

ASX ANNOUNCEMENT

Actinogen Presentation and Planned Conference Call

Sydney, 15 October 2020. Actinogen Medical ASX: ACW ('ACW' or 'the Company') is pleased to advise that Dr. Bill Ketelbey, CEO and MD of Actinogen, will provide an update on the clinical development plans for Xanamem during a conference call **on Monday, 19 October 2020 at 11:00am (AEDT)**. Dr. Ketelbey will provide an overview of the new indication in Fragile X syndrome, the planned Alzheimer's disease and Fragile X syndrome phase II clinical trials, and the capital raising to support the Alzheimer's trial.

The investor presentation is attached to this announcement and will be available on the webcast.

Participants are invited to register for the webcast using the link below. Upon registration, participants will receive a unique pin granting fast-track access to the conference call. Questions may be submitted prior to the conference call through this facility, and further questions accepted on the day.

Pre-register here: https://s1.c-conf.com/DiamondPass/10010450-pH45r6.html

If you are unable to register for the webcast, please call one of the numbers below prior to the start of the event and quote the following Conference ID: **10010450.**

| Australia Local: | 02 9007 8048 | Singapore Toll Free: | 800 101 2702 |
|-------------------------|----------------|---------------------------|---------------|
| Australia Toll Free: | 1800 908 299 | Malaysia Toll Free: | 1800 816 441 |
| New Zealand Toll Free: | 0800 452 795 | Hong Kong Toll Free: | 800 968 273 |
| USA / Canada Toll Free: | 1 855 624 0077 | United Kingdom Toll Free: | 0800 051 1453 |

A recording of the conference call will be uploaded on Actinogen's website when available.

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 11 β -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 11 β -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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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.

DEAL PRESENTATION

Dr. Bill Ketelbey: CEO & MD October 2020

Developing novel therapies for cognitive impairment and behavioural symptoms due to raised cortisol in chronic neurological, psychiatric, developmental and metabolic diseases





Executive summary



Developing Xanamem[™] for cognitive impairment and behavioural symptoms due to raised cortisol in chronic neurological, psychiatric, developmental and metabolic diseases



Xanamem an oral, brain penetrant, selective and effective 11β-HSD1 inhibitor. Comprehensive analysis of the substantial dataset completed with conclusions to define study parameters for next series of clinical studies



XanaMIA - Phase II study targeting an early stage of Alzheimer's disease characterised as Mild Cognitive Impairment, linking the compelling XanaHES efficacy results with an Alzheimer's population, and targeting a huge commercial opportunity



XanaFX - anxiety, sleep & behavioural problems in Fragile X syndrome selected as new indication. A compelling clinical application to target adolescents with an Orphan Disease. Highlighting the breadth of Xanamem's potential clinical indications



Strong outlook with Actinogen developing plans for multiple clinical trials expected to commence in 1H CY21



Capital raising of around A\$10.9 via a oversubscribed A\$6.0m Institutional Placement and a 1 for 5 Non Renounceable Entitlement Offer to existing shareholders to raise approximately A\$4.9m



Leveraging development across multiple indications

1. Cognitive impairment associated with Schizophrenia (CIAS)

Xanamem's strategic development across multiple target indications, complementing Alzheimer's disease with Fragile X syndrome selected as a new priority clinical development opportunity





Cognitive impairment associated with Type 2 Diabetes (CIAD)
 XanaHES – a phase I clinical study in healthy elderly subjects completed in October 2019, demonstrating robust safety and efficacy with Xanamem 20mg daily for 12 weeks (see slide 11)

Attractive development pipeline

Actinogen is targeting a broad portfolio of clinical indications to assess the efficacy of it's lead drug, Xanamem





Xanamem[™] - lead compound

Novel Mechanism of Action - designed to inhibit cortisol production in the brain (through inhibition of the 11B-HSD1 enzyme)





Key outcomes from Xanamem studies

Xanamem, an oral compound, demonstrated to be an efficacious, safe, brain penetrant, selective and effective 11B -HSD1 inhibitor producing significant pharmacodynamic effects on cortisol

Xanamem dose

| XanaHES | Cognitive Efficacy | Breakthrough results demonstrate a statistically significant clinical effect in improving cognition in healthy elderly patients | 20mg |
|-----------------|-----------------------|--|-------------|
| ٩ | Target Occupancy | Confirms Xanamem works as designed to penetrate the brain in concentrations that adequately inhibit the activity of 11B-HSD1 enzyme | 5mg - 30mg |
| Corti inhibi | Cortisol | Cortisol inhibition demonstrated pharmacodynamically in human trials | 10mg & 20mg |
| | inhibition | Statistically significant reduction in serum cortisol in human trial | 20mg |
| | Safety | Strong safety profile demonstrated in human trials | 10mg & 20mg |



