



## ASX ANNOUNCEMENT

### Actinogen CEO presents in 'Drug Developers - Finding the Next Neuren Part 2' session at the 2023 Bioshares Biotech Summit, Hobart

Sydney, 25 July 2023. Actinogen Medical ASX: ACW ("ACW" or "the Company") is pleased to announce that its Chief Executive Officer and Managing Director, Dr Steven Gourlay, will present at the **2023 Annual Bioshares Biotech Summit** in Hobart, Australia today.

Dr Gourlay's presentation is titled ***First-in-class/best-in-class Phase 2 oral drug candidate for Alzheimer's Disease & Depression***. It provides an overview of Actinogen, the Xanamem<sup>®</sup> therapeutic rationale, validation of the program from the positive results of four clinical trials, and upcoming catalyst points in the Company's clinical development program.

The presentation slides are attached to this announcement.

ENDS

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***Announcement authorised by the Board of Directors of Actinogen Medical***

#### About Actinogen Medical

Actinogen Medical (ACW) is an ASX-listed, biotechnology company developing a novel therapy for neurological and neuropsychiatric diseases associated with dysregulated brain cortisol. There is a strong association between cortisol and detrimental changes in the brain, affecting cognitive function, harm to brain cells and long-term cognitive health.

Cognitive function means how a person understands, remembers and thinks clearly. Cognitive functions include memory, attention, reasoning, awareness and decision-making.

© Xanamem is a registered trademark of Actinogen Medical Limited

Actinogen is currently developing its lead compound, Xanamem,<sup>®</sup> as a promising new therapy for Alzheimer's Disease and Depression and hopes to study Fragile X Syndrome and other neurological and psychiatric diseases in the future. Reducing cortisol inside brain cells could have a positive impact in these and many other diseases. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

#### About Xanamem

Xanamem's novel mechanism of action is to block the production of cortisol inside cells through the inhibition of the 11 $\beta$ -HSD1 enzyme in the brain. Xanamem is designed to get into the brain after it is absorbed in the intestines upon swallowing.

Chronically elevated cortisol is associated with cognitive decline in Alzheimer's Disease and excess cortisol is known to be toxic to brain cells. Cognitive impairment is also a feature in Depression and many other diseases. Cortisol itself is also associated with depressive symptoms and when targeted via other mechanisms has shown some promise in prior clinical trials.

The Company has studied 11 $\beta$ -HSD1 inhibition by Xanamem in more than 300 volunteers and patients, so far finding a statistically significant improvement in working memory and attention, compared with placebo, in healthy, older volunteers in two consecutive trials and clinically significant improvements in functional and cognitive ability in patients with biomarker-positive mild AD. Previously, high levels of target engagement in the brain with doses as low as 5 mg daily have been demonstrated in a human PET imaging study. A series of Phase 2 studies in multiple diseases is being conducted to further confirm and characterize Xanamem's therapeutic potential.

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<sup>®</sup> is a trademark of Actinogen Medical.

#### Disclaimer

This announcement and attachments may contain certain "forward-looking statements" that are not historical facts; are based on subjective estimates, assumptions and qualifications; and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements should be considered "at-risk statements" - not to be relied upon as they are subject to known and unknown risks, uncertainties and other factors (such as significant business, economic and competitive uncertainties / contingencies and regulatory and clinical development risks, future outcomes and uncertainties) that may lead to actual results being materially different from any forward looking statement or the performance expressed or implied by such forward looking statements. You are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Actinogen Medical does not undertake any obligation to revise such statements to reflect events or any change in circumstances arising after the date hereof, or to reflect the occurrence of or non-occurrence of any future events. Past performance is not a reliable indicator of future performance. Actinogen Medical does not make any guarantee, representation or warranty as to the likelihood of achievement or reasonableness of any forward-looking statements and there can be no assurance or guarantee that any forward-looking statements will be realised.

**ACTINOGEN MEDICAL ENCOURAGES ALL CURRENT INVESTORS TO GO PAPERLESS BY REGISTERING THEIR DETAILS WITH THE DESIGNATED REGISTRY SERVICE PROVIDER, AUTOMIC GROUP.**

<sup>®</sup> Xanamem is a registered trademark of Actinogen Medical Limited

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**Actinogen**

# First-in-class/best-in-class Phase 2 oral drug candidate for Alzheimer's Disease & Depression

Four trials validate Xanamem<sup>®</sup> as a novel, differentiated, safe and efficacious candidate

**Corporate Presentation July, 2023**

**Presented at the Bioshares Biotech Summit July 25, 2023**

**Non-confidential  
Dr Steven G Gourlay, CEO**

# Disclaimer

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# The answers to Alzheimer's Disease are starting to emerge....



# Actinogen (ACW.AX) & Xanamem Summary

- **Xanamem is an oral treatment with rapid onset of clinical activity**
- **Cortisol target validation in animal models and by cognitive benefit shown in multiple controlled trials of Xanamem**
- **Excellent safety profile, low drug interaction potential**
- **Commercial tablet formulation developed**
- **Intellectual property protection including composition of matter**
- **Experienced team based in Australia, US and UK**

# Actinogen (ACW.AX) Trials Underway

**Phase 2a proof-of-concept trial in Depression/Cognitive Impairment**

**n=160, results H1 2024**

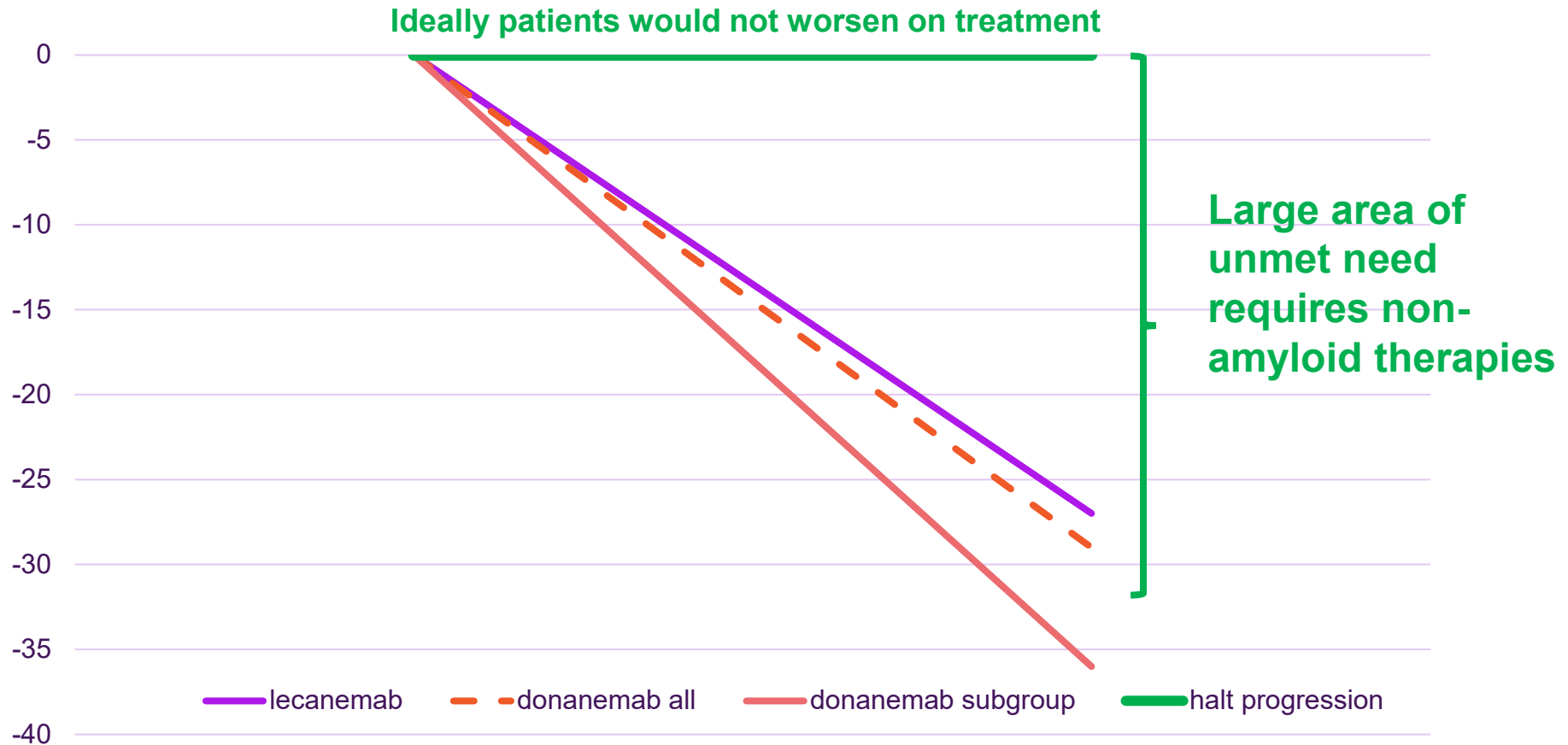
**Phase 2b confirmatory trial in mild-moderate AD**

