



## EXCELLENT RESEARCH PROGRESS WITH XANAMEM™ – A PROMISING ALZHEIMERS DRUG

- Ethics approval received for third and final stage of Xanamem™ Phase I trial.
- Primary endpoint is to demonstrate that Xanamem™ is efficiently delivered to the brain, the primary site of action in Alzheimer's disease.
- Follows the successful completion of stages one and two which demonstrated the safety and tolerability of Xanamem™ across the entire dose range of 10mg to 35mg twice daily
- Dosing also underway on the final pre-clinical toxicology study with results due fourth quarter 2015
- Results will enable regulatory submissions later this year, including to the FDA, for approval to run the Phase II trial of Xanamem™ in Alzheimer's patients in the US, UK and Australia.

**Sydney, 11<sup>th</sup> June 2015:** Actinogen Limited (Actinogen Medical, ASX: ACW), an Australian biotechnology company focused on the development of novel treatments for Alzheimer's disease and other major age-related neurodegenerative disorders, is pleased to announce that it has received ethics approval to initiate the third and final stage of the second Phase I trial of its lead Alzheimer's drug candidate, Xanamem™.

This final stage will examine the CNS pharmacokinetics of Xanamem™ and will involve the recruitment of four healthy volunteers. The primary endpoint is to demonstrate that Xanamem™ is efficiently delivered to the brain, its primary site of action in Alzheimer's disease. The trial is being conducted at Linear Clinical Research, a world-class clinical trial facility that is part of the QEII Medical Centre in Perth, Western Australia.

In addition, the second stage of the Phase I trial, a fed-fasted dosing of 12 participants on 35mg of Xanamem™, has successfully completed with results expected in August 2015. Both the first and second stages of this study demonstrated the safety and tolerability of Xanamem™, even at the highest dose of 35mg twice daily.

Actinogen is also pleased to announce that dosing in the final pre-clinical toxicology study is well underway with the results expected before the end of the year.

Significantly, all these studies remain on-track, with results to be incorporated into the research documentation supporting the all-important Phase II study of Xanamem™ in Alzheimer's patients. The results will enable an Investigational New Drug (IND) application to the FDA later this year for the Phase II trial to be run in the US. The trial will also be run in Australia, New Zealand and the UK, and is expected to commence in the first half of 2016

"The ongoing excellent progress of this Xanamem™ study sets us up well to start the Phase II trial of Xanamem™ in patients with Alzheimer's disease in the first half of 2016. It is particularly pleasing to continue on-track with our development plans for this promising new treatment for Alzheimer's disease," said Actinogen Medical CEO, Dr Bill Ketelbey.

**ENDS**

**Actinogen Medical**

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**About Xanamem™**

Xanamem™ is being developed as a promising new therapy for Alzheimer's disease, a condition with a multi-billion dollar market potential. The cost of Alzheimer's treatment in the US alone was estimated to be US\$250bn in 2013, with this cost estimated to increase to US\$1 trillion by 2050, outstripping the cost of treating all other diseases. Alzheimer's disease is now the second leading cause of death in Australia behind ischaemic heart disease. Xanamem™'s novel mechanism of action sets it apart from existing Alzheimer's treatments. It works by blocking the production of cortisol - the stress hormone - in the hippocampus and frontal cortex, the areas of the brain most affected by Alzheimer's disease. There is growing evidence that chronic stress and elevated cortisol levels lead to changes in the brain affecting memory and to the development of amyloid plaques and neural death – the hallmarks of Alzheimer's disease.

**About Actinogen Medical**

Actinogen Medical is focused on the treatment of Alzheimer's disease and mild cognitive impairment, a transitional stage of cognitive impairment between normal aging and the more serious condition of Alzheimer's dementia. It is developing a novel drug to treat the condition and other age-related neurodegenerative diseases. The lead candidate drug Xanamem™, blocks the development of cortisol which appears to contribute to cognitive impairment and amyloid plaques – hallmarks of Alzheimer's disease. The Company is currently completing a second Phase I trial in healthy volunteers with results due in mid-2015 and plans to undertake a Phase II study in Alzheimer's patients in 2016.