ASX ANNOUNCEMENT

Actinogen announces two new clinical trials and launches capital raising

Sydney, 15 October 2020. Actinogen Medical ASX: ACW (ACW or the Company) is pleased to announce that it has selected **Fragile X syndrome (FXS)** as an additional indication for Xanamem, ACW's lead compound. Actinogen plans to conduct a fully funded phase II clinical trial in FXS patients, evaluating Xanamem's safety and efficacy in treating anxiety, sleep, and behavioural problems associated with this condition, the **XanaFX** study.

In addition, Actinogen plans to initiate a new phase II clinical trial in **Mild Cognitive Impairment (MCI)** due to **Alzheimer's disease (AD),** the **XanaMIA** study. Actinogen today announces a capital raising to primarily fund the XanaMIA study.

Key Highlights

- **Fragile X syndrome selected as an additional indication for Xanamem, with a fully funded phase II clinical trial (XanaFX) scheduled to commence in 1H CY21**
- **Additionally, Actinogen announces a new phase II XanaMIA clinical trial, linking the compelling XanaHES efficacy results with an early AD population, scheduled to commence in 1H CY21**
- **Successfully received commitments for A$6m via an oversubscribed institutional placement, supported by existing shareholders and new investors**
- **A 1 for 5 non-renounceable rights issue offer to shareholders is planned to raise ~A$4.9m, with total funds raised from the capital raising to primarily fund the XanaMIA study**
- **Actinogen will host a teleconference call at 11am (AEDT) Monday, 19 October 2020 to provide an update on the upcoming clinical development plans**

Dr Bill Ketelbey, Actinogen CEO and MD, commented:
"We are delighted to embark on this significant new trial program and particularly excited to announce Fragile X syndrome as a new indication for Xanamem. The Company is committed to advancing Xanamem's clinical development to find an effective treatment for a number of devastating medical conditions and the upcoming FXS trial expands the potential clinical applications for Xanamem. In addition, significant support has been demonstrated by existing shareholders and new investors to fund a phase II trial targeting early stages of Alzheimer's disease, and we are pleased to announce an entitlement offer to eligible shareholders on the same terms. We look forward to initiating the planned studies next year and building on the significant progress made to date with the development of Xanamem."

Clinical Development Update

Fragile X syndrome selected as a new, additional indication for Xanamem

FXS has been selected as the Company's next clinical development opportunity for Xanamem, following significant clinical and scientific interest in evaluating Xanamem across a range of medical conditions associated with chronically raised cortisol. FXS is a genetic disorder, usually diagnosed at around 3 to 5 years of age and characterised by a range of intellectual developmental and behavioural issues. The anxiety and behavioural problems associated with FXS have a significant impact on the daily lives of many FXS patients and their carers, with only limited treatment options currently available. Recent advances in the understanding of

the underlying pathology of FXS, combined with the data generated by Actinogen confirming Xanamem's efficacy at inhibiting cortisol production, support Xanamem as an exciting new potential treatment for many of the debilitating symptoms associated with FXS.

Today, Actinogen announces a new clinical trial of Xanamem in FXS – the **XanaFX** study. This study will be a phase II double-blind placebo-controlled trial evaluating the efficacy and safety of Xanamem in approximately 40 male adolescents (age 12-18) with FXS. The study will assess the safety and tolerability of Xanamem in this population at two different doses. Additionally, the study aims to determine if Xanamem effectively treats the anxiety and sleep problems experienced by FXS patients, and to determine if the drug adequately manages the behavioural difficulties associated with FXS. To the Company's knowledge this is the first study to target cortisol inhibition as a treatment for anxiety, sleep and behaviour problems in FXS patients, and the XanaFX study represents an innovative approach to addressing a significant unmet clinical need. XanaFX is fully funded with Actinogen's available capital and will be conducted at the Murdoch Children's Research Institute and the Royal Children's Hospital in Melbourne, Australia. Patient enrolment is expected to begin in 1H CY21 with results anticipated within 12 months of commencement of the trial.

Importantly, Xanamem in FXS potentially meets the criteria for **Orphan Drug Designation (ODD)** and **Rare Paediatric Disease Designation (RPDD)**. ODD and RPDD designations provides multiple incentives in many major markets that include attractive development, regulatory and commercial advantages, possibly resulting in faster clinical development and commercialisation of Xanamem. Actinogen has plans to submit ODD and RPDD applications to the FDA for Xanamem in FXS.