**n=330, results H2 2025 (interim analysis early 2025)**

# Newer anti-amyloid antibodies shown to slow but not halt progression of AD<sup>1</sup>

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% worsening CDR-SB<sup>2</sup> over 18 months



**Drugs targeting other mechanisms like Xanamem are needed**

1. Lecanemab and donanemab are anti-amyloid antibodies given as an intravenous infusion every 2 or 4 weeks (van Dyck et al. 2022; DOI: 10.1056/NEJMoa2212948 n=1795 and Sims

JR at al. *JAMA*. Published online July 17, 2023. doi:10.1001/jama.2023.13239

2. CDR-SB is an 18-point scale measuring functional status and was the primary endpoint for lecanemab and a secondary endpoint for donanemab



# Newer amyloid antibodies and oral Xanamem have multiple, positive cognitive trials data<sup>1</sup>

Actinogen  
Oral Xanamem

- Safely targets **brain tissue cortisol**
- 2 trials: improved attention & working memory
- 1 trial: trends to reduce AD progression, improve cognition
- Low drug interaction potential – good combination candidate

Eisai-Biogen  
i.v. infusion of lecanemab  
every 2 weeks

- Approved on ability to reduce **brain amyloid**
- Potential to cause brain swelling and bleeding
- 2 trials reduced progression modestly
- Will need to be combined with other therapies

Lilly  
i.v. infusion of donanemab  
every 4 weeks until amyloid  
cleared

- Full approval expected ~8 months, reduces **brain amyloid**
- Higher rates of brain swelling and bleeding, 3 deaths reported
- 2 trials reduced progression modestly
- Will need to be combined with other therapies

<sup>1</sup> Companies claiming efficacy based on uncontrolled data, biomarkers or imaging not included in this comparison

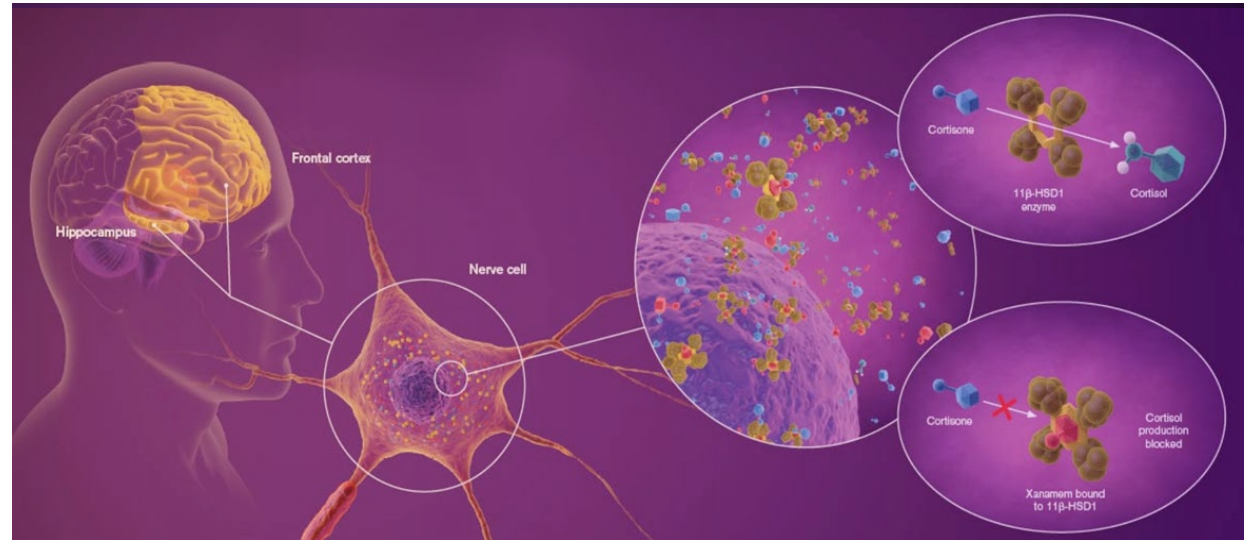
# Xanamem: oral, low-dose, once-a-day treatment with a unique, non-amyloid/tau mechanism

Mouse experimental studies & clinical trials validate cortisol target for treatment of AD<sup>1-4</sup>

**Brain penetrant** 11 $\beta$ -HSD1 small molecule enzyme inhibitor **reduces cortisol inside brain cells**<sup>3,4</sup> - modulating signalling pathways and underlying disease processes

Potential to be:

- Rapidly **cognitive enhancing**
- **Disease-modifying** (slow or halt progression) in AD<sup>1,3</sup>
- **Anti-depressant**

