ASX ANNOUNCEMENT

Actinogen Clinical Trials Science Forum 2025 – The critical importance of preparing for commercialization

ACW Chief Medical Officer Dr Dana Hilt and Chief Commercial Officer Andy Udell discuss the latest developments in the quest for effective Alzheimer's treatments and how Actinogen is preparing for the future commercialization of its novel once-a-day oral medication, Xanamem®

Special guest Geriatrician A/Prof Michael Woodward AM from Austin Health will also join the panel discussion: 11am, Thursday 15 May 2025

Event registration:
https://actinogenmedical.zoom.us/webinar/register/WN_EmFwifoRTZSI25qwoBy92g

Sydney, 24 April 2025. Actinogen Medical ASX: ACW ("ACW" or "the Company") is pleased to announce that the Company will be holding its next Clinical Trials Science Forum webinar on **15 May 2025** at **11am**.

Dr Hilt and Mr Udell will host a highly informative 'plain English' panel discussion that will review the scope of leading current and potential treatments in development for Alzheimer's disease (AD) and the ongoing significant unmet medical need for effective therapies. Then, relevant to the Xanamem program now in late-stage clinical development, Andy Udell will outline what commercialization planning means for a company like Actinogen. He will explain how the Company is actively engaging in an important range of initiatives that include 1) careful design of pivotal, phase 2b/3 and phase 3 trials with insurance and other payors in mind, 2) thought leader development in multiple geographies, and 3) refined messaging for doctors and patients. Furthermore, full value from any future partnership will depend upon these activities being successfully conducted.

Pre-register now for this event on Thursday, 15 May at 11am, or register and join on the day:
https://actinogenmedical.zoom.us/webinar/register/WN_EmFwifoRTZSI25qwoBy92g

A recording of the webinar will be made available as soon as possible after the conclusion of the event on the Company's website and YouTube channel.

Speakers:
Associate Professor Michael Woodward AM MB BS MD FRACP is Head of Dementia Research and a senior clinician in the Memory Clinic at Austin Health in Heidelberg, Victoria. He is a specialist in geriatric medicine with major interests in the treatment of Alzheimer's disease and other dementias. He is Principal Investigator for numerous research trials of new therapies for AD and related disorders.

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Mr Andy Udell is a US-based commercial leader with demonstrated success taking biotech companies from the clinic through market planning, commercial readiness and full commercial integration. He has experience working in depression, Parkinson's disease, and other large CNS markets as well as rare diseases.

Dr Dana C. Hilt MD is an eminent US-based neurologist with more than 25 years of drug development experience, primarily of CNS drugs. Dr Hilt has world-leading expertise and experience in Phases 1 to 4 of development for conditions including Alzheimer's disease, depression, Parkinson's disease and other neurologic and neuropsychiatric diseases.

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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 and neuropsychiatric 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, attention, reasoning, awareness and decision-making.

Actinogen is currently developing its lead compound, Xanamem, as a promising new therapy for Alzheimer's Disease and Depression and hopes to study Fragile X Syndrome and other neurological and psychiatric diseases in the future. Reducing cortisol inside brain cells could have a positive impact in these and many other diseases. 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.

Clinical Trials

The **XanaMIA Phase 2b/3 Alzheimer's disease trial** is a double-blind, 36-week treatment, placebo-controlled, parallel group design trial in 220 patients with mild to moderate AD and progressive disease, determined by clinical criteria and confirmed by an elevated level of the pTau181 protein biomarker in blood. Patients receive Xanamem 10 mg or placebo, once daily, and its ability to slow progression of Alzheimer's disease is assessed with a variety of endpoints. The primary endpoint of the trial is the internationally-recognized CDR-SB (Clinical Dementia Rating scale – Sum of Boxes). The trial is being conducted in Australia and the US. Initial results from an interim analysis triggered by the 100th participant reaching 24 weeks of treatment are anticipated in Q4 2025 and final results H2 2026.

The **XanaCIDD Phase 2a depression trial** was a double-blind, six-week proof-of-concept, placebo-controlled, parallel group design trial in 167 patients with moderate, treatment-resistant depression and a degree of baseline cognitive impairment. Participants were evenly randomized to receive Xanamem 10 mg once daily or placebo, in most cases in addition to their existing antidepressant therapy, and effects on cognition and depression were assessed. Trial results were reported in August 2024 and showed clinically and statistically significant benefits on depression symptoms with positive effects on the MADRS scale (a validated scale of depression symptom measurement) and the PGI-S (a valid patient reported assessment of depression severity). Cognition improved markedly and to a similar extent in both Xanamem and placebo groups.

About Xanamem (emestedastat)

Xanamem's novel mechanism of action is to control the level of cortisol in the brain through the inhibition of the cortisol synthesis enzyme, 11β-HSD1, without affecting production of cortisol by the adrenal glands. Xanamem is a first-in-class, once-a-day pill designed to deliver high levels of cortisol control in the brain.

Chronically elevated cortisol is associated with progression in Alzheimer's Disease and excess cortisol is known to be toxic to brain cells. Cortisol itself is also associated with depressive symptoms and when targeted via other mechanisms has shown some promise in prior clinical trials. The recent XanaCIDD trial demonstrated clinically and sometimes statistically significant benefits on depressive symptoms.

The Company has studied 11β-HSD1 inhibition by Xanamem in more than 400 volunteers and patients in eight clinical trials. Xanamem has a promising safety profile and has demonstrated clinical activity in patients with depression, patients with biomarker-positive Alzheimer's disease and cognitively normal volunteers. High levels of target engagement in the brain with doses as low as 5 mg daily have been demonstrated in a human PET imaging study.

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 not historical facts; are based on subjective estimates, assumptions and qualifications; and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements should be considered "at-risk statements" - not to be relied upon as they are subject to known and unknown risks, uncertainties and other factors (such as significant business, economic and competitive uncertainties / contingencies and regulatory and clinical development risks, future outcomes and uncertainties) that may lead to actual results being materially different from any forward looking statement or the performance expressed or implied by such forward looking statements. You are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Actinogen Medical does not undertake any obligation to revise such statements to reflect events or any change in circumstances arising after the date hereof, or to reflect the occurrence of or non-occurrence of any future events. Past performance is not a reliable indicator of future performance. Actinogen Medical does not make any guarantee, representation or warranty as to the likelihood of achievement or reasonableness of any forward-looking statements and there can be no assurance or guarantee that any forward-looking statements will be realised.

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