

#### **ASX ANNOUNCEMENT**

# Review of 2019 and outlook

**Sydney, 18 December 2019. Actinogen Medical ASX: ACW ('ACW', 'Actinogen' or 'the Company')** is pleased to provide investors with an end-of-year review and an outlook update, from Dr Bill Ketelbey, CEO and MD of Actinogen:

Dear Shareholders,

At this time of the year, it is tradition to reflect on the year that has been and to look forward to potential milestones in the coming year.

2019 has been a momentous year for Actinogen. Data generated from a number of studies over the year has significantly enhanced the dataset and deepened the understanding of our lead drug, Xanamem. We have demonstrated that Xanamem is an efficacious, brain penetrant, and appropriately safe oral drug having successfully produced clinical results for Xanamem in line with its intended mechanism of action.

Summary of the key results generated over the year include:

- Breakthrough XanaHES results demonstrating a robust and statistically significant clinical effect on improving cognition in healthy elderly patients taking 20mg Xanamem daily
- Target Occupancy results confirming that Xanamem works as designed to penetrate the brain in concentrations that adequately inhibit the activity of the 11ß-HSD1 enzyme
- Strong safety profile and cortisol inhibition demonstrated in human trials with 10mg and 20mg Xanamem

Actinogen Medical will present all these results, and more, at the international Advancement in Alzheimer's and Parkinson's Disease Therapies (AD/PD) Focus Meeting in April 2020. Held in Vienna, this international scientific meeting includes all the latest breakthroughs in drug development, translational R&D, early diagnosis, and clinical trials, and Actinogen is proud to have been accepted to add to this global body of knowledge by presenting the impressive results we achieved so far.

The potential of Xanamem's novel mechanism of action across a number of target indications enables Actinogen to explore multiple opportunities to maximise value for our shareholders. Actinogen is completing a comprehensive review of all the Xanamem data, new target indications, and potential funding options to inform Xanamem's optimum strategic direction. An updated clinical development plan is currently being produced to incorporate the data gathered this year, and to include potential new development opportunities, including new studies in Alzheimer's disease, and in cognitive impairment associated with schizophrenia, bipolar disorder, and diabetes. There is the expectation that studies will initiate during 2020, and we have already submitted grant applications with the aim of broadening and developing the Xanamem portfolio with non-dilutive funding alternatives. In parallel, potential collaboration and partnership discussions continue, along with engagement with key opinion leaders and relevant regulatory bodies.

I would like to take a moment to remind shareholders of the broad therapeutic potential of Xanamem and the significant positive impact that it could have. The target indications we have outlined (Alzheimer's disease, and cognitive impairment in schizophrenia and mood disorders, and diabetes) are all indications representing a significant unmet medical need, with truly debilitating effects on the lives of patients and their carers. These indications also represent an enormous cost to the healthcare system, and we are fully committed to developing Xanamem as a potential treatment for a number of these diseases.

2020 promises to be a particularly busy year for Actinogen, and we look forward to providing further updates on our strategic plans and clinical study progress in the new year. On behalf of the team at Actinogen, a most sincere thank-you to all our shareholders for your continued support, and I wish you and your family all the best for the holiday season.

Sincerely,

Bill Ketelbey **CEO & Managing Director** 

#### **ENDS**

#### **Actinogen Medical**

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Announcement authorised by the Board of Directors of Actinogen Medical

## **About Actinogen Medical**

Actinogen Medical (ASX: ACW) is an ASX-listed biotechnology company developing novel therapies for cognitive impairment associated with chronic neurological and metabolic diseases. The company is currently developing its lead compound Xanamem as a promising new therapy for Alzheimer's disease and cognitive impairment associated with schizophrenia and mood disorders. The cognitive dysfunction associated with these conditions is significantly debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

#### About Xanamem™

Xanamem's novel mechanism of action sets it apart from other therapies for Alzheimer's disease. It works by blocking the excess production of intracellular cortisol – the stress hormone – through the inhibition of the 11β-HSD1 enzyme in the brain. There is a strong association between persistent stress and the production of excess cortisol that leads to changes in the brain, affecting memory. The 11β-HSD1 enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain associated with cognitive impairment in neurological diseases, including Alzheimer's disease, schizophrenia and the mood disorders.

The Company's XanaHES Phase I trial exploring the safety and tolerability of Xanamam™ 20mg once daily in healthy elderly volunteers, showed that the drug exhibited a good safety profile with no treatment-related serious adverse events. Additionally, the trial demonstrated that Xanamem™ produced a statistically significant improvement in cognition, which, along with other data recently generated, confirms the underlying mechanism of action of Xanamem. The Company plans to initiate Phase II studies of Xanamem in various disease areas in 2020, including in Alzheimer's disease, and in cognitive impairment associated with schizophrenia, mood disorders and diabetes.

Actinogen Medical encourages all current investors to go paperless by registering their details with the designated registry service provider, Link Market Services.