



## Interim Analysis Recommends Continuation of XanADu Without Change

- DSMB recommends continuing the XanADu study without modification
- Interim Analysis conducted on data from first 50 evaluable XanADu trial patients
- Early safety and efficacy data reviewed by an independent Data Safety Monitoring Board (DSMB)
- XanADu on target to achieve full enrolment of 174 patients by Q4 2018
- 100 patients currently enrolled, represents 57% of the total 174
- Investor conference call with key members of management and the Company's Clinical Advisory Board to be held on Wednesday 30<sup>th</sup> of May at 10:30am AEST

**Sydney, 23 May 2018:** Actinogen Medical ASX: ACW ('ACW' or 'the Company') is pleased to announce the completion of a planned Interim Analysis of its Phase II XanADu trial by an independent *Data Safety and Monitoring Board* (DSMB), with the Company receiving the DSMB recommendation to continue the study without modification.

The DSMB recommendation affirms that the positive benefit-risk safety profile of Xanamem 10mg daily and supports the expectation that the study is progressing as planned. Importantly, no treatment-related serious adverse events have been reported. The outcome from the analysis supports the continuation of XanADu and the further development of Xanamem in other potential indications such as diabetes-associated cognitive impairment. The DSMB will conduct a follow-up meeting in three months' time.

The Interim Analysis was conducted on the first 50 evaluable patients to have fully completed the study. An additional 37 patients' safety data was also included in the analysis – this was data from patients still ongoing in the study.

XanADu is a randomized, double-blind, multi-centre clinical study comparing Xanamem to placebo in patients with mild dementia due to Alzheimer's disease. The Interim Analysis was performed by the DSMB using prespecified assessments, outlined in the DSMB Charter and study Protocol, of unblinded safety and efficacy patient data on the first 50 evaluable patients. Based on the data reviewed, the independent DSMB has recommended that the XanADu study continue as planned without modification.

The XanADu patient data remains blinded to the Company and to all non-DSMB personnel involved in the clinical study including individual patients, clinical investigators, study site staff, and all contracted Company vendors. Blinded studies safeguard the integrity and credibility of clinical data and ensure that no biases are introduced.

Actinogen continues to enrol patients into the XanADu clinical trial and as 23<sup>rd</sup> May, a total of 100 patients have been enrolled, which is 57% of the total planned enrolment of 174 patients. The study continues to progress on track and in line with management's projections, with the last patient expected to be enrolled by Q4 this year.

"We're delighted with the recommendation from the DSMB to continue the trial without modification and it helps build our confidence and optimism in the potential of Xanamem to be an effective treatment for Alzheimer's disease", said Dr Bill Ketelbey, CEO of Actinogen Medical. "If Xanamem is shown to safely and effectively treat dementia due to Alzheimer's disease, it would represent a significant breakthrough in the management of this devastating disease. We eagerly await the completion of the XanADu enrolment before the end of 2018 and the review of the full dataset in Q2 2019", he continued.

The Company will be hosting a conference call on Wednesday the 30<sup>th</sup> of May 2018 at 10:30am AEST. Key members of the management team and the Company's Clinical Advisory Board will be available during the conference call to discuss Xanamem, XanADu, the Interim Analysis and the Placement. **Actinogen Medical** 

Dr. Bill Ketelbey CEO & Managing Director P: +61 2 8964 7401

E: bill.ketelbey@actinogen.com.au

@BillKetelbey

**Media Enquires** 

Zena Chamas Media & Capital Partners

M: +61 434 153 055

E: zena.chamas@mcpartners.com.au

## **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.