

First patient treated in landmark Alzheimer's disease clinical trial

- Actinogen Medical reaches a major milestone with the first patient enrolled into XanADu – its Phase II clinical trial of Xanamem™ in Alzheimer's disease.
- The first trial patient was treated at the Central Coast Neurosciences Research site in New South Wales, Australia.
- This marks a defining moment in the development of Xanamem following more than a decade of research.
- Xanamem blocks excess production of cortisol, the stress hormone, in the brain and represents a promising new approach to treat Alzheimer's disease
- XanADu will enrol 174 patients at 20 research sites in the USA, the UK and Australia with the final patient expected in Q4 2018 and top-line results in Q1 2019

Sydney, 16 May 2017: Actinogen Medical (ASX: ACW) is delighted to announce the treatment of the first patient in XanADu, its Phase II clinical trial of Xanamem in Alzheimer's disease. This is the first patient to be enrolled into XanADu globally, and represents a significant milestone following more than a decade of research undertaken by Edinburgh University in Scotland and Actinogen Medical in Australia, to develop Xanamem as a promising new treatment for Alzheimer's disease.

The first patient was treated at the Central Coast Neurosciences Research site in New South Wales, Australia. Other trial sites in Australia, the US and the UK will soon start recruiting patients, with the final patient expected by Q4 2018, and top-line results for the trial expected in Q1 2019.

XanADu represents a major step forward in the global search for an effective treatment for this debilitating disease and reinforces Australia's role at the forefront of Alzheimer's disease research. Xanamem represents a potential breakthrough in treating the 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 a hormone produced by the body 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>).

Alzheimer's expert Professor Colin Masters, AO, Laureate Professor at The University of Melbourne, one of the AIBL study's key authors and a member of Actinogen's Scientific Advisory Board, said Xanamem could provide the turning-point needed in finding a new effective treatment for Alzheimer's disease.

“Earlier this year, the AIBL study, a 1100+ participant, 9-year study published data showing that raised cortisol is strongly associated with the development of Alzheimer’s disease. Xanamem, through its inhibition of cortisol in the brain, could represent a major advance in the treatment of Alzheimer’s,” he said.

“I am delighted that Australia is at the forefront of global Alzheimer’s research in initiating the XanADu trial, evaluating Xanamem as a treatment for this devastating disease.”

Professor Ralph Martins AO, Professor of Neurobiology at Macquarie University, Foundation Chair in Ageing and Alzheimer’s Disease at Edith Cowan University and also one of the lead AIBL authors added: “The evidence linking raised cortisol and the development of Alzheimer’s disease is very compelling and so I’m particularly excited to be participating in the XanADu study evaluating the inhibition of cortisol in Alzheimer’s patients. If the results from XanADu prove positive, Xanamem could be the blockbuster Alzheimer’s drug that the world has been waiting for.”

XanADu, the largest global Alzheimer’s dementia study ever conducted by an Australian biotech company, will enrol 174 patients at 20 research sites across Australia, the UK and the USA. The trial 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.

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

“It is significant that the first XanADu patient worldwide has been enrolled in Australia and we can all be justifiably proud that Australia is leading the way in developing this promising new treatment for Alzheimer’s disease,” said Dr Bill Ketelbey, CEO of Actinogen Medical.


“Given the growing number of people with Alzheimer’s and the critical importance of finding effective new drugs to treat this disease, our hope is that the development of Xanamem will make a real difference to Alzheimer’s patients, and their carers and families worldwide.”

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Actinogen Medical

Dr. Bill Ketelbey
CEO & Managing Director
P: +61 2 8964 7401

E: bill.ketelbey@actinogen.com.au

 @BillKetelbey

Media Enquires

Andrew Ramadge
Media & Capital Partners
M: +61 475 797 471

E: Andrew.ramadge@mcpartners.com.au

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.