First US patients treated in landmark Alzheimer's disease trial

- Another major milestone for Actinogen Medical with first two US patients enrolled into Alzheimer's trial, XanADu.
- XanADu is Actinogen Medical's Phase II clinical trial of Xanamem™ in Alzheimer's disease.
- These US patients highlight global reach of XanADu: the study will enrol 174 patients at 20 research sites in the USA, the UK and Australia.
- Momentum is building behind XanADu following the recent recruitment of the first patient into the trial, in Australia.
- Recruitment of US patients reflects success in taking Australian biotech research capability to the US market.

Sydney, 22 June 2017: Actinogen Medical (ASX: ACW) is delighted to announce the enrolment of the first two US-based patients into XanADu this week. XanADu is its Phase II clinical trial of Xanamem in Alzheimer's disease.

The milestone reflects the momentum building behind XanADu following the recent recruitment of the first patient into the trial in Australia and highlights the success in taking Australian biotech research capability to the US market.

It also illustrates the global reach of XanADu. The study will enrol 174 patients at 20 research sites in the USA, the UK and Australia with the last patient expected to be recruited in Q4 2018 and top-line results expected by Q1 2019.

The first US patients were enrolled at the Atlanta Centre for Medical Research in Atlanta, Georgia. Additional sites in the US are now open for active recruitment and more patients are expected to be recruited into XanADu over the next few weeks.

XanADu represents a landmark in the global search for an effective treatment for Alzheimer's disease and reinforces Australia's role at the forefront of Alzheimer's research. Xanamem is a promising new approach to treating this devastating disease at a time when several high-profile drug trials based on more traditional approaches have failed.

Xanamem has been specifically designed to block the production of excess cortisol in the brain. Cortisol is produced in times of stress and there is a growing body of independent research that shows a strong association between excess cortisol and Alzheimer's disease. The most significant supportive study, the Australian Imaging, Biomarker & Lifestyle Flagship Study of Ageing (AIBL) study, showed very promising evidence for the potential of cortisol inhibition to prevent the cognitive decline of Alzheimer's disease. The AIBL study was published in January 2017 and funded in part by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and a number of major Australian universities (Please click on this link for more details on AIBL: http://actinogen.com.au/wp-content/uploads/2016/07/AAIC-Maruff-AIBL.pdf).

Professor Jeffrey Cummings, M.D., Director of the Cleveland Clinic Lou Ruvo Center for Brain Health in the United States said Xanamem could represent a major advancement in the treatment of Alzheimer's, at a time when new treatments for the devastating disease are badly needed.

"This [XanADu] is one of the most significant studies that I have been involved in as it could provide the turning point needed in finding a new effective treatment for Alzheimer's disease. Given the compelling evidence linking raised cortisol and the development of Alzheimer's disease, the global medical community will be closely following this clinical trial," he said.

Robert A. Riesenberg, MD, founder, president and CEO at the Atlanta Center for Medical Research, and principal investigator on the XanADu study commented "Alzheimer's disease is ranked as the sixth leading cause of death in the United States. Being able to contribute to the search for a new, safe and quality medicine for this disease is integral to everything that the ACMR represents."

The commencement of patient enrolment into XanADu follows regulatory approval to conduct the study from the Food and Drug Administration (FDA) in the USA, the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK and from the Therapeutic Goods Administration (TGA) in Australia.

"We are very pleased to have successfully recruited our first US patient into XanADu and to have such strong momentum building behind this landmark study," said Dr Bill Ketelbey, CEO of Actinogen Medical.

XanADu, is registered on www.clinicaltrials.gov with the identifier: NCT02727699, where more details on the trial can be found, including the location of study sites open for patient recruitment.

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About Actinogen Medical

Actinogen Medical (ASX: ACW) is an ASX-listed biotech company focused on innovative approaches to treating cognitive decline that occurs in chronic neurodegenerative and metabolic diseases. Actinogen Medical is developing Xanamem™ a promising new therapy for Alzheimer's disease, a condition with a multibillion dollar market potential. In the US alone, the cost of managing Alzheimer's disease is estimated to be US$250bn, and is set to increase to US$2 trillion by 2050, outstripping the treatment costs of all other diseases. Alzheimer's disease is now the leading cause of death in the UK and second only to ischaemic heart disease in Australia

About Xanamem™

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 – through the inhibition of the 11β-HSD1 enzyme in the brain. This enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain most affected by Alzheimer's disease. There is a strong association between chronic stress and excess cortisol that leads to changes in the brain affecting memory, and to the development of amyloid plaques and neural death – all hallmarks of Alzheimer's disease.

About XanADu

XanADu is a Phase II double-blind, 12-week, randomised, placebo-controlled study to assess the safety, tolerability and efficacy of Xanamem, in subjects with mild dementia due to Alzheimer's disease. XanADu, will enrol 174 patients at 20 research sites across Australia, the UK and the USA. Patient recruitment into XanADu began in Q2 2017 – topline results are expected in Q1 2019. The trial is registered on www.clinicaltrials.gov with the identifier: NCT02727699.

Actinogen Medical encourages all current investors to go paperless by registering their details with the designated registry service provider, Link Market Services.