UK Regulatory Approval for Alzheimer's Disease Clinical Trial – XanADu

- Actinogen Medical receives UK regulatory approval from the MHRA to start recruiting patients into clinical trial of Xanamem™ in Alzheimer's disease (AD)
- This MHRA approval follows the FDA approval in January and provides further independent regulatory endorsement of the ongoing development of Xanamem™
- The XanADu Phase II clinical trial is on target to treat the first AD patients with Xanamem™ in early Q2 2017
- XanADu will enrol 174 patients at clinical sites across the USA, UK and Australia
- Regulatory approval from Australian TGA is expected to follow soon

Sydney, 10th January 2017: Actinogen Medical (ASX: ACW) is pleased to announce that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has approved their application to conduct XanADu, their Phase II clinical trial of Xanamem™ in mild Alzheimer's disease, in the UK.

The trial: **XanADu: 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,** will enrol 174 patients at research sites across the UK, USA and Australia. The trial is registered on www.clinicaltrials.gov with the identifier: NCT02727699.

This MHRA approval follows the regulatory approval received from the Food and Drug Administration (FDA) in the USA, in January 2017. These approvals provide strong endorsement of Xanamem™'s development in Alzheimer's disease and underscores the depth and quality of Actinogen's existing research data on Xanamem™.

Xanamem™'s novel mechanism of action differentiates it from other Alzheimer's drugs under development. Xanamem™ has been specifically designed to block the excess production of cortisol, the stress hormone, in the areas of the brain most affected in Alzheimer's disease. Raised cortisol has been strongly associated with Alzheimer's disease and lowering cortisol in the brain is an important new target for treating Alzheimer's disease.

"Inhibiting the production of cortisol in the brain with Xanamem™ could have a major impact on the wellbeing of people living with dementia as well as those at high risk of developing this condition. I am truly excited that this study will soon be open in the UK as well as in the USA and Australia. It represents a large and critical step in the ongoing development of Xanamem™ to manage Alzheimer's disease," commented Professor Craig Ritchie from the University of Edinburgh[1]

[1] Professor Craig Ritchie is Chair of the Psychiatry of Ageing and Director of the Centre for Dementia Prevention at the University of Edinburgh, UK. He is also the National Coordinating Investigator of the UK study sites participating in XanADu, as well as the Chair of the Xanamem™ Clinical Advisory Board.

Dr Bill Ketelbey, CEO of Actinogen Medical continued: "We are delighted with these ongoing regulatory approvals for XanADu as they represent critical milestones in the development of Xanamem™ for the treatment of Alzheimer's disease. New treatment options are desperately needed for Alzheimer's disease and XanADu is designed to demonstrate that Xanamem™ is an effective treatment option for this devastating disease."

Actinogen Medical expects to shortly receive approval from the Australian Therapeutic Goods Administration (TGA) to conduct XanADu in Australia. This will be the last major regulatory approval required and the trial will begin actively recruiting patients in early Q2 2017.

ENDS

Actinogen Medical
Dr. Bill Ketelbey
CEO & Managing Director
P: +61 2 8964 7401
E: bill.ketelbey@actinogen.com.au
@BillKetelbey

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. Xanamem™, Actinogen Medical's lead candidate drug, blocks excess production of the stress hormone cortisol in the brain. There is growing evidence that chronic stress and excess cortisol leads to changes in the brain affecting memory, and to the development of amyloid plaques and neural death – all 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. In the US alone, the cost of managing Alzheimer's disease in 2013 was estimated to be US$250bn, and is set to increase to US$1 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 hearth disease in Australia. 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.

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