

## **ASX ANNOUNCEMENT**

# DSMB again reaffirms XanADu trial should continue without change

- Third and final DSMB review reaffirms previous recommendations to continue the Phase II Alzheimer's trial XanADu without modification
- Positive recommendation reflects confidence in safety of Xanamem in the treatment of Alzheimer's disease
- Unblinded safety data from 162 patients were examined by the DSMB in this review
- Results from XanADu trial in Alzheimer's is on track to be announced within the next three months

Sydney, 26 March 2019: Actinogen Medical ASX: ACW ('ACW' or 'the Company') announces that the XanADu Data Safety Monitoring Board (DSMB) has again reaffirmed its recommendation that this Phase II trial in Alzheimer's disease, continue without modification.

The DSMB reviewed unblinded safety data from 162 patients who have completed the trial and reaffirmed its previous recommendations that XanADu continue without modification. This is the third and final DSMB review.

This positive recommendation from the DSMB, which is independent to the Company and constituted as the only group with access to unblinded data, reflects the ongoing confidence in the safety of Xanamem. This recommendation, as with the previous positive DSMB recommendations, continues to support the broader development and safety of Xanamem, and to underpin the XanADu trial in Alzheimer's disease.

The continued excellent progress of XanADu, which is on track to report out results within the next three months, corresponds with the significant expansion of the Xanamem clinical development program, as announced to the market in July 2018. Since then, nine additional studies have been initiated, including a target occupancy study, a higher dose safety study (XanaHES) and multiple safety toxicology studies.

## **ENDS**

**Actinogen Medical** 

@BillKetelbey

Dr. Bill Ketelbey
CEO & Managing Director
P: +61 2 8964 7401
E: bill.ketelbey@actinogen.com.au

**Investor and Media Enquiries** 

Arthur Chan WE Buchan M: +61 2 9237 2805

E: arthurc@we-buchan.com

### **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 its lead compound Xanamem, as 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 plagues 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 has fully enrolled 186 patients from 25 research sites across Australia, the UK and the USA. Results are expected in Q2 2019. 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.