Target Occupancy study: positive confirmatory data

Phase I target occupancy study demonstrates that 5mg to 30mg Xanamem dosed for seven days significantly binds to the neuronal 11B-HSD1 enzyme throughout the brain (32 of 36 patients completed)



50% to 85% occupancy, dependent upon brain region, dosage and study subject¹

Phase I Target Occupancy supports Xanamem as a potent, orally bioavailable and brain-penetrant 11β-HSD1 inhibitor



1. Study population consisted of ~50% healthy subjects (cognitively normal) and ~50% with Alzheimer's diseas

MCI due to Alzheimer's disease



Alzheimer's disease remains a focus

Market dynamics of Alzheimer's disease presents a compelling commercial opportunity for Actinogen

Substantial target market with significant upside¹



Underpinned by favourable market dynamics



Targeting **large addressable** markets (US, EU5⁵, JP)



All **currently approved drugs are symptomatic treatments** (that do not affect disease progression) **providing limited benefit**

>US\$13.7bn

Target annual peak sales²



Treatment **prices are robust** (despite generic competition) – with users paying for modest clinical efficacy



Source: Drugs.com, Biogen, Roche, Datamonitor, Alzheimer's Association, aibl study; Bio-Link

MCI: Mild Cognitive Impairment; AD: Alzheimer's disease 1. Target market statistics expected in 2020, based on the current US treatment landscape. 2. Sales in 2036. Case assumes: (1) Launch: US 2027, EU5, JP and ROW 2028; (2) Penetration: 30% of mild AD and MCI markets in 5 years, sustained for 6 years with patent extension; (3) Pricing: US – US\$24/day gross (US\$19/day net), ROW: 50% of US price; 3. Biogen 2015 27% >65y/o Aβ+; 4. Raised cortisol in 50%>65y/o (AIBL study, Pietrzak et al., 2017) (5) UK, France, Germany, Italy, Spain

Alzheimer's disease - Mild Cognitive Impairment due to AD

XanaMIA - evaluating Xanamem in patients with Mild Cognitive Impairment (MCI) due to AD (an early stage of the AD spectrum), linking the compelling XanaHES results with an Alzheimer's disease patient population



- MCI due to Alzheimer's affects ~8% of those over 65 years of age
- Conversion rate to mild Alzheimer's ~10-15% per annum
- Patients have characteristic pathophysiological changes of Alzheimer's (ie. functional impairment)

XanaMIA - Phase II trial to demonstrate Xanamem's pro-cognitive effects in MCI due to AD patients



XanaHES Significant cognitive efficacy signal achieved

New XanaMIA trial to leverage breakthrough XanaHES results¹ demonstrate robust statistically significant cognitive efficacy improvement in multiple cognition domains - based on Cogstate Cognitive Test Battery



Efficacy results reflect high quality and consistent data in a small study population



Notes: All values are the means of observed data. p values were calculated with an ANCOVA (analysis of covariance) model using Baseline values as a covariate. 1. XanaHES results announced to the ASX 1 October 2019

XanaMIA - Phase II clinical trial

XanaMIA: A Phase II trial to demonstrate the safety, tolerability and efficacy of Xanamem 10mg twice daily in patients with MCI due to Alzheimer's disease

Proposed clinical trial design

| Study design | Phase II proof-of-concept study; double-blind, placebo-controlled 24 weeks treatment; clinical sites in Australia 72 males & females (65-80yrs) with MCI (NIA-AA criteria / CDR 0.5 / compromised memory) due to AD AD diagnosis confirmed by pathology: CSF Aβ / CSF tau or amyloid PET | anaMIA planned to ommence recruitmen n 1H CY21 ¹ |
|--------------------------|--|---|
| Primary endpoints | Safety and tolerability assessment of Xanamem in this population | xpected completion /ithin 24 months ¹ |
| Secondary endpoints | Improvement in specific domains of attention and memory: Cogstate NTB, RBANS, CDR-SOB Xanamem PK in plasma and CSF PD biomarkers, including cortisol and cortisone using 24-hour micro-dialysis and 24-hour salivary sampling | rial to be funded by apital raising |
| Exploratory endpoints | Improvement in all domains of cognitive assessments (Cogstate NTB, RBANS, CDR-SOB) Change in CSF and plasma biomarkers: Aβ, tau, NfL, TREM2, GFAP Change in temporoparietal hypometabolism assessed by FDG-PET Assessment of sleep and anxiety patterns in correlation with circadian and ultradian rhythms measured via micro-dialysis Evaluation of change in Instrumental Activities of Daily Living (IADL) | . , |



Key milestones

Fragile X syndrome



Fragile X syndrome

Fragile X syndrome is a rare genetic condition with behavioural symptoms (including intense anxiety) and cognitive deficit representing a significant unmet medical need with limited treatment options

FXS is caused by mutations in the Fragile X gene (FMR1) of the X chromosome.

