



SUCCESSFUL COMPLETION OF FIRST STAGE OF ALZHEIMER'S DRUG CLINICAL TRIAL

- **Xanamem™ trial meets primary endpoint with participants successfully dosed to the maximum dose of 35mg twice daily**
- **Independent Safety Review Committee satisfied with safety and tolerability of Xanamem™ across the entire dose range of 10mg to 35mg**
- **Trial confirms safety and tolerability of Xanamem™. Study additionally demonstrates how the body absorbs and metabolises Xanamem™ and helps define the optimum dose for future clinical use.**
- **Xanamem™ fed/fasted study now expected to start dosing on 19th May 2015**
- **These results will enable an Investigational New Drug (IND) application to the Food & Drug Administration (FDA) for the Phase II trial in the US. The trial will also run in Australia and the UK.**

Sydney, 12th May 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 the successful completion of the first stage of its Phase I trial for its lead Alzheimer's drug candidate, Xanamem™.

As previously announced, the next stage of the second Phase I trial, a fed-fasted dosing of 12 participants with 35mg of Xanamem™, has received ethics approval. This stage is now expected to commence dosing on the 19th May 2015 with top-line results due in late July 2015.

In the first stage, a total of 24 healthy volunteers were given doses of 10mg, 20mg and 35mg of Xanamem™ twice daily in a multiple ascending dose. The primary endpoint of the study was to confirm the safety and tolerability of the drug. In addition, it demonstrated how the body absorbs and metabolises Xanamem™ and will help define the optimal dose for the drug.

The Independent Safety Review Committee reviewed the data from the final and highest dose cohort and is satisfied these data show no safety or tolerability concerns with Xanamem™ and that the drug has demonstrated its expected pharmacokinetic profile.

These results will enable an Investigational New Drug (IND) application to the FDA for a Phase II trial of Xanamem™ in the US. This trial will also be run in Australia and New Zealand and the UK.

The double-blinded, placebo controlled study was conducted at Linear Clinical Research, a world-class clinical trial facility that is part of the QEII Medical Centre in Perth, Western Australia.

Importantly, the trial was executed on-time and on-budget.

"These excellent results, combined with the successful capital raising from our shareholders last month, sets us up well to start the Phase II study of Xanamem™ in patients with Alzheimer's disease. I find it immensely gratifying to be able to work on developing another potentially effective treatment for this dreaded disease." said Actinogen Medical CEO, Dr Bill Ketelbey

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.

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 – hallmarks of Alzheimer's disease. 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.