XanaMIA: Phase II trial in Mild Cognitive Impairment due to Alzheimer's disease

As announced previously, Actinogen continues to focus on the development of Xanamem as a potential treatment for AD, leveraging the breakthrough efficacy results from the XanaHES trial into an AD patient population. Actinogen's new **XanaMIA** phase II clinical trial is designed to demonstrate the safety, tolerability and efficacy of Xanamem 10mg twice daily in patients with MCI due to AD. This patient population is at the very early stages of AD and presents with a significant unmet medical need, with no effective treatment currently available. The Company expects patient recruitment to commence in 1H CY21, and the trial to complete within 24 months of commencement of the trial. Proceeds from the capital raising announced today are to be primarily used to fund the XanaMIA study.

Capital Raising

The capital raising consists of an institutional placement **(Placement)** and a 1 for 5 non-renounceable entitlement offer **(Entitlement Offer)** (together, the **Capital Raising**). The offer price for the Capital Raising is A$0.022 per new share **(Offer Price).** The Offer Price represents a 21.4% discount to the last close price and a 20.6% discount to the 5-day VWAP as at 12 October 2020. All shares issued under the Capital Raising will rank equally with existing Actinogen shares on issue. Bell Potter Securities acted as Lead Manager.

Placement

The oversubscribed placement to institutions, sophisticated and professional investors will raise A$6m, before transaction-related costs. The Placement comprises the issue of 272,727,273 new, ordinary fully paid Actinogen shares (**New Shares**), at the Offer Price of A$0.022 per New Share. The Placement attracted strong demand from existing shareholders and new investors.

The Placement will be undertaken in a single tranche within the Company's existing placement capacity under ASX Listing Rule 7.1 and 7.1A - therefore no shareholder approval is required for the Placement. New Shares

subscribed for under the Placement are expected to settle on 21 October 2020 and commence trading on the ASX on 22 October 2020. New Shares issued will rank equally with existing fully paid ordinary shares in Actinogen.

Entitlement Offer

In addition to the Placement, the Company plans to undertake a 1 for 5 Entitlement Offer to existing shareholders, to raise approximately A$4.9m. Eligible shareholders at the Record Date of 7:00pm (AEDT) on Tuesday, 20 October 2020 with a registered address in Australia and New Zealand will be invited to participate in the Entitlement Offer, at the Offer Price (being the same price as the Placement). The Entitlement Offer will open on Friday, 23 October 2020 and close at 5:00pm (AEDT) on Tuesday, 3 November 2020. The Entitlement Offer is non-renounceable and entitlements will not be tradable or otherwise transferable. No shareholder approval is required for the Entitlement Offer

Actinogen's Board members have confirmed their intention to participate up to the maximum available pro-rata investment in the Entitlement Offer. Eligible shareholders who take up their entitlement in full can also apply for additional shares in excess of their entitlement under a top-up facility. Allocations for additional new shares above pro-rata entitlements will be determined at Actinogen's absolute discretion and is not guaranteed. The Company reserves the right to allot and issue any shortfall shares under the Entitlement Offer at its discretion.

The terms and conditions and further details of how to participate in the Entitlement Offer will be set out in the information booklet to be sent to eligible shareholders on Friday, 23 October 2020. The information booklet will include a personalised entitlement and acceptance form. Copies of the information booklet will also be available on the ASX and Actinogen's website.

Indicative Capital Raising timetable[1]

Event	Date
Capital Raising announcement and Company resumes trading	Thursday, 15 October 2020
Record date for Entitlement Offer	7pm (AEDT), Tuesday, 20 October 2020
Settlement of Placement	Wednesday, 21 October 2020
Allotment and trading of new shares under the Placement	Thursday, 22 October 2020
Entitlement Offer opens and information booklet despatched	Friday, 23 October 2020
Entitlement Offer closes	Tuesday, 3 November 2020
Announcement of Entitlement Offer results	Friday, 6 November 2020
Entitlement Offer allotment date	Wednesday, 11 November

1. This timetable is indicative only and subject to change. The Company reserves the right to amend the dates at its discretion and without notice, subject to the ASX Listing Rules and the *Corporations Act 2001 (Cth)*. All times are AEDT.

ENDS

Actinogen Medical
Dr. Bill Ketelbey
CEO & Managing Director
P: +61 2 8964 7401
E: bill.ketelbey@actinogen.com.au
@BillKetelbey

Investor Enquiries
Miranda Newnham
Vesparum Capital
P: +61 3 8582 4800
E: actinogen@vesparum.com

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.

Disclaimer

This announcement and attachments may contain certain forward-looking statements that are based on subjective estimates and assumptions and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements involve known and unknown risks, uncertainties, and other factors (such as significant business, economic and competitive uncertainties and contingencies, and regulatory and clinical development risks and uncertainties) which may cause the actual results or the performance of Actinogen Medical to be materially different from the results or performance expressed or implied by such forward looking statements. Past performance is not a reliable indicator of future performance. There can be no assurance that any forward-looking statements will be realised. Actinogen Medical does not make any representation or give any warranty as to the likelihood of achievement or reasonableness of any forward-looking statements.

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