



## CLINICAL TRIAL UPDATE ON XANAMEM™ DRUG FOR ALZHEIMERS DEMENTIA

- **First trial participants successfully dosed on 10mg**
- **Independent Dose Escalation Committee reviews safety and tolerability and approves dose escalation to 25mg**
- **The primary endpoint of the study is to confirm the safety and tolerability of the drug; in addition the study will demonstrate how the body absorbs and metabolises Xanamem™**
- **Results will add to the evidence base, enabling an Investigational New Drug (IND) application to the FDA for a Phase II study of Xanamem™ in the US. The study will also be run in ANZ and the UK**
- **Full results are expected by mid-2015**

**Sydney, 24th March 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 an update on the second Phase I study for its lead drug candidate, Xanamem™. Following the successful recruitment and dosing at 10mg of the first cohort of 8 participants, the results were reviewed by the independent Dose Escalation Committee. The Committee was satisfied with the safety, tolerability and pharmacokinetic results and allowed for a dose escalation to 25mg for the next cohort of 8 participants.

Actinogen Medical expects the next cohort to be dosed in late March and is pleased to reaffirm that the clinical trial program continues to execute on time and on budget.

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 last year by the American Alzheimer's Association. This cost is estimated to increase to US\$1 trillion by 2050, outstripping the cost of treating all other diseases.

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.

In this second Phase I study, a total of 24 healthy volunteers will be given doses of 10mg, 25mg and 35mg of Xanamem™, in a multiple ascending dose (MAD) with eight participants in each cohort. The primary endpoint of the study is to confirm safety and tolerability of the drug. In addition the study will demonstrate how the body absorbs and metabolises Xanamem™ and the optimal dose for the drug.

This double-blinded, placebo controlled study 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.

### ENDS

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### **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. The Company is currently undertaking a second Phase I multiple ascending dose trial in healthy volunteers with results in mid-2015 and plans to undertake a Phase II study in 2016.