

XanADu:
A Phase II trial of
Xanamem™ in mild
Alzheimer's disease

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Actinogen
Medical

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Xanamem

- A novel, first in class, potent, orally bioavailable, brain-penetrant, 11 β HSD1 inhibitor
- Differentiated mechanism of action: blocking cortisol production in the brain
- Symptomatic and disease modifying effects *in vivo*
- Well-tolerated: acceptable clinical safety, toxicity and PK/PD profile
- Efficacious human brain concentrations
- Compelling data package: clinical safety, in vitro and in vivo mechanistic and efficacy data
- XanADu – phase II clinical study underway, dosing subjects with mild AD dementia in USA, UK, AU
- Planning for Phase II study in Diabetes Cognitive Impairment
- Composition of matter IP coverage ≥ 2031 , patents granted in most major markets



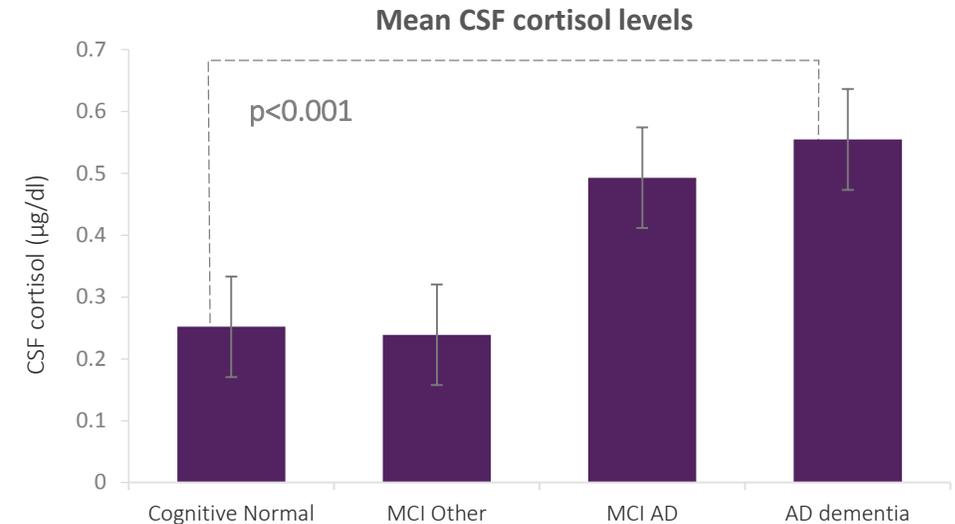
Cortisol: a validated biomarker and target for AD

Cortisol and Alzheimer's

- Recent independent studies support the association between cortisol and development and progression of Alzheimer's disease ¹⁻⁵
- Cognitive impairment in patients with neuroendocrine dysfunction ⁶⁻⁹
- Compelling evidence provided by the Australian Imaging, Biomarker & Lifestyle Study of Ageing (AIBL) study (2017) ⁵
 - subjects with higher plasma cortisol at much greater risk of developing AD
 - accelerated effect of A β + on decline in global cognition, episodic memory, and attention