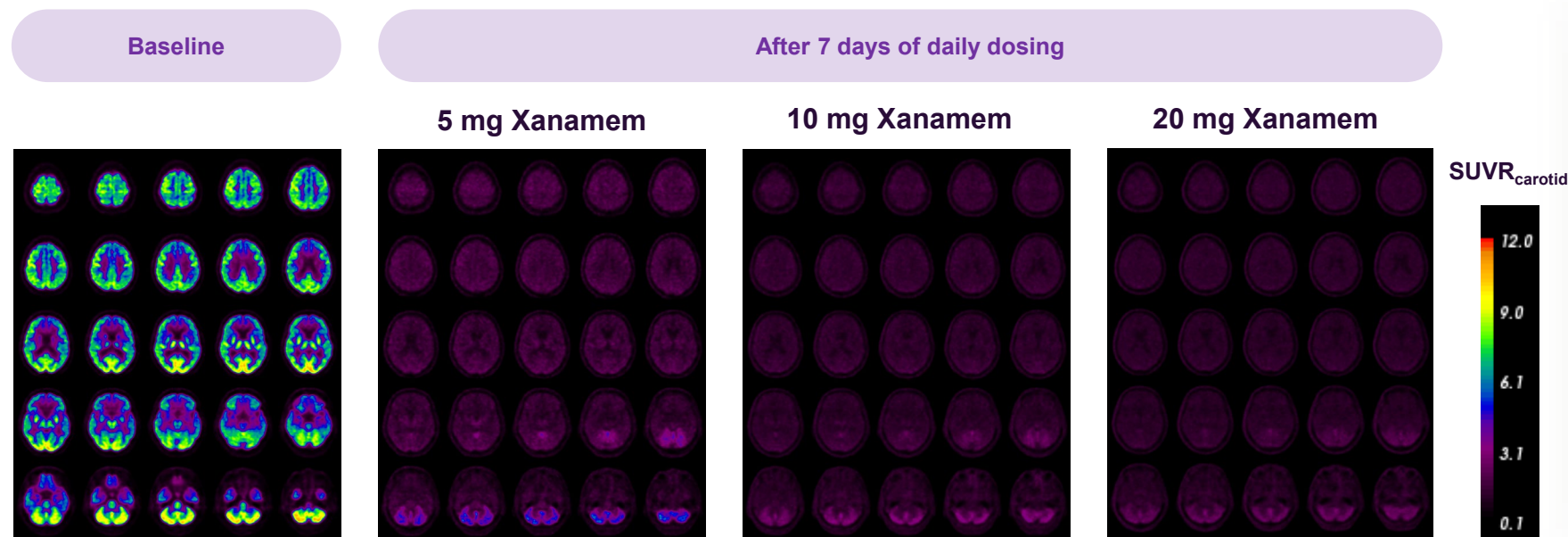


1. Sooy et al. 2015 showing effects on amyloid plaque reduction in an aged mouse model after 28 days associated with increases in insulin degrading enzyme – at 13 month cognitive protection was independent of continued amyloid deposition; 2. Popoli et al. 2011 microglial cell modulation in rats, effects on glutamate, cannabinoid and other signalling pathways; 3. Hilt, D. Oral symposium AD/PD International Conference 2023; Actinogen website: [Actinogen – News](#); 4. based on human PET scan evidence (data on file), Webster et al. 2017 Selection and early clinical evaluation of the brain-penetrant 11 $\beta$ -hydroxysteroid dehydrogenase type 1 (11 $\beta$ -HSD1) inhibitor UE2343 (Xanamem™)

# PET data shows full target engagement in the brain at low doses

Previous enzyme inhibitors<sup>1</sup> have not achieved adequate brain concentrations

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PET data<sup>2</sup> demonstrates that Xanamem extensively binds to the 11 $\beta$ -HSD1 enzyme throughout the brain, with high post-treatment effects (absence of colour) after 7 days at all doses, slightly less at a 5 mg dose.

This is consistent with full hormonal pharmacodynamic activity seen with 10 mg in clinical trials. 5 and 10 mg show excellent clinical tolerability and safety.

1. ABT-384 was claimed to have brain penetrant ability based on likely hepatic effects on deuterated cortisol (Katz et al. 2013), negative 12-week AD trial (Marek et al. 2014)

2. Study population consisted of ~50% healthy older subjects who were cognitively normal and ~50% with Alzheimer's disease. Subjects dosed for seven days.

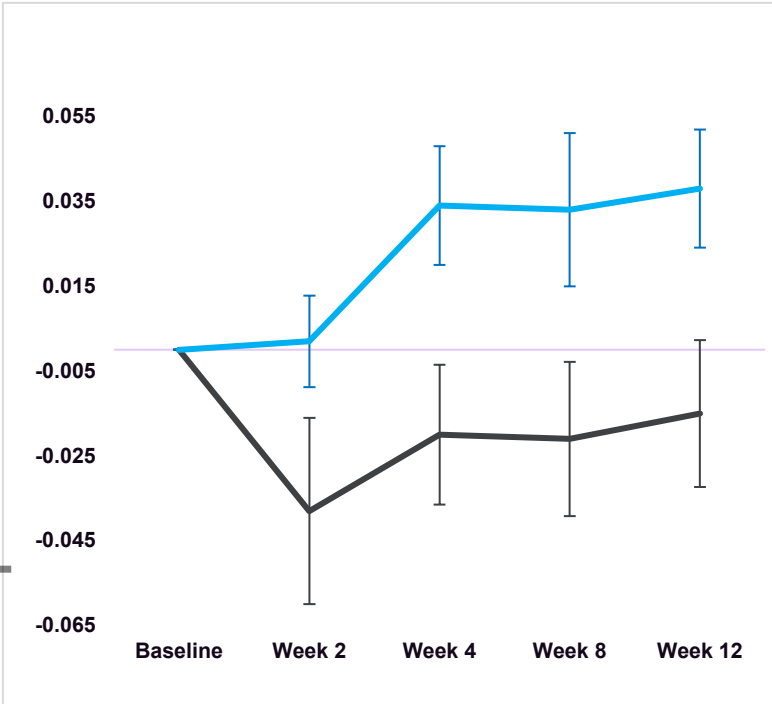
Baseline: Mean of baseline scans of patients in that dose group; After dose: Mean of post-dosing (7 days) scans in that dose group.

# Attention/Working Memory improved by 4 weeks\*

Cogstate computerized testing in cognitively normal older, 20 mg daily vs. placebo

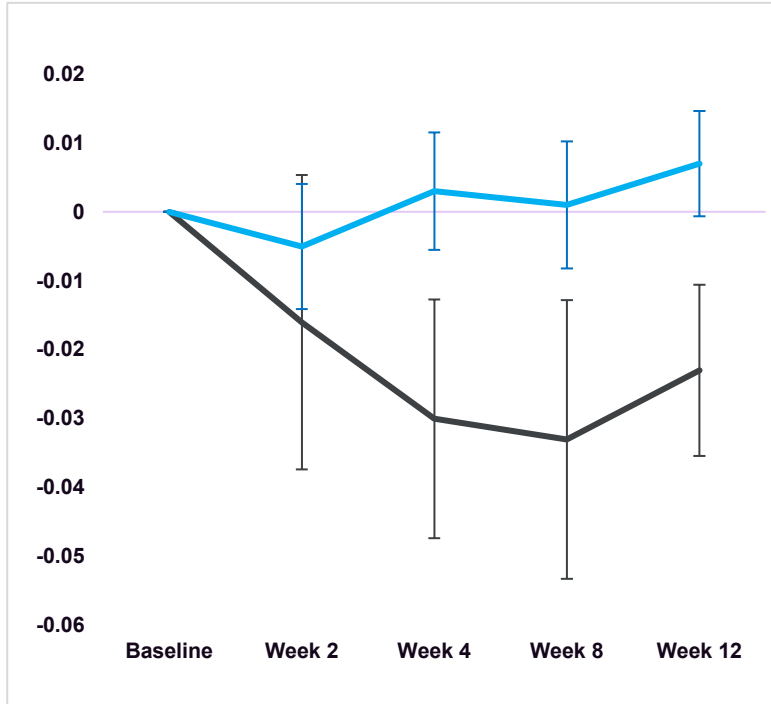
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One Back Test (working memory)



