TGA Regulatory Approval Received for Alzheimer's Phase II Trial

- Regulatory approval received from the TGA to commence patient recruitment into the Phase II clinical trial of Xanamem™ in Alzheimer's disease – "XanADu"
- TGA approval follows earlier FDA (USA) and MHRA (UK) approvals and is the final regulatory approval being sought for this clinical trial
- XanADu remains on target to treat first patients with Xanamem™ in early Q2 2017
- XanADu to enrol 174 patients at clinical sites across the USA, UK and Australia
- XanADu is the largest global Alzheimer's dementia study conducted by an Australian biotech company

Sydney, 8th March 2017: Actinogen Medical (ASX: ACW) is pleased to announce that it has received approval from the Australian Therapeutic Goods Administration (TGA) to conduct XanADu, its Phase II clinical trial of its drug candidate, Xanamem™.

The TGA approval follows similar approvals from the Food and Drug Administration (FDA) in the USA and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. It is the final regulatory approval required for the trial to begin actively recruiting patients in Australia, the USA and the UK by early Q2 2017.

XanADu is a 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.

It 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 can be found.

These regulatory approvals provide strong endorsement of the development of Xanamem™ to treat Alzheimer's disease and underscore 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. It has been specifically designed to block excess production of cortisol, the stress hormone, in the areas of the brain most affected by Alzheimer's disease. Raised cortisol levels have been strongly associated with Alzheimer's disease and lowering cortisol in the brain is an important new target for treating the disease.

"We are delighted with these ongoing regulatory approvals for XanADu, as we are now finally able to start treating Alzheimer's patients with Xanamem™. New treatment options are desperately needed and XanADu is designed to demonstrate that Xanamem™ is an effective treatment option for this devastating disease," said Dr Bill Ketelbey, CEO of Actinogen Medical.

Prominent Australian Alzheimer's expert, Associate Professor Michael Woodward AM, from the Medical and Cognitive Research Unit at Austin Health in Victoria, welcomed the XanADu trial and Actinogen's work on Xanamem™.

"Novel treatment approaches are our best hope of effectively treating Alzheimer's, so I am extremely pleased to participate in this landmark, global study of Xanamem™ in mild Alzheimer's disease," he said.

“Too many drugs are failing to show efficacy. Xanamem™ is different as its novel mechanism of action of inhibiting cortisol production in the brain has the potential to make a truly meaningful difference to those with Alzheimer’s. It is especially gratifying that this study is an Australian initiative and that so much of the development of Xanamem™ will be carried out in Australia. It’s an impressive achievement that reaffirms our ability to punch well above our weight in medical research and should make Australians proud.’’

ENDS

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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 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.