**ASX ANNOUNCEMENT**

# XanaHES trial to continue

- **Dose Escalation Committee's safety review recommends XanaHES to continue, with protocol enhancements**
- **XanaHES is a Phase I dose escalation safety study of Xanamem involving healthy elderly adult volunteers**
- **Safety review encompassed data from 34 subjects dosed with 20mg Xanamem daily, up to the data cutoff date of 1st May**
- **XanaHES is designed to expand the safety dataset for Xanamem, with two cohorts at higher doses (20mg and 30mg Xanamem once daily)**
- **The trial is one of nine fully funded new studies initiated by Actinogen, designed to enhance the Xanamem dataset**

**Sydney, 29 May 2019. Actinogen Medical ASX: ACW ('ACW' or 'the Company')** announces the Dose Escalation Committee has recommended that the XanaHES 20mg Phase I trial should continue, with some protocol enhancements, based on a review of safety data.

XanaHES is Actinogen's Phase I dose escalation safety study of Xanamem in healthy elderly volunteers. The study is designed to expand the safety dataset for Xanamem, while exploring the potential for higher doses of the drug to be used in future trials in Alzheimer's disease and other indications.

The XanaHES study will randomise 42 participants into the first cohort to receive either 20mg Xanamem or placebo daily, for 12 weeks. Following a Dose Escalation Committee review of all data from the 20mg cohort, a second cohort of 42 participants may be randomised to receive 30mg Xanamem or placebo daily.

As of the date of the Dose Escalation Committee safety review meeting, 34 subjects had been randomised into the first cohort of 20mg, and safety data from all subjects was reviewed, using a data cut-off of 1st May.

XanaHES is primarily designed to evaluate the safety of higher doses of Xanamem, however additional computerised cognitive efficacy tests (Cogstate test battery) are being performed on each participant to assess the extent to which Xanamem 20mg daily enhances cognition in this healthy elderly population, following a 12-week treatment period.

XanaHES is one of nine additional Xanamem studies initiated over the past year that will expand and enhance the Xanamem dataset, and inform the future development of Xanamem.

Commenting on the outcome of the XanaHES safety review meeting, CEO Dr Bill Ketelbey noted: "The recommendation to continue XanaHES, with refinements to the protocol, is a validation of the XanaHES dose escalation trial and its design. This trial enables Actinogen to further enhance the Xanamem dataset, and as we progress with XanaHES and the other Xanamem studies, we look forward to updating the market on further positive news on Xanamem's ongoing development".

**ENDS**

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**About Actinogen Medical**

Actinogen Medical (ASX: ACW) is an ASX-listed biotechnology company focused on innovative approaches to treating cognitive decline that occurs in chronic neurological and metabolic diseases. Actinogen Medical is developing its lead compound Xanamem, as a promising new therapy for Alzheimer's disease, a condition with multibillion-dollar market potential and material human impact. In the US alone, the cost of managing Alzheimer's disease is estimated to be US$250bn and is projected 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. In addition, Actinogen is currently planning an expanded clinical development program for Xanamem in cognitive impairment in mood disorders and schizophrenia. In the US alone, the collective economic costs of mood disorders and schizophrenia are estimated to exceed $550bn, with the burden increasing every year. The cognitive dysfunction associated with these conditions is significantly debilitating for affected patients, with a substantial unmet medical need for novel, improved treatments.

**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. There is a strong association between chronic stress and excess cortisol that leads to changes in the brain affecting memory. The 11β-HSD1 enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain associated with cognitive impairment in neurological diseases, including Alzheimer's disease, mood disorders and schizophrenia.

**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. 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.

**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.

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