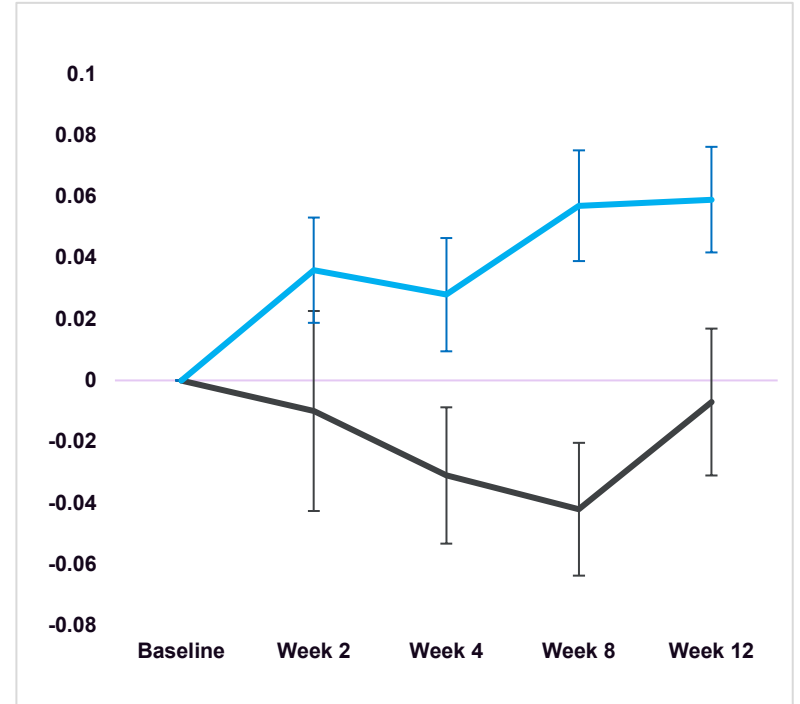
P<0.01

Identification Test (visual attention)



P=0.05

Detection Test (psychomotor function)



P=0.09

Improved performance ↑

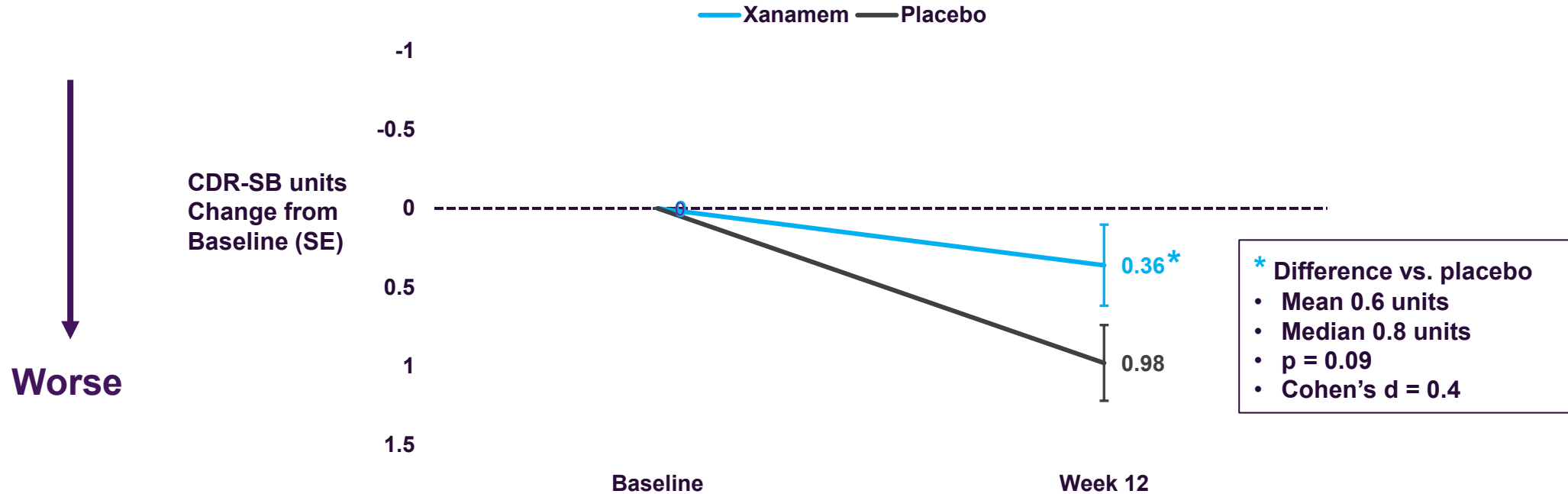
\* XanaHES trial, n = 30 Xanemem 20mg vs n = 12 Placebo; no treatment effects on three other tests of episodic memory (Actinogen data on file)

# Xanamem slows the rate of CDR-SB (functional) decline in mild AD\*



Patients with elevated plasma pTau181 indicating progressive, amyloid-positive disease (n=34)

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Extrapolated to 18 months effect size would be more than 3 points

\* Patients with a pre-treatment plasma pTau181 level greater than the pre-specified median of 6.74 pg/mL to indicate AD pathology and likelihood of progressive disease; similar effect size for pTau >10.2 pg/mL cutoff; effect size 8-10 times greater than 0.4-0.45 reported for lecanemab (USPI Leqembi 2023 & van Dyck et al. 2022; DOI: 10.1056/NEJMoa2212948) if extrapolated to 18 months

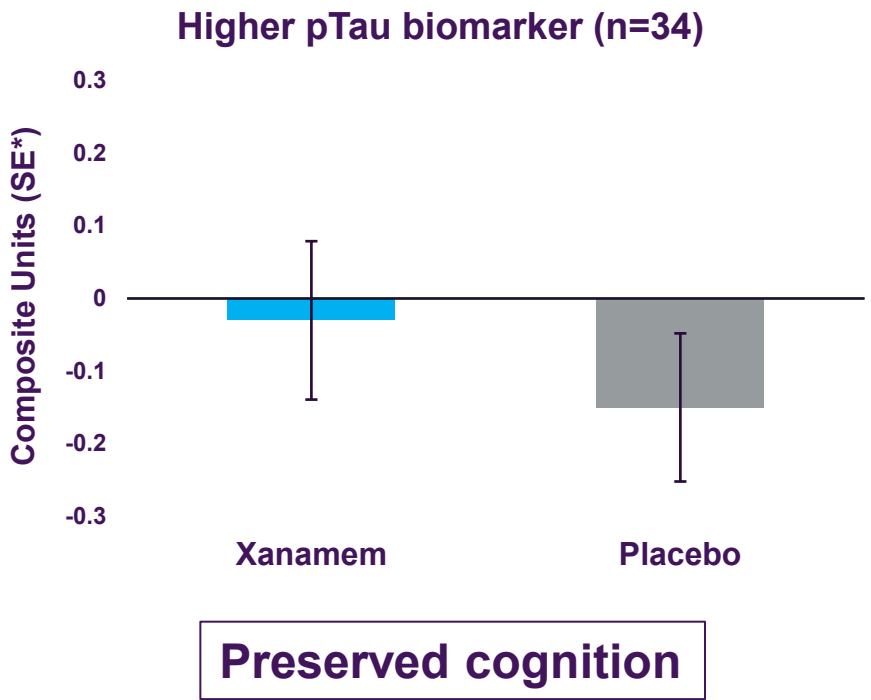
# Cognitive composite scores suggest potential clinical benefit across dementia patient sub-types\*



