

### **ASX ANNOUNCEMENT**

# **Clinical Development and Scientific Conference Update**

Sydney, 3 July 2019. Actinogen Medical ASX: ACW ('ACW' or 'the Company') is pleased to provide an update on the ongoing progress with the clinical development of Xanamem<sup>™</sup>, as well as advise of an upcoming presentation at the Alzheimer's Association International Conference (AAIC) in Los Angeles, USA.

## XanaHES Phase 1 Higher Dose Safety Study - Final subject enrolled in 20mg cohort

As previously communicated to the market, the Company has made positive progress on this study being conducted in Perth by Linear Clinical Research. The final subject in the 20mg cohort has now been enrolled and a Dose Escalation Committee will determine, once all subjects have completed the 16-week study period, if the study should proceed with the second cohort of 30mg. Actinogen expects to provide full results on the 20mg cohort by Q4 CY19, including the safety profile of 20mg, and the results on the Cogstate cognition test battery.

Results from XanaHES will provide important data on the potential use of higher doses of Xanamem in future studies, should this be necessary.

# **Target Occupancy Phase I Study - Cohort updates**

As noted in Actinogen's most recent announcement (26 June 2019), this Phase I study has made positive progress, with the 10mg cohort demonstrating encouraging initial results, supporting Xanamem as a potent, orally bioavailable and brain-penetrant  $11\beta$ -HSD1 inhibitor.

The study has now completed the 20mg cohort and the Company is pleased to confirm that the results continue to be encouraging, with this dose also demonstrating significant inhibition of the  $11\beta$ -HSD1 enzyme.

The study will now proceed with 30mg and 5mg cohorts, to enable a full analysis and understanding of the dose-inhibition response of Xanamem.

# Alzheimer's Association International Conference (AAIC)

Actinogen is pleased to note that on behalf of the Company, Sarah Gregory, PhD from the University of Edinburgh, will present a scientific poster at AAIC. Dr Gregory's research involved a year-long review that examined published literature for hypotheses, trends, outcomes, and conclusions associated with the therapeutic potential of inhibiting the  $11\beta$ -HSD1 enzyme. Her presentation is entitled " $11\beta$ -hydroxysteroid dehydrogenase type 1 inhibitors: pharmacological mechanisms and potential therapeutic uses - a systematic review".

AAIC is the largest and most influential international meeting dedicated to advancing the science of dementia and attendees include clinical researchers, investigators, clinicians and the wider research community, who all come together to share the latest findings on Alzheimer's disease. AAIC runs from 14-18 July 2019 in Los Angeles, USA.

#### **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  $11\beta$ -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  $11\beta$ -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.