

DSMB reaffirms recommendation to continue XanADu without change

- Follow-up DSMB meeting reaffirms recommendation to continue the Phase II XanADu trial without change
- Safety data from 125 patients was evaluated in this periodic review
- XanADu enrolment continues as planned with last patient expected before the end of 2018
- Top-line XanADu results expected in Q2 2019, less than 12 months from now

Sydney 22 August 2018. Actinogen Medical ASX:ACW ('ACW' or 'the Company') is pleased to announce that the XanADu Data Safety Monitoring Board (DSMB) has, following its most recent review, reaffirmed its recommendation that the Phase II trial should continue without modification.

This periodic review was conducted as part of the DSMB's responsibilities to oversee the safety of the trial. The DSMB reviewed safety data from 125 patients and reaffirmed its previous recommendation that the XanADu trial should continue without modification. The DSMB will hold a third periodic review, and likely their last meeting, before the end of 2018.

This pleasing outcome from the ongoing safety surveillance of the XanADu trial by the DSMB comes on top of the positive progress made with patient enrolment. To date, a total of 136 patients have been enrolled (78% of the planned 174) and the Company continues on track to finalise recruitment into the trial before the end of 2018.


The excellent progress with XanADu is reinforced by the expansion of the clinical development program for Xanamem, as announced in late July. This includes a target occupancy study that is already underway; a higher dose safety study and multiple standard safety toxicology studies expected to initiate in Q4 this year. There is also an ongoing in-depth review of potential market expansion opportunities in various additional indications for which Xanamem could be developed.

With 50 million Alzheimer's disease sufferers globally and the limited clinical benefit provided by the currently available therapies, there has never been a greater urgency to discover new effective drugs to treat this devastating disease. Actinogen eagerly awaits the results from XanADu, its Phase II trial of Xanamem in Alzheimer's disease, as a first step in tackling this important disease.

Top-line results for XanADu, and some of the recently announced Xanamem studies including the target occupancy study, are expected in Q2 2019, less than 12 months from now.

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 11β-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.