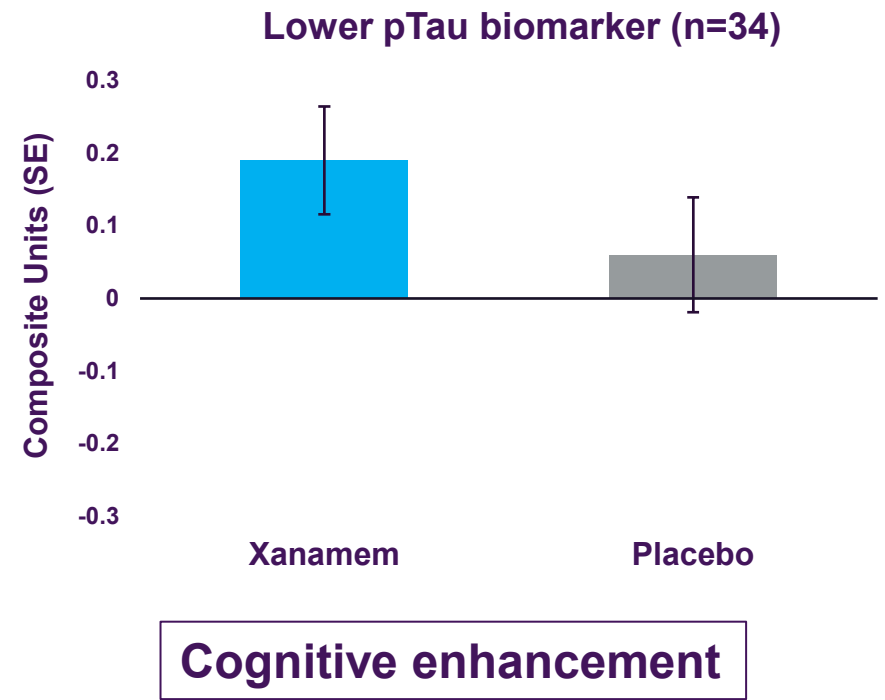
Positive trends in both high and low plasma pTau biomarker groups

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Worse



Preserved cognition



Cognitive enhancement

Consistent with Xanamem activity as a cognitive enhancer & disease-modifier

\* Post hoc analysis of composite of word recall & recognition, CFT & COWAT tests (p=NS), error bars show Standard Error of the Mean; low pTau patients less likely to have amyloid-positive disease, results consistent with volunteer data

# Well-demonstrated, excellent safety profile



## No emerging safety signals

TEAE term ACW0002*	Xanamem (n=91)	Placebo (n=94)	Total (n=185)
Headache	5 (5.5%)	2 (2.1%)	7 (3.8%)
Dizziness	4 (4.4%)	3 (3.2%)	7 (3.8%)
Diarrhea	1 (1.1%)	4 (4.3%)	5 (2.7%)
Fatigue	3 (3.3%)	1 (1.1%)	4 (2.2%)
Nerve conduction abnormal	1 (1.1%)	3 (3.2%)	4 (2.2%)
Somnolence	1 (1.1%)	3 (3.2%)	4 (2.2%)
Decreased appetite	2 (2.2%)	0 (0.0%)	2 (1.1%)

\* TEAEs reported by more than one patient in any group in the largest clinical study to date

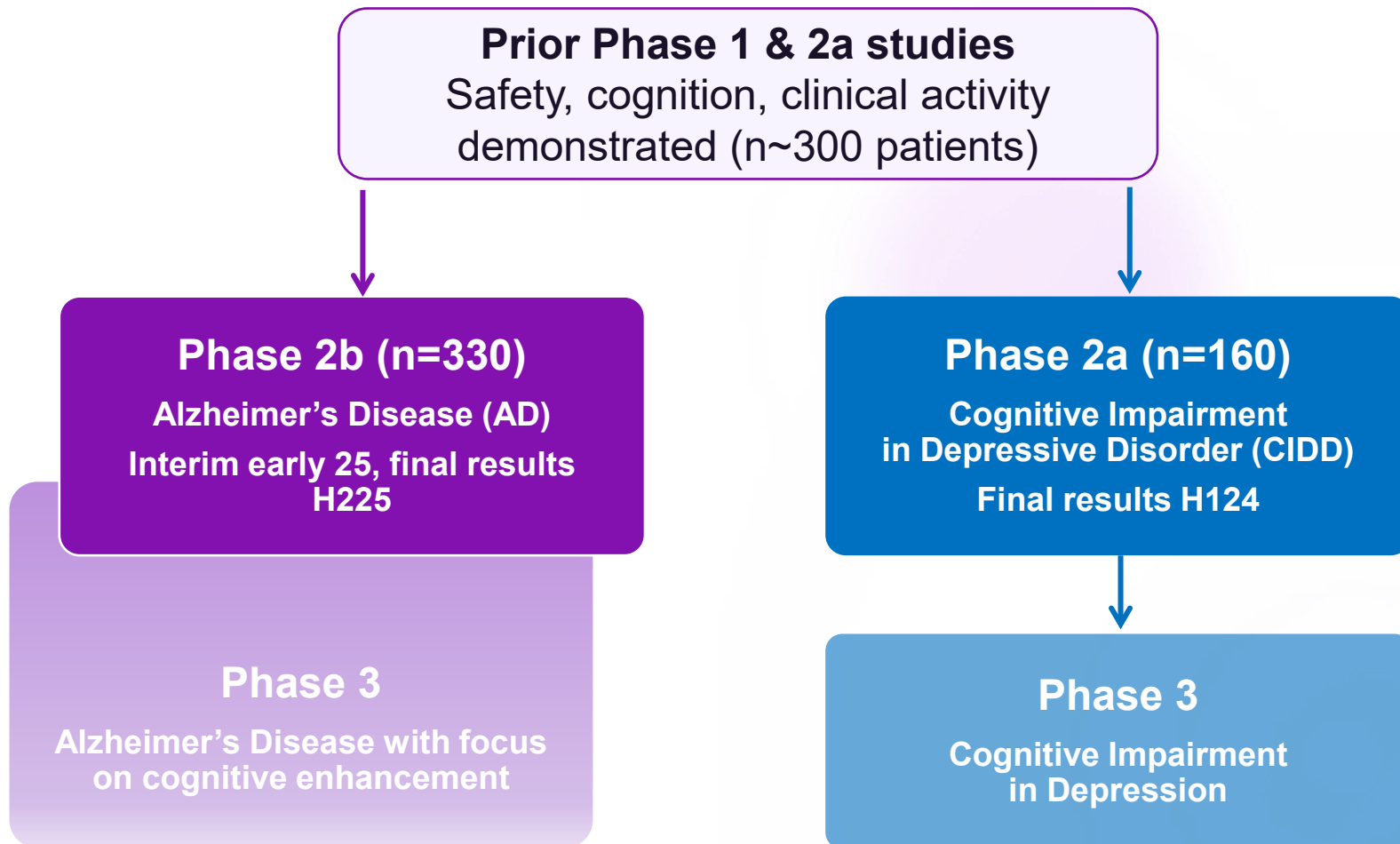
✓ No treatment-related Serious Adverse Events in clinical program

