ASX ANNOUNCEMENT

Actinogen announces open IND for Phase 2 protocol in Fragile X Syndrome and signed Letter of Intent to implement the trial

Sydney, 9 November 2021. Actinogen Medical ASX: ACW ("ACW" or "the Company") is pleased to announce receipt of approval today from the US FDA to proceed under the Investigational New Drug (IND) application with its Phase 2 protocol entitled "XanaFX: A Phase II Double-Blind, Randomized, Placebo-Controlled trial, to Assess the Safety, Tolerability, and Efficacy of the 11β-HSD1 Inhibitor Xanamem in Treating Male Adolescents and Young Adults with Fragile X Syndrome". The trial will enrol approximately 50 patients for a 12-week treatment period, with results expected in 2023.

A letter of intent (LOI) with Worldwide Clinical Trials Limited (WWC) to operationalise the trial was signed today. WWC is a research organisation specialising in neurological, paediatric and rare diseases. The LOI amount of A$944,724 is for start-up activities to enable prompt activation of sites. The LOI duration is 60 days (extendable) while a full contract is negotiated, and cancellable with 30 days' notice and subsequent refund of unused funds.

ENDS

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Announcement authorised by the Board of Directors of Actinogen Medical

About Actinogen Medical

Actinogen Medical (ACW) is an ASX-listed, biotechnology company developing a novel therapy for neurological diseases associated with dysregulated brain cortisol. There is a strong association between cortisol and detrimental changes in the brain, affecting cognitive function, harm to brain cells and long-term cognitive health.

Cognitive function means how a person understands, remembers and thinks clearly. Cognitive functions include memory, reasoning, awareness and decision-making, and to a large extent, influence our personality.

We are currently developing our lead compound, Xanamem®, as a promising new therapy for Alzheimer's Disease, Fragile X Syndrome, and other neurological diseases where reducing cortisol inside brain cells could have a positive impact. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

About Xanamem®

Xanamem's novel mechanism of action works by blocking the production of intracellular cortisol through the inhibition of the 11β-HSD1 enzyme in the brain. Xanamem is designed to get into the brain after it is absorbed in the intestines upon swallowing its capsule.

Chronically elevated cortisol is associated with cognitive decline in Alzheimer's Disease, potentially linked to cognitive impairment and anxiety in Fragile X syndrome, and cognitive impairment in other diseases.

The Company has studied 11β-HSD1 inhibition by Xanamem in more than 250 volunteers and patients, so far finding a statistically significant improvement in cognition over placebo in healthy, older volunteers. A series of Phase 2 studies in multiple diseases is being conducted to further confirm and characterise Xanamem's therapeutic potential.

Xanamem is an investigational product and is not approved for use outside of a clinical trial by the FDA or by any global regulatory authority. Xanamem® is a trademark of Actinogen Medical.

Disclaimer

This announcement and attachments may contain certain forward-looking statements that are based on subjective estimates and assumptions and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements involve known and unknown risks, uncertainties, and other factors (such as significant business, economic and competitive uncertainties and contingencies, and regulatory and clinical development risks and uncertainties) which may cause the actual results or the performance of Actinogen Medical to be materially different from the results or performance expressed or implied by such forward looking statements. Past performance is not a reliable indicator of future performance. There can be no assurance that any forward-looking statements will be realised. Actinogen Medical does not make any representation or give any warranty as to the likelihood of achievement or reasonableness of any forward-looking statements.

ACTINOGEN MEDICAL ENCOURAGES ALL CURRENT INVESTORS TO GO PAPERLESS BY REGISTERING THEIR DETAILS WITH THE DESIGNATED REGISTRY SERVICE PROVIDER, AUTOMIC GROUP.