



ASX ANNOUNCEMENT

Actinogen Clinical Trials Science Forum 2024 – Pipeline in a Pill

Actinogen CMO, Dr Dana Hilt and guests explore the unique properties of Xanamem® for the potential treatment of cognitive impairment in multiple diseases

Professors John Harrison & Paul Rolan join Dr Dana Hilt in a panel discussion: 3pm, 23 May 2024

Event registration: https://actinogenmedical.zoom.us/webinar/register/WN_3YoG2A5JS7Ky5qe67dfkIA

Sydney, 13 May 2024. Actinogen Medical ASX: ACW (“ACW” or “the Company”) is pleased to announce that Professor John Harrison, Professor Paul Rolan and Dr Dana Hilt, leaders in their respective fields of cognition, clinical pharmacology and neuroscience will hold a webinar at **3pm on Thursday 23 May 2024**.

This highly informative ‘plain English’ panel discussion will focus the unique pharmacology and properties of ACW’s easy to use, oral medication Xanamem, and the clinical need for effective treatments of cognitive impairment in numerous neurodegenerative and neuropsychiatric conditions.

Dr Hilt will host the panel discussion and review the current state of Xanamem development and its promising safety profile. Professor Rolan will introduce the unique pharmacological properties of Xanamem, including its low potential for interaction with other drugs, that make it particularly suitable for the treatment of a broad range of diseases. And Professor Harrison will discuss cognitive impairment as a manifestation of many neurologic conditions and how Xanamem might fit into their treatment paradigms. There will be an opportunity for questions from webinar attendees to the panel that will generate further discussion and debate.

Xanamem is a novel once-a-day oral medication, currently under clinical development in two phase 2 trials. The XanaCIDD Phase 2a trial in patients with both cognitive impairment and major depressive disorder is fully enrolled and will report results early next quarter. The XanaMIA phase 2b trial is currently enrolling patients with biomarker-positive, mild to moderate AD and will report initial results mid-2025. Xanamem works by lowering brain tissue cortisol and has demonstrated clinical activity in tests of cognition across multiple placebo-controlled trials, and promising effects in one trial of biomarker-positive patients with mild AD.

Professor John Harrison is based in the UK and is a psychologist and renowned cognition expert whose principal professional interest is in helping people understand, maintain, and enhance their cognitive skills. In the past 25 years, Professor Harrison has assisted more than 80 CNS¹ drug development organisations with the selection and successful integration of cognitive testing into therapeutic development programs. He is the Chief Scientific Officer at Scottish Brain Sciences, a pioneering brain sciences research organisation. He is also an Associate Professor with the AUmc Alzheimer Center and Visiting Professor at King’s College London.

[©] Xanamem is a registered trademark of Actinogen Medical Limited

¹ CNS = Central nervous system

Professor Harrison holds Chartered Psychologist status and has authored/co-authored more than 100 books and scientific articles.

Professor Paul Rolan is a clinical pharmacologist, pharmaceutical and pain management physician who has worked in both academia and industry in the UK and Australia. He has extensive expertise in the development of medicines as principal investigator in more than 750 early phase proof-of-concept, clinical pharmacology, drug interaction and special patient groups studies. Formerly Actinogen's CMO, Professor Rolan continues to provide expert consultancy in clinical pharmacology and drug development, primarily in relation to the depression clinical trial program.

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.

Pre-register now for this event on Thursday, 23 May at 3pm, or register and join on the day:

https://actinogenmedical.zoom.us/webinar/register/WN_3YoG2A5JS7Ky5qe67dfkIA

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

ENDS

Investors

Dr. Steven Gourlay
CEO & Managing Director
P: +61 2 8964 7401

E. steven.gourlay@actinogen.com.au

Michael Roberts
Investor Relations
M: +61 423 866 231

E. michael.roberts@actinogen.com.au

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.

Current Clinical Trials

The **XanaCIDD Phase 2a cognition & depression trial** is a double-blind, six-week proof-of-concept, placebo-controlled, parallel group design trial in 167 patients. Participants are evenly randomized to receive Xanamem 10 mg once daily or placebo, in some cases in addition to their existing antidepressant therapy, and effects on cognition and depression are assessed.

The **XanaMIA Phase 2b 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 effects on cognition, function and progression of Alzheimer's disease are assessed. Thus, Xanamem is being assessed in this trial for its potential effects as a both a cognitive enhancer and a disease course modifier.

About Xanamem

Xanamem's novel mechanism of action is to block the production of cortisol inside cells through the inhibition of the 11 β -HSD1 enzyme in the brain. Xanamem is designed to get into the brain after it is absorbed in the intestines upon swallowing.

Chronically elevated cortisol is associated with cognitive decline in Alzheimer's Disease and excess cortisol is known to be toxic to brain cells. Cognitive impairment is also a feature in Depression and many other diseases. Cortisol itself is also associated with depressive symptoms and when targeted via other mechanisms has shown some promise in prior clinical trials.

The Company has studied 11 β -HSD1 inhibition by Xanamem in more than 300 volunteers and patients, so far finding a statistically significant improvement in working memory and attention, compared with placebo, in healthy, older volunteers in two consecutive trials and clinically significant improvements in functional and cognitive ability in patients with biomarker-positive mild AD. Previously, 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. A series of Phase 2 studies in multiple diseases is being conducted to further confirm and characterize 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 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.

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