Xanamem in healthy elderly volunteers.

XanaHES is designed to expand the safety data-set for Xanamem, while exploring the potential for higher doses of the drug to be used, if considered necessary, in future trials in Alzheimer's disease and other indications. It is planned that 42 participants will be randomised into the first cohort and receive either 20mg Xanamem or placebo daily for 12 weeks. Following a review of the 20mg safety data, a second cohort of 42 participants may be randomised to receive 30mg Xanamem or placebo daily.

While XanaHES is primarily designed to evaluate the safety of higher doses of Xanamem, computerised cognitive efficacy tests will be performed on each participant to assess the extent to which Xanamem enhances cognition in this healthy elderly population, following a 12-week treatment period. Earlier clinical data (Sandeep et al 2004) provided compelling evidence that Xanamem may enhance cognition in an otherwise apparently cognitively normal elderly population.

Results from the first XanaHES cohort are expected in Q2 2019, around the same time that the Phase II XanADu Alzheimer's disease study results read out.

XanaHES is one of nine additional Xanamem studies initiated over the past few months that will expand and enhance the Xanamem data-set. Results from these nine studies will inform the future development of Xanamem and value-add to the ongoing engagement with potential partners across multiple indications.

Commenting on the dosing of the first participant in XanaHES, CEO Dr Bill Ketelbey said: "We are very excited to have reached yet another important milestone in the development of Xanamem, with dosing of the first participant in our XanaHES study. This study will allow us to potentially explore higher doses of Xanamem in future studies in Alzheimer's disease and other indications, should this be considered necessary. The nine additional studies initiated over the past few months will substantially enhance the Xanamem data-set and help inform the optimum way forward with the development of Xanamem. These results will provide a number of important catalysts for the business over the next six to 12 months."

ENDS

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About Actinogen Medical

Actinogen Medical (ASX: ACW) is an ASX-listed biotech company focused on innovative approaches to treating cognitive decline that occurs in chronic neurodegenerative and metabolic diseases. Actinogen Medical is developing its lead compound Xanamem, as a promising new therapy for Alzheimer's disease, a condition with a multibillion-dollar market potential. In the US alone, the cost of managing Alzheimer's disease is estimated to be US\$250bn and is set to increase to US\$2tn by 2050, outstripping the treatment costs of all other diseases. Alzheimer's disease is now the leading cause of death in the UK and second only to ischaemic heart disease in Australia

About Xanamem™

Xanamem's novel mechanism of action sets it apart from other Alzheimer's treatments. It works by blocking the excess production of cortisol - the stress hormone – through the inhibition of the 11β-HSD1 enzyme in the brain. This enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain most affected by Alzheimer's disease. There is a strong association between chronic stress and excess cortisol that leads to changes in the brain affecting memory, and to the development of amyloid plaques and neural death – all hallmarks of Alzheimer's disease.

About XanaHES

XanaHES is a Phase I, randomised, single blinded, central reader blinded, placebo-controlled, dose escalation study to assess the safety and tolerability of Xanamem™ 20mg & 30mg once daily in healthy elderly volunteers. Changes in cognitive performance from baseline to end-of-treatment will be measured as an exploratory efficacy outcome.

About XanADu

XanADu is a Phase II double-blind, 12-week, randomised, placebo-controlled study to assess the safety, tolerability and efficacy of Xanamem in subjects with mild dementia due to Alzheimer's disease. XanADu has fully enrolled 186 patients from 25 research sites across Australia, the UK and the USA. Results are expected in Q2 2019. The trial is registered on www.clinicaltrials.gov with the identifier: NCT02727699, where more details on the trial can be found, including the study design, patient eligibility criteria and the locations of the study sites.

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