# Xanamem AD & Depression programs



Building on three independent Phase 1 and 2 studies showing safety and procognitive activity

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# Upcoming catalysts

## 2023

- Phase 2b trial in AD to commence
- Results of FDA End-of-Phase 2, EMA, UK regulatory interactions
- Peer-reviewed publications
- CTAD (AD) and other presentations

## 2024

- Depression Phase 2a trial results H1
- Phase 2b AD interim analysis late H2 / early 2025

## 2025

- Commence Depression Phase 3
- Phase 2b AD results H2

# Timetable for trial results for oral AD therapies



Year	Drug or company	Target	Steve's probability of success
2023	deferiprone	Iron	Low
	TauRx	Tau*	Low
	NE3107	ERK1/2	Low
	simufilam	Filamen A*	Low-Medium
<b>2023</b>	<b>varoglutamstat</b>	<b>pglu-A<math>\beta</math>/QC*</b>	<b>Medium</b>
	CT1812	Sigma-2*	Low
2024	Valiltramprostate	Amyloid form.*	Low-Medium
	LY337268	OGA*	Low
<b>2025</b>	<b>Xanamem</b>	<b>cortisol</b>	<b>Medium-High</b>
<b>2026</b>	<b>semaglutide</b>	<b>GLP-1</b>	<b>Medium</b>

\* Amyloid or tau protein-related mechanisms

**Xanamem is one of just a few credible oral drug candidates in development**

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# Actinogen summary

Actinogen Medical (ASX:ACW) is developing a novel oral treatment with rapid onset of clinical activity to improve cognition, function and quality of life



**Attractive disease indications and rationale**

- ✓ **Strong cortisol rationale for treatment of multiple diseases:** early stages of Alzheimer's disease & other dementias, depression & related cognitive impairment; cognitive impairment in schizophrenia; many others



**Favourable pharmaceutical properties**

- ✓ Demonstrated target engagement in brain and HPA axis<sup>1</sup> in human trials
- ✓ **Low dose and cost of goods, ≤10mg**
- ✓ **Low drug-drug interaction potential** suitable for combination therapy



**Substantial clinical data**

- ✓ **>300 subjects or patients safely treated**
- ✓ Cognitive enhancement **activity in three placebo-controlled trials**
- ✓ Positive Phase 2a data - **clinical benefit** in biomarker-positive AD patients



**Protected and funded**

- ✓ Molecule in-licensed from U Edinburgh in 2014 to ASX-listed shell co. (ACW.AX)
- ✓ Key patents in place<sup>2</sup> ~A\$100m funding for Xanamem program to date
- ✓ **Cash ~A\$12.2M (Mar 23), mkt cap. ~A\$70m, seeking development partners**



**High functioning semi-virtual company model**

- ✓ Core team of 15 highly skilled employees based in Australia & US
- ✓ Leveraging senior consultants in various fields in Australia, Asia, UK and USA
- ✓ **Australian-based projects gain 48% as R&D cash rebate**

1. Hypothalamic-Pituitary-Adrenal axis (body's system to regulate blood levels of cortisol)

2. Composition of matter to 2031 plus 5-year extension in most countries, new patents published and in process including use and manufacturing

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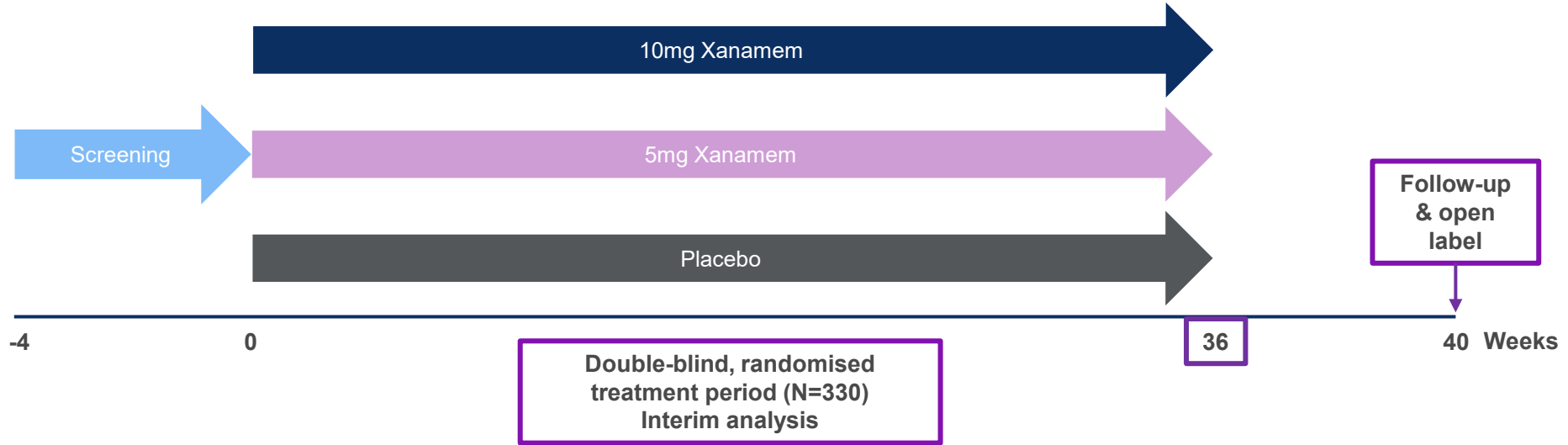
# Appendix



# XanaMIA Phase 2b trial in Alzheimer's Disease

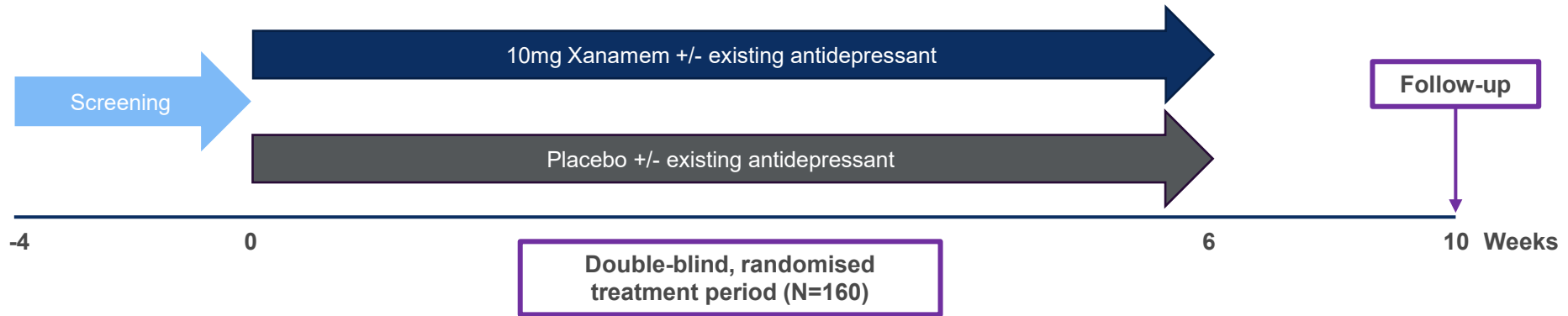
## Matching patients and endpoints used in the positive Ph 2a analysis

