



## ASX ANNOUNCEMENT

### **Actinogen awarded UK Innovation Passport for Xanamem®**

*Actinogen receives approval of its application for an Innovation Passport as part of the Innovative Licensing and Access Pathway (ILAP) for Xanamem in the treatment of Alzheimer's disease*

**Sydney, 15 February 2024. Actinogen Medical ASX: ACW ("ACW" or "the Company")** is pleased to announce approval by the UK Medicines and Healthcare products Regulatory Agency (MHRA) of its application for an Innovation Passport as part of the ILAP for Xanamem in the treatment of Alzheimer's disease.

Key benefits of this approval include:

- Entry point to the ILAP which aims to accelerate time to market
- Linkage to a portfolio of activities through the product-specific creation of the Target Development Profile (TDP) in conjunction with the MHRA
- Opportunities for enhanced regulatory and other stakeholder input including from partner agencies such as the MHRA and National Institute for Health and Care Excellence (NICE).

**Dr Steven Gourlay, Actinogen's CEO and MD, said:**

*"The MHRA's approval of the ILAP application validates our belief in Xanamem's unique and encouraging profile for the treatment of Alzheimer's disease. Following on from three prior trials showing promising activity, Actinogen's 220-person phase 2b trial in Alzheimer's is now underway and will report initial results as early as the first half of 2025."*

The next step in the ILAP process will be to commence development of the TDP.

**ENDS**

#### **Investors**

**Dr. Steven Gourlay**  
CEO & Managing Director  
P: +61 2 8964 7401  
E: [steven.gourlay@actinogen.com.au](mailto:steven.gourlay@actinogen.com.au)

**Michael Roberts**  
Investor Relations  
M: +61 423 866 231  
E: [michael.roberts@actinogen.com.au](mailto:michael.roberts@actinogen.com.au)

® Xanamem is a registered trademark of Actinogen Medical Limited

## **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 and Upcoming Clinical Trials**

The **XanaCIDD Phase 2a depression trial** is a double-blind, six-week proof-of-concept, placebo-controlled, parallel group design trial in 160 patients. Patients 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 $\beta$ -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 $\beta$ -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<sup>®</sup> 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.**

For personal use only