



## MEDIA RELEASE

22 March 2016

### **XanADu: A New Pivotal Global Clinical Trial to Treat Mild Alzheimer's Disease**

#### **Highlights**

- **Actinogen Medical launches XanADu, a new global clinical trial of Xanamem™ in mild Alzheimer's disease.**
- **Follows consistently positive research results for Xanamem™ over the past year.**
- **Global team of Alzheimer's experts help shape the latest in cutting edge clinical science for this Phase II trial.**
- **XanADu trial expected to generate significant commercial partnership interest.**

**Sydney 22<sup>nd</sup> March 2016:** Actinogen Medical Limited (**ASX: ACW**) today announced the start of **XanADu**, their pivotal global Phase II clinical trial investigating **Xanamem™** as a treatment for mild Alzheimer's disease.

Xanamem™ has been specifically designed to inhibit the excess production of cortisol, the "stress hormone", in the brain. Recent global research has consistently demonstrated that excess cortisol is associated with cognitive decline, and amyloid plaque build-up and neurotoxicity in the brain, which are the hallmarks of Alzheimer's disease.

Actinogen CEO Dr Bill Ketelbey said: "It's been a tremendously productive year for our company as we accelerate our Xanamem™ research program. We continue to observe very positive results with Xanamem™ from our Phase I and preclinical research and we expect to build on these results with this new global XanADu Phase II trial. Alzheimer's disease has a profound impact on patients and carers, so medical breakthroughs are critical. We are proud to be leading the way."

XanADu has been registered on the [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) website where an outline of the trial is publically available. Over the next several months additional details will be added on the global research sites that have been selected to participate in the study. XanADu will be run at trial sites in Australia, the United Kingdom (UK) and United States of America (USA), with the first of 200 mild Alzheimer's patients expected to be treated with Xanamem™ in the next few months. Actinogen Medical is currently applying for all the necessary regulatory and ethical approvals to run XanADu in Australia, the UK and the USA and selecting and preparing the research sites for recruiting mild Alzheimer's patients onto the trial.

An Advisory Board of world leading Alzheimer's specialists with particular expertise in early diagnosis and treatment of Alzheimer's disease helped design the XanADu trial. Members of the Advisory Board include:

- Professor Craig Ritchie, Professor of Psychiatry of Ageing at the University of Edinburgh

- Professor Colin Masters, Executive Director of the Mental Health Research Institute and Laureate Professor at the University of Melbourne
- Professor Jeff Cummings, Camille and Larry Chair of the Neurological Institute of Cleveland Clinic and Professor of Medicine (Neurology)

Alzheimer's disease is the single greatest cause of disability in older Australians, and the second leading cause of death. Worldwide there are nearly 50 million people with the disease. In 2015 the total estimated global cost of treating the disease was close to US\$1 trillion. If Alzheimer's disease were a country, it would be the 18<sup>th</sup> largest economy.

Dr Ketelbey continued: "Given the large unmet patient need, the patent expiry of existing Alzheimer's treatments and the sheer size of the addressable global Alzheimer's market, we expect to see rapidly growing interest in Xanamem™. As the XanADu Phase II trial progresses and gets closer to completion, this could provide the basis for entering into significant licensing negotiations with a large pharmaceutical industry player."

For further information and updates on XanADu, and for more information on Xanamem™ in Alzheimer's disease, please refer to [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) (protocol number: ACW0002) and the Actinogen Medical website: [www.actinogen.com.au](http://www.actinogen.com.au)

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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 Actinogen Medical successfully completed all the necessary pre-clinical and clinical research on Xanamem in preparation for the launch of their Phase II clinical trial program in 2016. It is anticipated that the first of these trials, XanADu, will begin recruiting patients in Q2 2016.