

**ASX ANNOUNCEMENT****Strategic Update and Teleconference Call Notification**

Sydney, 21 April 2021. Actinogen Medical ASX: ACW ('ACW' or 'the Company') is pleased to provide a strategic update and release a corporate investor presentation. Actinogen's Chief Executive Officer and Managing Director, Dr Steven Gourlay, will be hosting a teleconference on Friday, 23 April 2021 at 9.00am AEST. This teleconference will be used to update existing shareholders, potential investors and other strategic parties on Actinogen's clinical development pipeline, commercial strategy and outlook going forward.

**Key highlights:**

- **Xanamem™ is a brain penetrant 11β-HSD1 small molecule enzyme inhibitor, that works to inhibit excess cortisol production inside brain cells**
- **Review of data completed to optimise clinical trial planning, with Phase I data highlighting modern and sensitive, computerised measurement tools and PET brain scan data supporting efficacy of Xanamem in doses as low as 5mg**
- **XanaMIA Phase II trial to commence in CY21 and to be executed in two parts;**
  - Part A: Dose ranging study seeking to confirm minimum effective Xanamem dose
  - Part B: Investigating efficacy of Xanamem in patients with mild cognitive impairment due to Alzheimer's disease, bridging positive Phase I data (healthy older subjects and PET brain scan data) to an early stage Alzheimer's population
- **XanaFX Phase II trial in adolescents with Fragile X syndrome is fully funded, with strategic benefits from Rare Paediatric Disease Designation awarded by the FDA supporting clinical development and a pre-IND interaction with the FDA pending**
- **Strong cash balance of ~\$15.23m as 31 March 2021, with XanaMIA and XanaFX fully funded**
- **Dr Steven Gourlay to deliver presentation on a Teleconference at 9:00am on Friday, 23 April 2021**

**Dr Steven Gourlay, Actinogen CEO and MD, commented:**

*"After many years of working in the biopharma industry, I am excited by the huge potential of Actinogen. In my last major role at Principia Biopharma as Chief Medical Officer, I steered two small molecules from a microcap company valuation, through successful Phase II development and into Phase III, resulting in a significant value appreciation for shareholders when the company was acquired for US\$3.7B. I find Actinogen to be a similar investment opportunity: excellent science, a promising Phase II molecule for multiple indications, with an attractive valuation, and so accepted the role as CEO / MD, and personally invested over A\$300K into the Company prior to my appointment.*

*We are now planning for multiple shots on goal and strongly believe the upcoming trials are designed to achieve informative and positive outcomes. I look forward to working with the team to further develop Xanamem as we progress the development pipeline."*

Alzheimer's disease remains a focus for Actinogen, with the XanaMIA trial expected to commence this year. This trial is designed to leverage the positive Phase I cognition data in healthy elderly subjects to bridge the gap to an early Alzheimer's population, with the potential to limit further impairments as Alzheimer's progresses. XanaMIA is planned to utilise the sensitive Cogstate Neurological Test Battery ("Cogstate"), a

computerised test battery measuring a range of cognitive capabilities which was used in the Phase I trial, including the Digit Symbol Substitution Test or iDSST. The iDSST has been recognised in the past by the FDA as an approvable endpoint for a cognitive marketing claim. The PET human brain scan data generated in Actinogen's Target Occupancy study supports daily doses as low as 5mg.

XanaMIA Part A is a dose ranging study designed to confirm the minimum effective dose of Xanamem before moving into larger trials. The study will assess healthy elderly patients at 5mg, 10mg and placebo. The results will be used to inform XanaMIA Part B, which will investigate the efficacy of Xanamem in patients with mild cognitive impairment (MCI) due to Alzheimer's disease. The trial has been designed to utilise serum biomarkers to positively identify MCI as related to Alzheimer's, and dementia assessment scales to ensure patients are early stage, and do not have the functional impairment present in later stage Alzheimer's. Part B endpoints will also include Cogstate and iDSST, as well as other endpoints previously accepted by regulators.

Plans for the XanaFX Phase II trial targeting adolescents with Fragile X syndrome (FXS) are advancing, with a FDA Pre-IND interaction expected in mid CY21 which will inform trial commencement, currently expected in CY21. Actinogen was recently awarded Rare Paediatric Disease Designation in FXS which includes priority review and potentially faster clinical development and commercialisation of Xanamem in FXS, as well as a separate, tradeable priority review voucher.

Actinogen continues to focus on various shareholder value drivers through a strong commercialisation strategy, including multiple trials in clinical development and a focus on business development activities. As part of this, Actinogen continues to assess additional opportunities to expand the clinical pipeline beyond Alzheimer's and FXS.

Actinogen's presentation is attached to this announcement.

### **Teleconference Notification**

#### **Conference call details:**

Date: Friday, 23 April 2021

Time: 9.00am (AEST)

#### **Registration details**

Participants are encouraged to pre-register for the webcast through the link below. Upon registration, participants will receive a unique pin granting fast-track access to the conference call.

<https://s1.c-conf.com/diamondpass/10013510-v1ru5s.html>

If you do not pre-register for the event, you can dial into the event using one of the numbers below. Please dial in five minutes before the webcast begins and provide your name and the participant PIN code.

**Participant PIN code:** 10013510

#### **Dial-in numbers:**

|                     |              |                             |                 |
|---------------------|--------------|-----------------------------|-----------------|
| <b>Australia:</b>   | 1800 455 963 | <b>USA/Canada:</b>          | 1 855 624 0077  |
| <b>New Zealand:</b> | 0800 452 795 | <b>UK:</b>                  | 0800 051 1453   |
| <b>Singapore:</b>   | 800 101 2702 | <b>Spain:</b>               | 900 823 322     |
| <b>Hong Kong:</b>   | 800 968 273  | <b>Switzerland:</b>         | 0800 802 498    |
| <b>Malaysia:</b>    | 1800 816 441 | <b>Other International:</b> | +61 7 3145 4005 |

A transcript of the conference call will be made available on the ASX in the days following the call.

**ENDS**

**Actinogen Medical**

**Investor Enquiries**

**ACTINOGEN MEDICAL LIMITED** TRADING AS ACTINOGEN MEDICAL ACN 086 778 476 ASX | ACW

Suite 901, Level 9, 109 Pitt Street, Sydney NSW 2000 AUSTRALIA

TELEPHONE +61 2 8964 7401

WEB [www.actinogen.com.au](http://www.actinogen.com.au)

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

Miranda Newnham  
Vesparum Capital  
P: +61 3 8582 4800  
E: [actinogen@vesparum.com](mailto: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 diseases associated with dysregulated brain cortisol. The company is currently developing its lead compound, Xanamem™, as a promising new therapy for Alzheimer's Disease, Fragile X syndrome, and other potential neurological diseases. 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 Company has studied 11β-HSD1 inhibition by Xanamem in more than 200 volunteers and patients, finding a statistically significant improvement in cognition over placebo in healthy, older volunteers. A series of Phase II studies in multiple indications will be conducted to further confirm and characterise Xanamem's efficacy and safety.

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.**