POSITIVE TRIAL RESULTS FOR ALZHEIMERS DRUG XANAMEM™

• Positive trial results confirm Xanamem™ is effectively delivered to the brain, the primary site of action in Alzheimer’s disease
• Xanamem™ is present in concentrations that are predicted to very effectively inhibit the 11beta-HSD1 enzyme in the brain
• The 11beta-HSD1 enzyme produces cortisol, the “stress hormone”
• Excess cortisol in the brain is associated with the development of Alzheimer’s disease
• Inhibition of 11beta-HSD1 decreases cortisol and reverses memory loss and amyloid plaquing – hallmarks of Alzheimer’s disease

Sydney, 29 September 2015: Actinogen Limited (Actinogen Medical, ASX: ACW) is pleased to announce that the much anticipated results from its final Phase I clinical trial confirm that Xanamem™, its lead Alzheimer’s drug candidate, crosses the blood-brain barrier and is effectively delivered to the brain, its primary site of action in Alzheimer’s disease.

These positive results follow a trial conducted at Linear Clinical Research in Perth, which was designed to measure the amount of Xanamem™ reaching the brain, and required participants to undergo lumbar punctures, after taking Xanamem™ for 5 days.

These results are particularly encouraging as they confirm that following oral administration, Xanamem™, reaches the brain in concentrations that are predicted to very effectively inhibit the 11beta-HSD1 enzyme in the brain. The 11beta-HSD1 enzyme produces cortisol, the “stress hormone”, and excess cortisol in the brain is associated with memory loss, amyloid plaquing and neural death – the hallmarks of Alzheimer’s disease. Inhibition of the 11beta-HSD1 enzyme has been shown to decrease cortisol levels, reverse memory loss and amyloid plaquing in the brain.

Professor Brian R. Walker of the University of Edinburgh commented on the results “Unlike other 11beta-HSD1 inhibitors in development for type 2 diabetes, Xanamem™ was designed with the explicit goal of maximising penetration of the drug into the brain. These results confirm that this goal has been achieved in humans. Xanamem™ is therefore an excellent drug with which to evaluate the benefits of 11beta-HSD1 inhibition in patients with memory loss.”

With these results, Actinogen Medical is ready to move to a Phase II trial to demonstrate the effectiveness of Xanamem™ in treating patients suffering from mild Alzheimer’s disease. Design of this trial is under way, and the Company expects to be able to start treating Alzheimer’s patients in the trial in the first half of 2016. The trial will treat around 200 patients in Australia, the UK and the USA, under a U.S. Food & Drug Administration (FDA) approved Investigational New Drug (IND).

“We are particularly pleased with these much anticipated results showing that Xanamem™ effectively crosses the blood-brain barrier. Our entire team is passionate about this novel new treatment for Alzheimer’s dementia, as it’s a disease where a new treatments are desperately needed, to help millions of patients worldwide,” said Actinogen Medical CEO, Dr Bill Ketelbey.
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. The Company plans to undertake a Phase II study in mild Alzheimer’s patients in 2016.