Most common cause of genetically inherited intellectual disability.

Diagnosis typically occurs around 3-5 years of age.

FXS is characterised by a range of developmental problems including learning disabilities, behavioural issues including autism features, cognitive impairment, speech and language deficits, sleep problems, anxiety, and severe difficulties with regulating stress and emotions.

Management of FXS is often complex, with life-long treatment required for patients.

There are no approved drugs to treat Fragile X syndrome.







Research supports Xanamem as a FXS treatment

Medical and scientific research validates cortisol as a therapeutic target in FXS



Raised cortisol associated with stressinduced behavioural problems in FXS

- Biological changes in FXS promotes elevated cortisol in the brain
- Higher salivary cortisol linked to cognitive demands and behavioral problems in FXS
- Elevated baseline cortisol associated with working memory deficits in FXS
- Increased cortisol associated with elevated symptoms of general anxiety and social avoidance in young adult males with FXS



Xanamem safely and effectively inhibits cortisol production

- Association between persistent stress and production of excess cortisol leading to changes in the brain
- Actinogen's studies demonstrate cortisol inhibition and cognitive enhancement with Xanamem in human trials
- ✓ Further, recent clinical results confirm that Xanamem works as designed, to penetrate the brain in concentrations that adequately inhibit the activity of the 11β-HSD1 enzyme



Solution Valuable FXS market opportunity

While FXS is a rare disease, anxiety, sleep, and behavioural symptoms in FXS represent substantial commercial opportunities

Target population

Anxiety, sleep, and behavioural problems in FXS adolescents

Prevalence

Approx. 1 in 2500-4000 males and 1 in 7000-8000 females (averages to 1/4500)

Substantial market opportunity¹

~US\$250m

With 14.4% compound annual growth



Clinical development underpinned by strategic benefits

Xanamem in FXS - attractive regulatory, development, and commercial benefits through potential increased speed to market, reduced costs, and enhanced competitive protection

Benefits provided by Orphan Drug and Rare Paediatric Disease Designation^{1,2,3}



Clinical trials for rare diseases **typically enrol fewer patients**, potentially **decreasing costs and shortening development timelines**



Regulatory exclusivity / competitive protection, with extended period of exclusivity in majority of key markets, including USA, Europe and Japan



Increased speed to market from priority review², with potential to receive a second, transferable, **Priority Review Voucher (PRV)**³ from the FDA (applicable to other indications / drugs or can be sold)



Direct commercial incentives, including tax credits, potential sale of second PRV (approx. US\$130m)³



Data generated for FXS could be leveraged for other indications, potentially decreasing the time to market for the AD indication; **also presents a significant potential upside with FXS-related conditions (e.g. Autism Spectrum Disorder)**



1. FXS is an orphan disease, whose rarity means that there is potential for novel therapeutics targeting FXS to be granted Orphan Drug Designation; leading to regulatory, development and commercial incentives for drug developers.

2. In the USA, developers of orphan drugs for paediatric indications that have been granted a Rare Paediatric Disease Designation may apply for a Rare Paediatric Disease priority review voucher (PRV) from the FDA.

Phase II clinical trial

XanaFX: A Phase II trial to demonstrate the safety and efficacy of Xanamem on anxiety, sleep, and behavioural problems in adolescent males with Fragile X syndrome

Key upcoming milestones

Clinical trial design

| Study design | Phase II proof-of-concept study | Planned FXS clinical trial to |
|------------------------|--|---|
| | Double-blind, placebo-controlled Investigator-Initiated Trial, conducted at the Melbourne Children's Trials Centre at Murdoch Children's Research Institute and the Royal Children's Hospital Planning for ~40 adolescents (12-18yrs) with FXS | Expected completion within 12 months ¹ Trial funded, with grant applications submitted to |
| Primary endpoints | Safety and tolerability assessments of Xanamem in this population | assist with funding |
| Secondary endpoints | Efficacy assessment - improvement in anxiety, sleep, behavioural problems, communication, socialisation, and daily living skills | |



Outlook



Next steps and key catalysts

Plans for key clinical trials, expected to commence in 1H CY21

□ Finalise optimal study parameters and trial protocols (4Q CY20)

- Apply for FXS Orphan Drug and Rare Paediatric Disease
 Designation
- □ Receive regulatory approval and commence next phase of clinical trials (1H CY21)
 - **XanaMIA MCI due to Alzheimer's disease**
 - □ XanaFX anxiety, sleep and behavioural problems in FXS
- **XanaFX study readout** (12 months from trial commencement)
- □ Submit further grant applications and explore potential funding opportunities with external partners, including for cognitive impairment in both schizophrenia and diabetes





