ETHICS APPROVAL GRANTED FOR SECOND PHASE I STUDY OF XANAMEM™

- **Ethics approval granted for lead drug candidate Xanamem™ in a second Phase I study in Alzheimer's dementia**
- **Approval of the first phase of a three cohort study**
- **Total of 40 patients are expected to be enrolled in the double-blind, placebo controlled study over three cohorts**
- **The primary endpoint of the study is to confirm how the body absorbs and metabolises Xanamem™**
- **The follow-on cohort results 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 Food and Drug Administration's (FDA) for a Phase II study of Xanamem™ in the US**
- **Full results are expected by mid-2015**

Sydney, 16 February 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 for the second Phase I study for its lead drug candidate, Xanamem™.

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.

The drug works by blocking the development 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.

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

In the 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 patients in each cohort. The primary endpoint of the study is to confirm how the body absorbs and metabolises Xanamem™ and the optimal dose for the drug.

In addition, two follow-on Phase I studies are expected shortly. The first will be a fast fed study of Xanamem™ in a cohort of twelve patients. The second 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.

Full results of the study are expected by mid-2015.

Linear Clinical Research Principal Investigator, Dr Janakan Krishnarajah said: "Our team is very excited to be involved in this Phase I Xanamem™ trial. It's so important to investigate new approaches to treating Alzheimer's disease and the relevance of this trial has only increased in light of the changing competitive and regulatory landscape for Alzheimer's drugs under development."

Actinogen Medical Chief Executive Officer, Dr Bill Ketelbey added: "Through my past work on Alzheimer's disease, I'm only too well aware of the significant limitations of the few therapies that are currently available. We aim to demonstrate that Xanamem™ is a valuable treatment option for Alzheimer's disease and this trial is a very important further step in that process."

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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.