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Key inclusion/exclusion criteria	Primary Endpoints	Key Secondary Endpoints	Key Implementation Features
<ul style="list-style-type: none"> <li>Clinical diagnosis of <b>mild to moderate dementia</b> due to AD (NIA-AA, MMSE 18-26)</li> <li>Blood <b>p-tau181</b> to confirm progressive AD diagnosis</li> <li>Cognitive impairment test</li> </ul>	<ul style="list-style-type: none"> <li><b>Cognitive Test Battery (cognitive measures)</b></li> </ul>	<ul style="list-style-type: none"> <li><b>CDR-SB (functional measure)</b></li> <li><b>Amsterdam Activity of Daily Living scale</b></li> <li>Executive Function &amp; Episodic Memory Function Composites</li> <li>Care Giver questionnaire / Patient Global Improvement</li> </ul>	<ul style="list-style-type: none"> <li><b>Global</b> trial sites including US, AU, Asia, EU and other</li> <li><b>Actinogen “hands-on” operational model</b></li> <li><b>FPI H2 CY23</b></li> <li><b>Interim analysis late CY24/25</b></li> <li><b>Final results CY25</b></li> </ul>

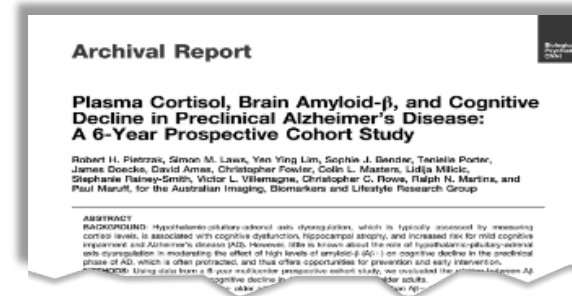
# XanaCIDD proof-of-concept trial in Depression



Key inclusion/exclusion criteria	Primary Endpoints	Key Secondary Endpoints	Key Implementation Features
<ul style="list-style-type: none"> <li>Primary diagnosis of <b>MDD</b></li> <li><b>Persistent depressive symptoms despite existing therapy</b></li> <li><b>Cognitive impairment</b> relative to demographic norms</li> </ul>	<ul style="list-style-type: none"> <li><b>Cogstate Cognitive Test Battery Attentional Composite</b> (attention and working memory)</li> </ul>	<ul style="list-style-type: none"> <li>Montgomery-Åsberg Depression Rating Scale (<b>MADRS</b>)</li> <li>Executive Function Cognitive Composite</li> <li>Memory Function Cognitive Composite</li> </ul>	<ul style="list-style-type: none"> <li><b>Australia &amp; UK</b> trial sites</li> <li><b>Actinogen “hands-on” operational model</b></li> <li>First patient treated Dec 22</li> <li><b>Final Results H1 CY24</b></li> </ul>

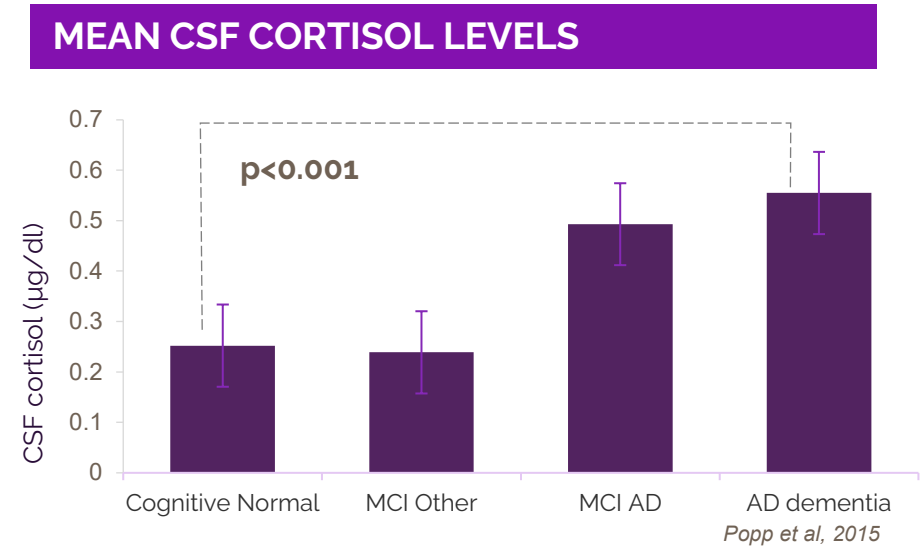
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# Many studies support the association between elevated cortisol and AD development and progression<sup>1-9</sup>



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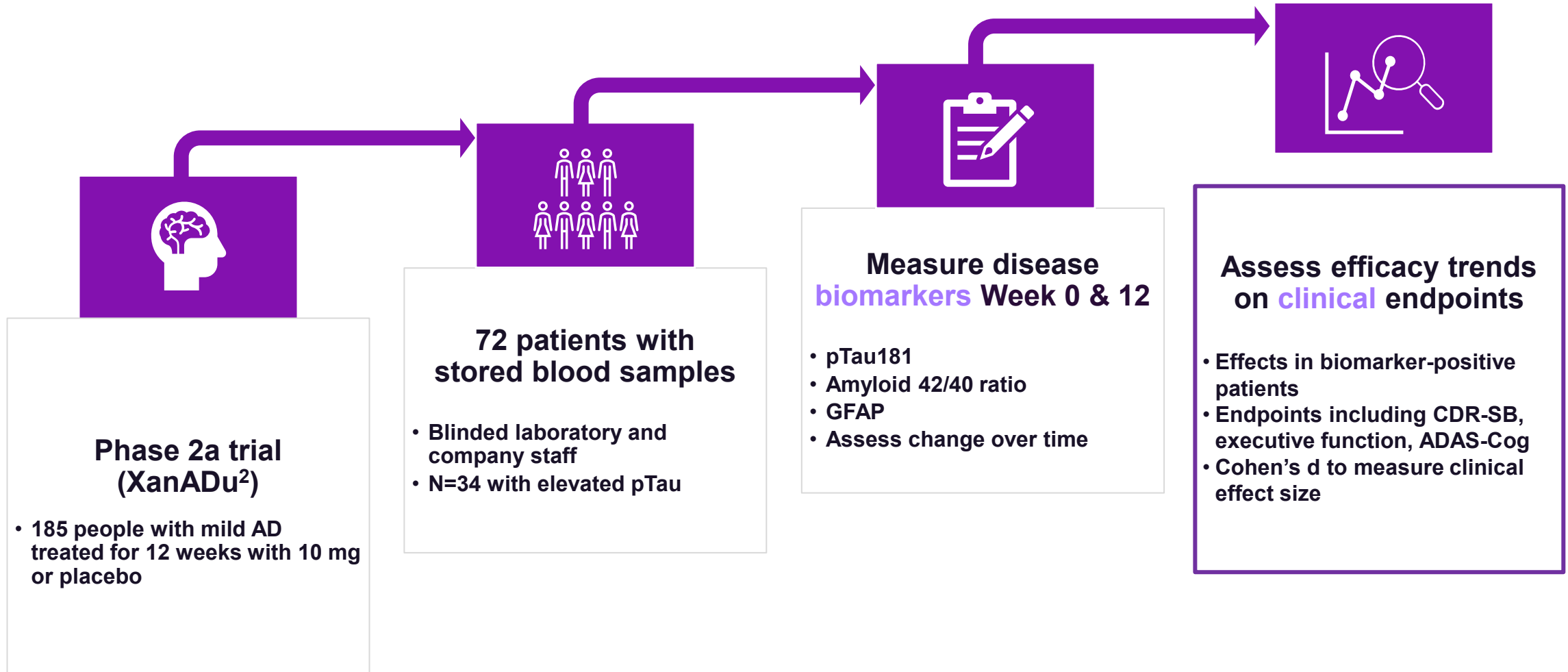
- Higher cortisol levels in human aging are associated with hippocampal atrophy<sup>1,2</sup>
- Chronic corticosteroid medication is associated with hippocampal and amygdalar atrophy and cognitive impairment<sup>3</sup>
- Higher plasma cortisol leads to a much greater risk of developing AD<sup>4,5</sup> and accelerated effect of Aβ+ on decline in global cognition, episodic memory, and attention<sup>6,7</sup>
- Higher CSF cortisol levels in AD patients are associated with more rapid clinical worsening and cognitive impairment<sup>3</sup>
- Individuals at high risk of AD due to the APOE-ε4 allele have higher CSF cortisol<sup>9</sup> and lecanemab showed no treatment effect in ε4/ε4 patients<sup>10</sup>