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Appendix A: Corporate background

Corporate overview ASX:ACW

Actinogen is an ASX-listed biotech company focused on innovative approaches to treating cognitive impairment associated with neurological and metabolic diseases

Trading metrics

| Share price (12 October 2020) | A\$0.028 |
|-------------------------------|----------|
| No. of shares | 1,116.2m |
| Market cap. | A\$31.3m |
| Net cash | A\$5.0m |
| Enterprise Value | A\$26.3m |

Key shareholding metrics



Share price performance





Board of Directors

Commercially experienced and globally recognised leadership team with decades of experience in drug development and biotech investment



Dr. Geoff Brooke Chairman

- **30+ years experience** in the healthcare investment industry
- Founder and MD of Medvest Inc and GBS Venture Partners
- Significant expertise in biotech: development strategy, capital raising and investments
- MBBS (University of Melbourne); MBA (IMEDE, Switzerland)



tinoqen



- 30+ years experience in healthcare, biotech and pharmaceutical industries
- Formerly senior international roles at Pfizer; Director at the Westmead Institute of Medical Research
- Involved in clinical development and commercialisation of Aricept[™]
- MBBCh (University of Witwatersrand); FFPM; MBA (Macquarie); GAICD





- 25+ years experience in biotech investment and drug development
- Board member of Cancer Therapeutics, Symbio and Biomedvic; Former Senior VP and CMO at Amgen
- Global responsibility for Amgen's drug development in all therapeutic areas

SymBio Pharmaceuticals Limited

Cancer Therapeutics CRC

 MBBS (Monash University); PhD (Walter and Eliza Hall Institute); FRACP; MAICD
 SymBio



Dr. George Morstyn Non-executive director



Mr. Malcolm McComas

Non-executive director

- 25+ years experience in the financial services industry
- Chairman of Pharmaxis and Fitzroy River Corporation; previously senior leadership roles in investment banking
- Extensive experience in corporate finance, M&A, debt and equity funding transactions across multiple sectors
- BEc, LLB (Monash University); FAICD; SF Fin



Advisory Boards

World-leading, premier academics involved in the development of Xanamem

Xanamem Clinical Advisory Board

Positions Xanamem at the forefront of drug development

Scientific Advisory Board

Combining deep understanding of endocrinology, 11β-HSD1 and drug discovery





IP protection

Actinogen maintains a broad composition of matter patent estate, with key patents granted in all major target markets, and new patent applications filed or in development

Patent overview



>90% of the global Alzheimer's disease and FXS markets

- Actinogen's patent portfolio **covers a broad range of neurological and metabolic diseases** including Alzheimer's disease
- Xanamem patents granted in key markets that account for over 90% of the global pharmaceuticals market
- Additional patents and patent extensions being actively prosecuted



Appendix B: Other clinical development opportunities

Occupitive impairment associated with schizophrenia

Cognitive impairment can be a debilitating feature of schizophrenia, with no targeted treatments available representing a significant unmet medical need

| Schizophenia | Schizophrenia is a complex and chronic mental health disorder that has increasingly been recognized as a cluster of different disorders | |
|---|--|--|
| Cognitive impairment in schizophrenia | Cognitive impairment is one of the most debilitating negative symptoms in schizophrenia, affecting ~75% of patients¹ Associated with poor treatment outcomes and patient reintegration into society - a major issue with ongoing patient management Potentially a side-effect of current anti-psychotic therapy (used to treat schizophrenia positive symptoms) | |
| Scientific rationale | Good scientific rationale for cortisol as a therapeutic target | |



Cognitive impairment associated with diabetes

Diabetics are at increased risk of developing cognitive impairment and Alzheimer's disease

| At-risk population | Elderly diabetics have double the risk of developing cognitive impairment and dementia over a non-diabetic population Diabetics often present with chronically raised cortisol, a risk factor for developing Alzheimer's disease | 100 |
|-------------------------|---|-----|
| High Prevalence | The American Diabetes Association currently estimates 14.3 million diabetics >65yrs (26.8% of the senior population) in the US¹ | |
| Scientific rationale | Clinical trial (Sandeep, 2004²; Edinburgh) in this population demonstrated a pro-cognitive effect of 11β-HSD1 inhibition Pro-cognitive efficacy of Xanamem 20mg daily demonstrated in healthy elderly volunteers in XanaHES, some of which had T2DM³ | |

Actinogen evaluating feasibility of new study, given strong likelihood of successfully demonstrating a similar pro-cognitive effect (seen in XanaHES) of Xanamem in an elderly diabetic population

