

ASX ANNOUNCEMENT

## Phase II Alzheimer's Disease Trial – results

- Safety clearly established and significant pharmacodynamic effects of lowering cortisol observed in the Xanamem treatment group
- Efficacy endpoints did not achieve statistical significance at 10mg Xanamem dose
- Results provide great encouragement to pursue higher dose and longer duration studies, consistent with ongoing Xanamem safety and target occupancy studies
- Initial results from current Xanamem studies expected by the end of June 2019

**Sydney, 7 May 2019. Actinogen Medical ASX: ACW ('ACW' or 'the Company')** announces initial data from XanADu, its Phase II clinical trial of 10mg Xanamem in patients with mild dementia due to Alzheimer's disease.

XanADu established that a 10mg daily dose of Xanamem is safe and has the ability to effectively inhibit cortisol production, as demonstrated by the expected increase in related hormones, including ACTH (adrenocorticotrophic hormone).

Xanamem at 10mg did not demonstrate adequate efficacy in improving cognition in mild Alzheimer's disease. The primary and secondary endpoint measures did not demonstrate statistical differences between Xanamem 10mg and placebo.

Further analysis is underway to explore trends in the data and to identify any specific cognitive domains in which positive trends may be evident. Whilst a 10mg daily dose of Xanamem appears safe and pharmacologically active, higher doses and longer treatment duration may be necessary to effectively demonstrate its potential to improve cognition in Alzheimer's disease.

The Company's development program, including the target occupancy and the XanaHES higher dose (20mg & 30mg) safety studies, is designed to provide greater insight into Xanamem's safety and its activity on cortisol production in the brain. Initial results from these studies are expected to read out by the end of June and will provide important data to further inform and refine Xanamem's ongoing clinical development program.

The Company is confident in the relationship between raised cortisol and cognitive impairment. The inhibition of cortisol production in the brain with Xanamem represents a compelling approach to treating cognitive impairment in Alzheimer's and other neurological diseases, such as bipolar disorder and schizophrenia.

"These XanADu results are certainly encouraging. While 10mg Xanamem was not shown to be a clinically effective dose in Alzheimer's disease, the safety and pharmacodynamic effects observed show potential that higher doses and a longer treatment duration of Xanamem may be efficacious," said Dr Bill Ketelbey, CEO.

"Alzheimer's disease is a major health crisis with limited treatment options, and these results will help with the ongoing fight to find new effective therapies. The Company is extremely grateful to the patients and their carers who participated in XanADu, and to the 25 research sites and their personnel in Australia, the UK, and USA that made this study possible. Their involvement has helped generate important clinical data on the treatment of Alzheimer's disease with Xanamem and for the ongoing development of this drug."

The Company will provide updates to investors following completion of further analysis of the XanADu data and the initial results from the ongoing Xanamem studies.

## 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](http://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.**

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