ASX ANNOUNCEMENT

Actinogen receives positive Pre-IND FDA advice for its second disease program: FXS

Key Highlights:

- **Positive US Food and Drug Administration (FDA) advice received in written response to Actinogen's Fragile X syndrome (FXS) program Pre-IND submission**
- **Pre-clinical program and proposed Phase II XanaFX trial design considered sufficient for a US Investigational New Drug (IND) submission subject to final FDA review of all supportive documentation submitted**
- **The Phase II XanaFX study is a randomised, placebo-controlled 12-week trial that will be conducted in Australia and is expected to commence in 4Q CY21**
- **While not required to conduct trials in Australia, IND approval ensures the trial incorporates all FDA requirements**

Sydney, 23 June 2021. Actinogen Medical ASX: ACW ('ACW' or 'the Company') is pleased to announce that it has received written supportive US FDA advice in response to its Pre-Investigational New Drug Application (Pre-IND) submission for its FXS program.

Actinogen sought a Pre-IND meeting with the FDA to discuss its lead molecule, Xanamem®, and the FXS clinical program. The advice received indicates that the data package and trial design proposed for the IND submission would be sufficient, subject to final review of all supportive documentation submitted. The Company plans to file the full IND submission in Q3 21.

The FDA and the Company are also in agreement on the proposed Phase II adolescent patient population to be studied. The Phase II **XanaFX** study will be a randomised, placebo-controlled, double-blind, 12-week trial investigating the safety and efficacy of Xanamem in male adolescents who suffer from FXS. The study will be conducted in Australia and is expected to commence in 4Q CY21.

Dr Steven Gourlay, Actinogen CEO and MD, commented:

"The FDA's positive Pre-IND advice for FXS marks a significant milestone in the clinical development of our second disease program. It provides greater confidence that we will obtain support from the FDA for the investigation of Xanamem in this disease that has a high unmet medical need for effective therapies. There are no currently approved therapies for FXS. The Company is advancing the planning for its Phase II XanaFX trial which is expected to commence by the end of the year. Actinogen is now positioned to progress its clinical programs with multiple Phase II trials and is well funded to advance the development pipeline."

US IND approval is not required to conduct the trial in Australia; however, approval will ensure that the trial incorporates all FDA requirements and is of an international regulatory standard.

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 an innovative treatment for cognitive impairment associated with neurological diseases amenable to modifications of raised cortisol levels inside brain cells. 'Cognition' relates to how a person understands and acts in the world around them. Cognitive functions include memory, reasoning, awareness and decision-making, and to a large extent, influence our personality.
Actinogen Medical's lead drug candidate, **Xanamem®,** has been specifically designed to block the production of cortisol – the stress hormone – in the brain. 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 neuropsychiatric diseases.

Xanamem offers a promising new approach to treat cognitive impairment associated with these neurological diseases. In the Company's recent XanaHES Phase I trial, Xanamem exhibited a statistically significant improvement in cognition among healthy older volunteers, and recent human target engagement data for the drug in the brain suggests good activity of doses as low as 5mg daily. The Company plans to initiate a range of Phase II studies evaluating Xanamem in the treatment of cognitive impairment associated with Alzheimer's disease, Fragile X syndrome, and other indication(s) with a strong scientific rationale.

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 registered trademark of Actinogen Medical.

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