# Methods for double-blind, prospective assessment of biomarker-positive mild AD patients in Phase 2a<sup>1</sup>

## A simulation of the Phase 2b XanaMIA trial

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1. Used a pre-specified protocol and statistical analysis plan, blinded laboratory and company personnel  
2. Prior phase 2a trial completed in 2019 <https://clinicaltrials.gov/ct2/show/results/NCT02727699?term=actinogen&draw=2&rank=3>



# Experienced Leadership and Management



Extensive drug development and commercial experience, two new key appointments in 2023

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## Experienced Board of Directors...



**Dr. Geoff Brooke**  
Chairman  
MBBS; MBA



- 30+ years experience in the healthcare investment industry
- Founder and MD of Medvest Inc and GBS Ventures, Chairman of Cynata Therapeutics, Board Member of AcruX



**Dr. George Morstyn**  
Non-Executive Director  
MBBS; PhD; FRACP; MAICD



- 25+ years experience in biotech investment and drug development
- Board member of Cancer Therapeutics and Symbio



**Mr. Malcolm McComas**  
Non-Executive Director  
BEc, LLB; FAICD; SF Fin



- 25+ years experience in the financial services industry
- Chairman of Pharmaxis and Fitzroy River Corporation



**Dr. Nicki Vasquez**  
Non-Executive Director  
PhD



- 25+ years experience in biopharmaceutical discovery research and development
- Chief Portfolio Strategy & Alliance Officer at Sutro Biopharma

## ...with a talented management team in place



**Dr. Steven Gourlay**  
CEO & MD  
MBBS; FRACP; PhD; MBA



- 30+ years experience in development of novel therapeutics
- Former founding CMO at US-based Principia Biopharma Inc



**Jeff Carter**  
Chief Financial Officer  
B. Fin Admin; M. App. Fin; CA



**Tamara Miller**  
SVP Product Development  
M.Med Sci; BSc; MSc; PMP; CPPM



**Dana Hilt**  
Chief Medical Officer  
MD



**Cheryl Townsend**  
VP Clinical Operations  
RN, M Health Law



**Dr Christian Touli**  
Head of Business Development  
PhD; GAICD

See full team and bios at:  
<https://actinogen.com.au/about-us/>

# International Cognition Clinical Advisory Board



Preeminent global thought-leaders in clinical trials for assessment of cognition



**Prof. John Harrison**

Metis Cognition Ltd

- Expert psychologist with a special interest in cognition
- Chartered psychologist with two PhDs and author/co-author of more than 80 books and scientific articles
- Principal Consultant at Metis Cognition, which advises on selection and integration of cognitive testing into therapeutic development programs



**Dr Dana C. Hilt (CMO)**



- 25+ years of drug development experience, primarily of Central Nervous System (CNS) drugs
- Deep experience in Phases 1 to 4 drug development
- CMO at Frequency Therapeutics and has held senior management positions as Chief Medical Officer at various pharmaceutical companies



**Dr Christina Kurre Olsen**

ORPHA Z YME

- 20+ years research expertise in neuroscience, neuropsychopharmacology, CNS therapeutics and monoclonal antibody immunotherapy
- Strong hands-on knowledge across drug development value chain and a passion for cognition
- Medical Director at Orphazyme A/S



**Prof. Paul Maruff**



- Chief Innovation Officer at Cogstate Ltd
- Professor in Neuroscience at the Florey Institute of Neuroscience and in Psychology Monash University, Melbourne Australia
- Senior management committee of the Australian Imaging, Biomarkers and Lifestyle (AIBL) study of Alzheimer's Disease
- Involved in the development and approval of 13 new drugs that affect cognition including most recently esketamine for treatment resistant depression



**A/Prof Christopher Chen**



- Senior Clinician-Scientist, Associate Professor at the Departments of Pharmacology and Psychological Medicine, Yong Loo Lin School of Medicine, National University of Singapore, and Director of the Memory Aging and Cognition Centre, National University Healthcare System.
- Major research and clinical interests are in neuroimaging, molecular biology and treatment of stroke and dementia.
- President of the Asian Society Against Dementia, Secretary-Treasurer of the Asian & Oceanian Association of Neurology.

# International Scientific Advisory Boards



## Preeminent thought-leader academics involved in the development of Xanamem

### Alzheimer's Disease Clinical Advisory Board



**Prof. Craig Ritchie**

Chair



- World-leading authority on dementia; senior investigator on 30+ drug trials
- Chair of the Scottish Dementia Research Consortium; Professor of the Psychiatry of Ageing' Director of the Centre for Dementia Prevention (University of Edinburgh)



**Prof. Colin Masters**  
AO



- 35+ years research on Alzheimer's Disease and other neurodegenerative diseases
- Laureate Professor of Dementia Research and Head, Neurodegeneration Division at The Florey Institute (UniMelb)



**Prof. Jeffrey Cummings**



- World-renowned Alzheimer's researcher and leader of clinical trials
- MD, ScD; Founding Director of the Cleveland Clinic Lou Ruvo Center for Brain Health
- Recognised for his work through various awards

### Scientific Advisory Board



**Prof. Jonathan Seckl**



- Undertaken extensive research in endocrinology
- Senior VP at the university of Edinburgh; Chaired Panels for MRC, Innovate UK and Wellcome Trust
- MBBS UCL, PhD (London)



**Prof. Brian Walker**



- 20+ years research in the area of disease
- Extensive experience advising for pharmaceutical R&D
- Pro Vice Chancellor for Research Strategy & Resources at Newcastle University, UK



**Prof. Scott Webster**



- Chair of Medicines at the Centre of Cardiovascular Science, University of Edinburgh
- Former positions across both biotech and academia
- Founder and Chief Scientific Officer at Kynos Therapeutics

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