ASX ANNOUNCEMENT

New Clinical Development Opportunities for Xanamem™

- Actinogen's lead drug candidate, Xanamem, is specifically designed to inhibit excess cortisol in the brain, which is associated with cognitive impairment in a large range of neurological diseases.
- Alzheimer's disease is the lead indication for the development of Xanamem, with results expected from the phase II XanADu Alzheimer's disease trial in Q2 2019.
- Today, Actinogen announces the selection of cognitive impairment in mood disorders and schizophrenia as the next indications for the development and commercialisation of Xanamem.
- The new indication selection follows significant clinical interest in evaluating Xanamem in a range of medical conditions associated with raised cortisol.
- Mood disorders (including depression and bipolar disorder) together with schizophrenia, often present with raised cortisol and are frequently associated with cognitive impairment.
- Cognitive impairment in mood disorders and schizophrenia represents a significant unmet medical need and a substantial market opportunity, with limited or no existing therapeutic options available for clinicians and their patients.

Sydney, 10 April 2019. Actinogen Medical ASX: ACW ('ACW' or 'the Company') is pleased to announce an expanded clinical development program for Xanamem following the conclusion of an extensive scientific, clinical and commercial review of numerous additional potential clinical indications for the drug. This review follows on from the completion of the XanADu Phase II study, evaluating Xanamem in Alzheimer's disease (read-out of results scheduled in Q2 2019), and the significant interest expressed from various medical specialists in trialling Xanamem as a potential therapy for a range of other medical conditions associated with raised cortisol.

The review, with input from expert advisors, has identified **cognitive impairment in mood disorders and schizophrenia** as the next development opportunity for Xanamem. Mood disorders encompass a spectrum of interrelated conditions covering depression and bipolar disorder, and along with schizophrenia, often present with cognitive impairment as a debilitating feature of these conditions. While mood disorders and schizophrenia may be treated and managed with currently available therapies, there are very few options for treating the cognitive impairment associated with these conditions. Furthermore, cognitive impairment often persists long term, limiting the capacity for patients to lead normal lives. Consequently, cognitive impairment is a significant burden for the majority of patients affected by these chronic diseases. Cognitive impairment in mood disorders and schizophrenia represents a major unmet medical need and an important development opportunity for Xanamem.

Medical research has repeatedly demonstrated the clear association between raised cortisol and cognitive impairment, and raised cortisol is a well described feature of the mood disorders and schizophrenia. Additionally, patients who present for the first time to a practitioner with complaints of mood disorders or schizophrenia are at greater risk of subsequently developing Alzheimer's disease. Xanamem has been specifically, and uniquely, designed to inhibit the production of excess cortisol in the brain, and thus the cognitive impairment associated with mood disorders and schizophrenia presents a promising additional development opportunity for Xanamem.

Cognitive impairment in mood disorders and schizophrenia represents a significant new market opportunity for Actinogen. In the USA, there are collectively, approximately 24 million patients with mood disorders, including depression and bipolar disorder, and schizophrenia. There are limited to no options for the treatment of cognitive impairment in these patients, which account for between 40 – 95% of all patients, depending on the condition. Targeting raised cortisol with Xanamem represents a differentiated, promising approach to treating cognitive impairment in patients with these conditions.

Having selected cognitive impairment in mood disorders and schizophrenia for the further development of Xanamem, a specialist Advisory Board will now be established to assist the Company to design the most appropriate clinical development plan for Xanamem, that most effectively demonstrates the drug's potential in these conditions.

ENDS

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

Investor and Media Enquiries
Arthur Chan
WE Buchan
M: +61 2 9237 2805
E: arthurc@we-buchan.com

About Actinogen Medical

Actinogen Medical (ASX: ACW) is an ASX-listed biotechnology company focused on innovative approaches to treating cognitive decline that occurs in chronic neurological and metabolic diseases. Actinogen Medical is developing its lead compound Xanamem, as a promising new therapy for Alzheimer's disease, a condition with multibillion-dollar market potential and material human impact. In the US alone, the cost of managing Alzheimer's disease is estimated to be US$250bn and is projected to increase to US$2tn 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. In addition, Actinogen is currently planning an expanded clinical development program for Xanamem in cognitive impairment in mood disorders and schizophrenia. In the US alone, the collective economic costs of mood disorders and schizophrenia are estimated to exceed $550bn, with the burden increasing every year. The cognitive dysfunction associated with these conditions is significantly debilitating for affected patients, with a substantial unmet medical need for novel, improved treatments.

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. There is a strong association between chronic stress and excess cortisol that leads to changes in the brain affecting memory. The 11β-HSD1 enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain associated with cognitive impairment in neurological diseases, including Alzheimer's disease, mood disorders and schizophrenia.

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 has fully enrolled 186 patients from 25 research sites across Australia, the UK and the USA. Results are expected in Q2 2019. The trial is registered on www.clinicaltrials.gov with the identifier: NCT02727699, where more details on the trial can be found, including the study design, patient eligibility criteria and the locations of the study sites.

About XanaHES

XanaHES is a Phase I, randomised, single blinded, central reader blinded, placebo-controlled, dose escalation study to assess the safety and tolerability of Xanamem™ 20mg & 30mg once daily in healthy elderly volunteers. Changes in cognitive performance from baseline to end-of-treatment will be measured as an exploratory efficacy outcome.

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