

# Early Efficacy and Safety Data Read-Out Planned for Alzheimer's Trial

- Interim efficacy and safety data to be available on the first 50 patients completing XanADu, Actinogen's
   Phase II trial of Xanamem™ in Alzheimer's disease, in April-June 2018
- Efficacy and safety data from interim analysis available one year earlier than full study results
- Analysis may provide useful early efficacy and safety data on Xanamem in Alzheimer's disease
- Approvals to implement interim analysis received for all study sites in the USA. Australia and the UK
  approvals expected before year end
- Interim analysis comes on top of the positive progress made with patient enrolment into XanADu. Forty-four (44) enrolled, with 6 having already completed the trial

**Sydney, 29 November 2017: Actinogen Medical (ASX: ACW)** is pleased to announce that an efficacy and safety interim analysis will be undertaken on the first 50 patients completing XanADu, its Phase II trial of Xanamem in Alzheimer's disease.

The efficacy and safety data from this interim analysis are expected to be available in April-June 2018 - a year earlier than the planned full study results from XanADu.

This refinement to the XanADu trial could provide an early indication of the potential for Xanamem in the treatment of Alzheimer's disease and confirm the quality of the conduct of the study and the statistical assumptions underpinning its design.

Approvals to implement the interim analysis have been received from all study sites in the USA, and the FDA has acknowledged the receipt of the required documentation. Approvals from the study sites in Australia and the UK are still pending, however they are expected before the end of 2017.

The design of XanADu remains unchanged, including the efficacy and safety endpoints and the total patient numbers planned for the study. Actinogen remains on track to enrol the final patient by the end of 2018, with top-line results due in April-June 2019

As the proposed interim analysis is being performed on only 50 patients, and the full study is expected to include up to 174 patients, statistically valid conclusions on the efficacy of Xanamem in Alzheimer's disease are unlikely from these data. However, the interim analysis report, which will be provided by an independent Data Safety Monitoring Board, could identify early efficacy and safety trends developing as the study progresses. In addition, these data could provide further substantiation to support the cortisol hypothesis underpinning the development of Xanamem.

This interim analysis comes on top of the positive progress made with patient enrolment into XanADu. Forty-four (44) patients have been enrolled and the first 6 patients have already completed the study. It is expected that the 50 patients included in this interim analysis should be enrolled into XanADu before the end of 2017.

"We are particularly pleased to be implementing this added enhancement to the XanADu study. We hope this will provide the Company and its shareholders some valuable information on Xanamem's use in patients with

Alzheimer's disease, a year earlier than originally planned. Additionally, we are delighted to now have the study fully funded through to completion." said Dr Bill Ketelbey, CEO of Actinogen Medical.

### **ENDS**

### **Actinogen Medical**

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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 Xanamem 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  $11\beta$ -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 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, will enrol 174 patients at 20 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.

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