US FDA FEEDBACK ENHANCES ALZHEIMERS STUDY

- **Productive interaction with the US Food and Drug Administration (FDA)**
- **Protocol enhancement will strengthen the value of the Phase II trial**
- **Harmonising Australian and UK trial with US FDA increases potential global value**
- **Fits into broader US strategy of medical publications slated for 2H16 and US investor campaign in 2H16**

Sydney, 8th June 2016: Actinogen Medical Limited (Actinogen Medical, ASX: ACW) is pleased to announce productive progress with the US Food and Drug Administration(FDA) to enhance the safety profile of XanADu, the Phase II trial of its lead Alzheimer's drug candidate, Xanamem™.

Good progress has been made with the Actinogen Medical team towards securing final US FDA approval under an Investigational New Drug (IND) for the Phase II study.

After discussions with the US FDA, the enhanced protocol will be harmonised with both Australian and UK regulators and hospital sites, with patients expected to be enrolled in the second half of 2016.

Importantly, a US focused study and protocol design will allow for broader value creation, as the US is the largest market for Alzheimer's drugs. Since initiating the trial the relevance of this phase II trial and its design has only increased, in light of the changing competitive and regulatory landscape in Alzheimer's drugs in development.

As part of the US focused strategy, Actinogen Medical is presenting its Xanamem™ research at major North American Alzheimer's congresses and publishing the results in peer-reviewed medical journals over the second half of 2016. This is an important part of communicating on promising new therapies, like Xanamem™, to the wider medical and scientific community globally.

Prof. Craig Ritchie, Director for the Centre of Dementia Prevention from Edinburgh University said, "There is overwhelming scientific evidence linking stress with the onset and progression of Alzheimer's disease. To be able to interfere with this important pathological process with Xanamem™ creates a really exciting therapeutic opportunity for both the symptomatic treatment of Alzheimer's dementia and the modification of the course of the underlying disease. I am proud to be part of this new research programme and the results it could produce."

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.

US phase II clinical trial initiation increases the attractiveness of Xanamem™ as this novel approach to treating Alzheimer's is backed by pre-clinical and clinical data supporting the mechanism around the suppression of the "stress" hormone cortisol.

A paradigm shift is occurring in Alzheimer's dementia drug development that combines a better understanding of Alzheimer's clinical science and how to impact the pathology, along with the earlier diagnosis and treatment of Alzheimer's disease. From this many new promising Alzheimer's drugs are now in development globally. Xanamem™ is expected to be complementary to other Alzheimer's treatments as it has a unique mechanism of action involving cortisol inhibition and is likely to be used in combination therapy with other Alzheimer's drugs

"It is particularly pleasing to progress these development plans with the US FDA 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 management is desperately needed to help millions of patients, and their carers, worldwide." said Actinogen Medical CEO, Dr Bill Ketelbey.

ENDS

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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 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 initiate a Phase II study in Alzheimer's patients in 2016.