ASX ANNOUNCEMENT

Actinogen XanaMIA Part A trial results expected in April

Sydney, 11 February 2022. Actinogen Medical ASX: ACW ("ACW" or "the Company") is pleased to announce that following the final trial patient visit yesterday it now expects top-line results for the XanaMIA Part A trial to be available in April[1], allowing for an approximate two-month period of data entry, quality control and analysis.

- **The XanaMIA Part A Phase 2 trial:**
  - **Enrolled 107 healthy volunteers aged 50 to 80 years**
  - **Is a randomised, double-blind, dose-ranging trial evaluating 5mg and 10mg Xanamem® dosing levels, over 6 weeks versus placebo**
  - **Assesses cognitive improvement using the computerised Cogstate Neurological Test Battery that includes a version of the International Digit Symbol Substitution Test**
  - **Is the first evaluation of the efficacy, safety and pharmacodynamics of a 5mg Xanamem dosing level**
- **The XanaMIA data, in combination with the results from a planned retrospective data analysis of biomarkers from a prior 12-week Phase 2 trial, will be used to design Actinogen's future Alzheimer's Disease clinical program.**

The XanaMIA Part A trial was established to assess the efficacy of 5mg and 10mg Xanamem doses compared to placebo in older healthy patients (aged 50 to 80 years old), over six weeks, to confirm the minimum effective dose needed to improve cognition (ability to think and remember things). The target dose range was determined by the results of a dose-ranging positron emission tomography (PET) study of Xanamem's inhibition of its target in the brain.

This study uses the Cogstate Neuropsychological Test Battery, which previously showed improvements in cognition at a higher dose, supplemented by the Digit Symbol Substitution Test (iDSST) which has been recognised in the past by regulatory bodies such as the FDA as an appropriate endpoint for a cognitive marketing claim[2].

Dr Steven Gourlay, Actinogen CEO and MD, commented:

"We are pleased to complete final participant visits for the XanaMIA Part A trial which will provide a detailed analysis of the cognitive effects and safety of 5mg and 10mg Xanamem® dosing levels.

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1. Previously the Company had advised that trial results would be available in Q2 CY2022
2. Vortioxetine cognitive benefit marketing label claim (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204447s017lbl.pdf)

We are excited to see the clinical data for these lower dose levels that are now scheduled to be released in April 2022. In our dose-ranging PET study, 5mg and 10mg daily doses achieved high levels of target enzyme inhibition in the brain.

Xanamem has the potential to be a novel daily oral therapy for Alzheimer's Disease and other neurological diseases that could be used alone or in combination with other therapies to help make a difference to the lives of patients and their families living with serious neurological conditions."

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, Depression 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 Depression and other diseases.

The Company has studied 11β-HSD1 inhibition by Xanamem in more than 300 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.

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