ASX ANNOUNCEMENT

FDA IND update

Sydney 4 November 2020. Actinogen Medical Limited ASX:ACW ('ACW' or 'the Company') has an active FDA IND (investigational new drug) that allows for dosing and duration of Xanamem at 10mg daily for 3 months in Alzheimer's disease trials conducted in the USA. In anticipation of proceeding to the next phase of its US Alzheimer's disease clinical program, the Company has commenced a process with the FDA to obtain approval to increase Xanamem's dose and the duration of treatment in US trials.

The FDA has just responded to Actinogen requesting further submissions and additional data to enable the FDA to consider the proposed design of future US trials, and in particular for the Company to increase dosing and duration of Xanamem in excess of 10mg daily for 3 months.

This process does not currently appear to have any material impact on our planned clinical trials, including the **MCI in Alzheimer's disease (XanaMIA) and Fragile X syndrome (XanaFX)** trials, as they are to be conducted in Australia. These trials are expected to commence in H1 2021.

The Company will provide further updates to the market as and when discussions with the FDA concerning US clinical trials progress in any material way.

ENDS

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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 neurological, psychiatric and metabolic diseases associated with chronically elevated cortisol. The company is currently developing its lead compound, Xanamem, as a promising new therapy for Alzheimer's disease, Fragile X syndrome, schizophrenia and diabetes. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden 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 works by blocking the 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 detrimental changes in the brain, affecting memory, cognitive function and behaviour and neuropsychological symptoms. The 11β-HSD1 enzyme is particularly highly concentrated in the hippocampus and frontal cortex, areas of the brain impacted by a

number of diseases and disorders, including Alzheimer's disease, Fragile X syndrome, schizophrenia, diabetes and other conditions associated with chronically raised cortisol.

The Company's XanaHES Phase I trial exploring the safety and tolerability of Xanamem 20mg once daily in healthy elderly volunteers, confirmed the drug's safety profile with no treatment-related serious adverse events. Additionally, the trial demonstrated that Xanamem produced a statistically significant improvement in cognition over placebo, which, along with other recently generated data, confirms 11β-HSD1 inhibition by Xanamem as a promising potential treatment for cognitive impairment associated with raised cortisol.

The Company plans to initiate Phase II studies of Xanamem in various disease areas in 2021, including MCI due to Alzheimer's disease, and Fragile X syndrome.

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