CLINICAL TRIAL SUCCESSFULLY COMPLETED WITH XANAMEM™ – AN ALZHEIMERS DRUG

- **Successful completion of final stage of the second Phase I Xanamem™ trial**
- **Primary endpoint of this third part designed to demonstrate that Xanamem™ is efficiently delivered to the brain, the primary site of action in Alzheimer's disease**
- **Results from the full trial demonstrated the metabolism, safety and tolerability of Xanamem™ across the entire dose range of 10mg to 35mg twice daily**
- **Results are planned for publication in a peer-reviewed medical journal**
- **Clinical work has been executed on-time and on-budget**
- **Study results will enable regulatory submissions, including to the US FDA (Food & Drug Administration), for approval to run the Phase II trial of Xanamem™ in Alzheimer's patients**

Sydney, 11th August 2015: Actinogen Limited (Actinogen Medical, ASX: ACW) is pleased to announce that it has successfully completed the clinical part of the third and final stage of the second Phase I trial, of its lead Alzheimer's drug candidate, Xanamem™.

A total of 40 healthy volunteers participated in this study in Australia with 36 as placebo-controlled double-blinded study participants. Previously, an additional 48 healthy volunteers participated in a placebo-controlled double-blinded Phase I study in the UK.

This final stage was designed to examine the CNS (central nervous system) pharmacokinetics of Xanamem™ and involved the recruitment of four healthy volunteers. The primary endpoint of this study is to demonstrate that Xanamem™ is efficiently delivered to the brain, its primary site of action in Alzheimer's disease. The trial was conducted at Linear Clinical Research, a world-class clinical trial facility that is part of the QEII Medical Centre in Perth, Western Australia.

With the successful completion of the final clinical part of the study, the samples will now be analysed in a laboratory at the University of Edinburgh, and the final results to be will be reported and published. Publishing in a peer-reviewed medical journal is a very important part of communicating results of promising new therapies such as Xanamem™ to the wider medical and scientific community globally.

Importantly, results from the full trial consistently demonstrated the metabolism, safety and tolerability of Xanamem™ across the entire dose range of 10mg to 35mg twice daily. The completion of this final stage of the study follows the equally successful completion of a multiple ascending dose study and a fed/fasted study earlier this year.

Dr Janakan Krishnarajah, trial principal investigator and Medical Director of Linear said "Our research team is very pleased to have successfully completed this part of the Xanamem™ trial. Every now and again you come across a new and very exciting approach in medicine that really stands out. Xanamem™ is exactly that for Alzheimer's disease, as it works on the inhibition of the "stress" hormone cortisol in the brain. High levels of cortisol have been shown to impact memory and cognition, and to affect the brain, particularly the hippocampus, similar to Alzheimer's disease."

Actinogen Medical is also pleased to announce that dosing in the final pre-clinical toxicology study is nearing completion with the results expected before the end of the year.

Significantly, for Actinogen Medical all these studies remain on-time and on-budget, with results to be incorporated into the research documentation supporting the all-important Phase II study of Xanamem™ in Alzheimer's patients. The results will enable an Investigational New Drug (IND) application to the US FDA (Food & Drug Administration) for the Phase II trial to be run in the US. The trial will also be run in Australia, and the UK, and is expected to commence in the first half of 2016.

The Company will continue to regularly update the market on the ongoing clinical progress of Xanamem™ and sees many important news catalysts over the next 6-12 months, including US FDA discussions that expect to start in Q4 2015.

Successful completion of this clinical trial increases the attractiveness of Xanamem™ as this new approach to treating Alzheimer's is backed by pre-clinical and clinical data supporting the novel mechanism around the suppression of "stress" hormone cortisol. A paradigm shift is occurring in Alzheimer's dementia drug development that combines a better understanding of the Alzheimer's clinical science and how to impact the pathology, along with the earlier diagnosis and treatment of Alzheimer's by the medical community. From this many new promising Alzheimer's drugs are now in development globally. Xanamem™ is unlikely to compete with other Alzheimer's treatments as it's likely to be used in combination therapy due to its unique mechanism of action around cortisol inhibition.

"The ongoing excellent progress of this Xanamem™ study sets us up well to start the Phase II trial of Xanamem™ in patients with Alzheimer's disease in the first half of 2016" said Actinogen Medical CEO, Dr Bill Ketelbey.

"It is particularly pleasing to continue on-track with our development plans for this promising new treatment. Our entire team is passionate about this novel new treatment for Alzheimer's dementia as it's a disease where a new approach to its management is desperately needed to help millions of people worldwide."

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About Xanamem™

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.

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. In 2015 the Company has completed a second placebo-controlled double-blinded Australian Phase I trial in 40 healthy volunteers (36 blinded). Previously, an additional 48 healthy volunteers participated in a placebo-controlled double-blinded study Phase I study in the UK. Actinogen plans to undertake a Phase II study in Alzheimer's patients in 2016.