FDA Approval to Commence Alzheimer's Disease Clinical Trial

- **Actinogen Medical receives IND approval from FDA to start recruiting patients into clinical trial of Xanamem™ in Alzheimer's disease**
- **XanADu will enrol 174 patients at clinical sites across USA, UK and Australia**
- **IND approval provides independent regulatory endorsement from the FDA for the ongoing development of Xanamem™**
- **Phase II trial is the largest global Alzheimer's dementia study conducted by an Australian biotech**
- **First patients treated with Xanamem™ in XanADu trial expected by Q2, 2017**

Sydney, 3rd January 2017: Actinogen Medical (ASX: ACW) announced today that the US Food and Drug Administration (FDA) has approved their Investigational New Drug (IND) application to initiate XanADu, a Phase II clinical trial of Xanamem™ in mild Alzheimer's disease, in the US.

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

The IND approval follows an extensive in-depth review by the FDA of all past research and clinical data on Xanamem™ and of the design of the Phase II XanADu clinical trial. This IND approval provides strong endorsement by the FDA for Xanamem™ 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 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.

Dr Bill Ketelbey, CEO of Actinogen Medical said: "We are delighted with the IND approval as it represents a major milestone for Actinogen Medical in the development of Xanamem™ in the treatment of Alzheimer's disease. New treatment options are desperately needed for Alzheimer's disease and this IND approval is a significant step forward in demonstrating that Xanamem™ is an effective treatment option for this devastating disease."

Actinogen Medical expects to receive similar approvals from regulatory authorities in Australia and the UK within the next two months, and for the trial to begin actively recruiting patients by Q2, 2017.

XanADu, is the largest global Alzheimer's disease study conducted by an Australia biotech company[1]. With nearly half the planned sites in the US, the study will have a predominant US focus. This will allow for a broader value creation for Actinogen Medical as the US represents around 50% of the market for Alzheimer's drugs.

ENDS

Actinogen Medical
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[1] clinicaltrials.gov and Medtracker – accessed September 2016.

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