Xanamem

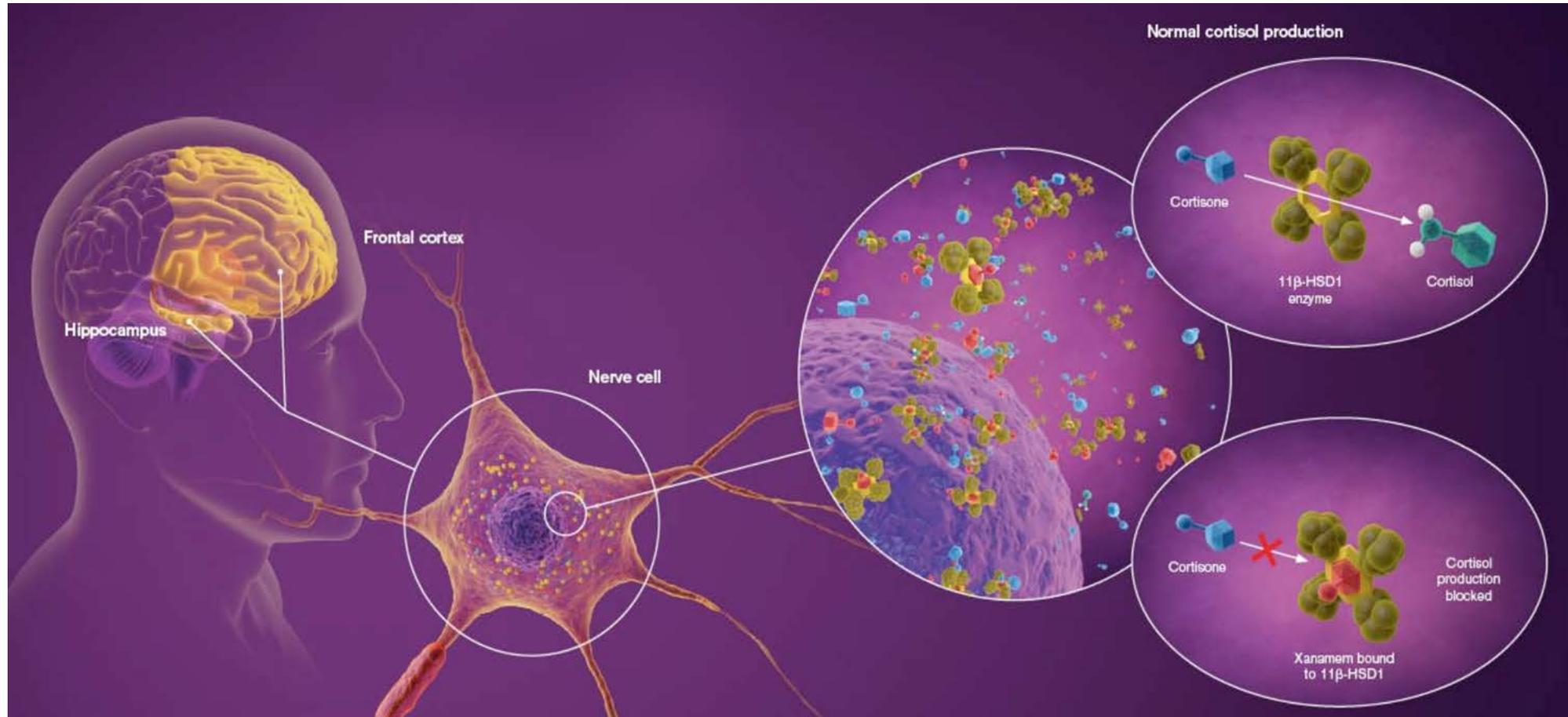
- Data presented at four major international medical congresses in 2016 – AAIC Toronto; CTAD San Diego; ICE Beijing; MMC Lisbon
- Pre-clinical and Phase I data published ¹⁰⁻¹¹



