



ETHICS APPROVAL GRANTED FOR SECOND STAGE OF PHASE I STUDY OF XANAMEM™

- **Ethics approval granted for promising lead drug candidate Xanamem™ in the second stage of a Phase I study in Alzheimer's dementia**
- **Approval of the second stage of a three-stage study – first stage near completion**
- **Total of 40 patients are to be enrolled in the double-blind, placebo controlled study over three stages**
- **The primary endpoint of stages 1 & 2 is to confirm how the body absorbs and metabolises Xanamem™**
- **Results from the final stage will confirm the central nervous system pharmacokinetics of Xanamem™**
- **Results will add to the evidence base, enabling an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) for a Phase II study of Xanamem™**
- **Full results expected in mid-2015**

Sydney, 24 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 it has received ethics approval for the second stage of its Phase I study of Xanamem™, its promising lead research candidate in Alzheimer's disease.

Xanamem™ is being developed as a potential 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, and Alzheimer's is the second-leading cause of death in Australia, behind ischaemic heart disease.

The drug works by blocking the development of cortisol - the stress hormone - in the hippocampus, the area 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.

Actinogen Medical's second Phase I study is a double-blind, placebo-controlled study and is being conducted at Linear Clinical Research, a world-class clinical trial facility that is part of the QEII Hospital in Perth, Western Australia.

The first stage of the study is nearing completion with the recently announced approval to escalate dosing to the highest and final dose of 35mg. This ethics approval is for the second stage of the Phase I study - a fed-fasted study of 12 participants at 35mg. The primary endpoint of the study is to confirm how the body absorbs and metabolises Xanamem™ with and without food, at the highest dose of the drug.

The third and final stage of the Phase I study will involve a cohort of four patients to confirm the central nervous system pharmacokinetics of Xanamem™.

All these studies will add to the evidence base enabling an Investigational New Drug (IND) application to the Food and Drug Administration's (FDA) for a Phase II study of Xanamem™ in the US, to start in 2016.

Full results of this Phase I study are expected by mid-2015.

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.