



FURTHER CLINICAL TRIAL UPDATE ON XANAMEM™, DRUG FOR ALZHEIMERS DEMENTIA

- **Second cohort of trial participants successfully dosed on 20mg Xanamem™**
- **Independent Dose Escalation Committee reviews safety and tolerability and approves dose escalation to 35mg in the final study cohort**
- **Following successful dosing at 35mg, this part of the Phase I MAD study will be complete**
- **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, 16 April 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 a further update on the second Phase I study for its lead drug candidate, Xanamem™. Following the successful dosing at 20mg of the second cohort of 8 participants, the independent Dose Escalation Committee was satisfied with the safety, tolerability and pharmacokinetic results and approved a dose escalation to 35mg for the final cohort of 8 participants.

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

This stage of the trial will be complete with the successful dosing of the third cohort of 8 participants at 35mg. The next stage is a fed-fasted study in a cohort of 12 participants. The ethics submission for this part of the study has been made, and dosing is expected to commence on 19 May 2015 following ethics approval.

Xanamem™ is being developed as a promising new therapy for Alzheimer's disease, a condition with a multibillion 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 are given doses of 10mg, 20mg 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. Following successful dosing of the 35mg cohort, a fed-fasted study will be run in a cohort of 12 participants.

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 an Australian biotechnology company focused on the treatment of Alzheimer's disease and prodromal Alzheimers/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 Alzheimer's disease and other age-related neurodegenerative diseases. The lead candidate Xanamem™, blocks the development of cortisol which appears to contribute to cognitive impairment and amyloid plaques – hallmarks of Alzheimer's. The Company is currently undertaking a second Phase I multiple ascending dose trial in healthy volunteers with results expected in mid-2015. Actinogen Medical plans to initiate a Phase II study in Alzheimer's and Mild Cognitive Impairment in 2016.

About Xanamem™

Xanamem™ is under development as a potential new therapy for Alzheimer's disease and prodromal Alzheimers/Mild Cognitive Impairment, conditions with a multi- billion dollar market potential. 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.