Popp et al, 2015

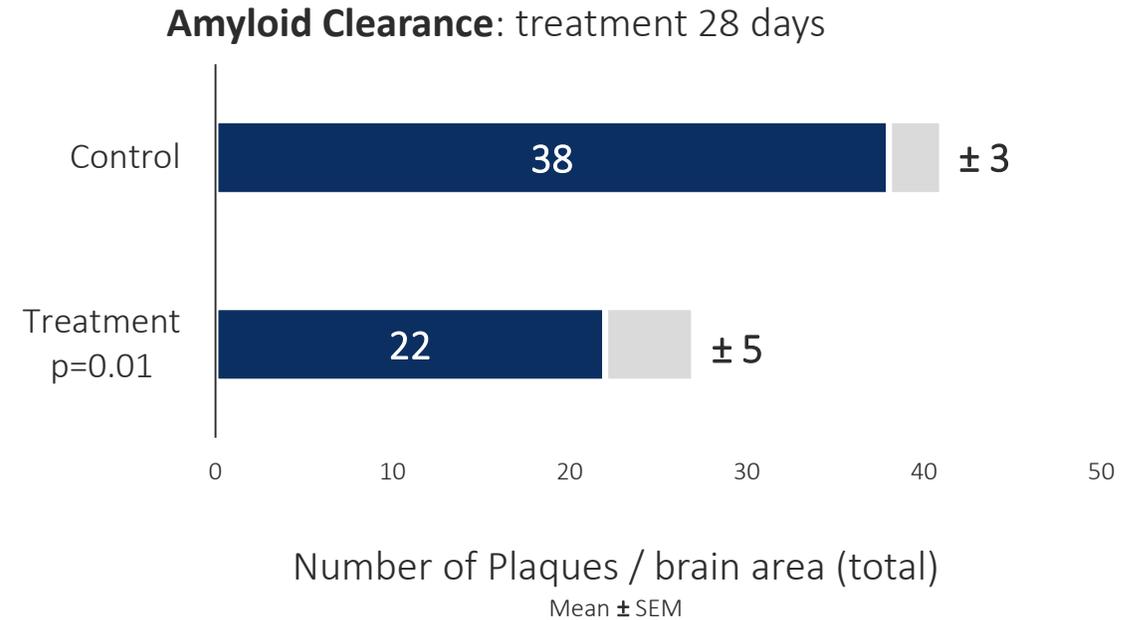
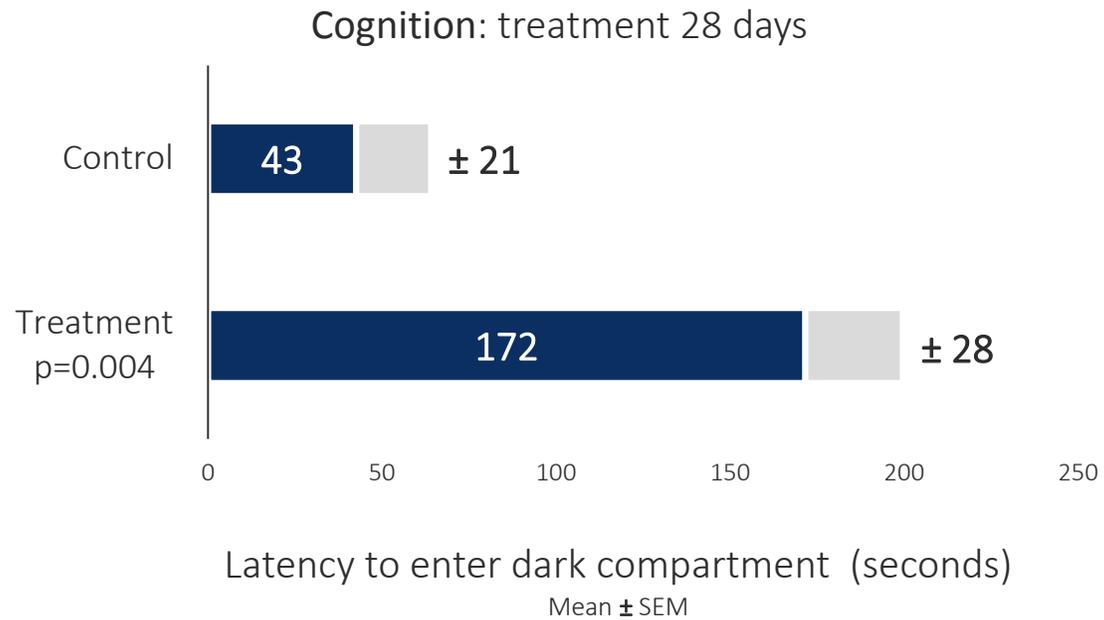
Mechanism of action

Xanamem binds to 11 β HSD1, reducing brain cortisol production



Xanamem

Symptomatic and disease modifying effects in mouse models



Significant improvement in cognition after only 28 days treatment, continuing out to 41 weeks

Xanadu Phase II trial

Phase II double blind, randomised, placebo-controlled study to assess the efficacy and safety of Xanamem in participants with mild Alzheimer's disease*

- 33 patients enrolled (end-Sept) and first patient has already completed study.
- All 20 study sites open and patients enrolled in USA, UK and Aus



Xanamem treatment course

12 weeks



174

Mild Alzheimer's patients



Xanamem 10mg daily
for 12 weeks vs placebo



Trial conducted at 20 sites in
AUS, USA and UK

Primary and secondary endpoints are standard and experimental cognitive outcome measures used in Alzheimer's research: ADASCog14, ADCOMs, CDR-SOB, MMSE, RAVLT, NTB-ED