



# Actinogen Medical

## ASX ANNOUNCEMENT

### FDA FEEDBACK ON XANAMEM ALZHEIMER'S TRIAL

**Sydney, 29 September 2016:** Actinogen Medical Limited (ASX: ACW) advises that it has received feedback from the FDA today with further questions around potential safety surveillance of the drug Xanamem to be answered before patients can be treated in the US. Actinogen will communicate with the FDA shortly and if the questions cannot be resolved in a reasonable time Actinogen will not be able to recruit patients in the Phase II Alzheimer's disease clinical trial by the end of 2016.

**ENDS**

#### Actinogen Medical

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#### About Actinogen Medical

Actinogen Medical (ASX:ACW) is an Australian Stock Exchange listed biotech company focused on an innovative approach to treating cognitive impairment in chronic neurodegenerative and metabolic diseases. The lead candidate drug Xanamem™, blocks the production of excess cortisol in the brain. Excess cortisol is associated with cognitive impairment and the development of amyloid plaques and neural death – the hallmarks of Alzheimer's disease. In 2016, the Company initiated XanADu, a Phase II efficacy and safety trial of Xanamem™ in mild Alzheimer's disease.

#### About Xanamem™

Xanamem™ is being developed as a promising new therapy for Alzheimer's disease, a condition with a multibillion dollar market potential. The cost of managing Alzheimer's disease in the US alone was estimated to be US\$250bn in 2013, increasing to an estimated US\$1 trillion by 2050 and 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 other Alzheimer's treatments. It works by blocking the excess 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 leads to changes in the brain affecting memory and to the development of amyloid plaques and neural death – the hallmarks of Alzheimer's disease.

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