Actinogen

Oral Xanamem®

Controlling brain cortisol to slow progression in Alzheimer's disease and treat depression

Corporate Presentation

February 2026

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Corporate Summary

ASX-listed company focussed on oral Xanamem development in Alzheimer's disease

Phase 2b/3 pivotal XanaMIA trial to report topline final results in November 2026

- Positive independent Data Monitoring Committee (DMC) recommendation to continue trial January 2026
- Fully enrolment of 247 participants December 2025
- Broad agreement on a streamlined development path including one additional pivotal trial of 10mg vs. placebo

Novel 11β-HSD1 cortisol control mechanism, oral, attractive safety profile

- Brain cortisol has long been proposed as a pathogenic mechanism in Alzheimer's disease and depression
- Unique brain-penetrant tissue cortisol synthesis inhibitor that leaves adrenal cortisol functionality unaffected
- ~500 people treated with excellent safety and low drug interaction risk

Large clinical and commercial opportunities

- No other brain-penetrant cortisol control drugs in development, first to be awarded INN and USAN names[1]
- Alzheimer's market likely to be $20 billion by 2030, with major opportunity for a safe & effective oral agent
- Positive US neurologist feedback from primary market research on Xanamem target product profile

Patent/data protection and advanced manufacturing

- Composition of matter protection to 2031, and 2036 with extensions in major markets, newer patents in process
- Data exclusivity protects Xanamem data from use by others for 5 to 10 years from approval e.g. 10 years in EU
- Manufacturing process scaled up and patented, contractors Asymchem (China) & Catalent (US)

Highly experienced Board and management with strong track record

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VP Clinical Operations
RN, M Health Law

Fujun Li
Head of Manufacturing
PhD

Michael Roberts
Head of IR & Comms
B.Ec (Hons), CPA, FFIN

Interim analysis positive trial recommendation

Assessments of safety and efficacy futility January 27, 2026

Recommendation:

- Continue the XanaMIA trial without amendment to its final conclusion for the 247 participants

Methods:

- Independent DMC chaired by Alzheimer's disease trials expert Dr Hans Moebius
- The DMC was not empowered to recommend stopping for observed positive Xanamem efficacy in order to preserve the statistical integrity and "alpha" of the trial
- Data confidentially reviewed included "unblinded" data on:
  - ✓ Safety (n=247, i.e. all enrolled participants)
  - ✓ Efficacy data from approximately 37% of total, expected trial dataset (code broken to see treatment group assignment) from Week 12 (n=136), Week 24 (n=87) and Week 36 data (n=52)

Positive result confirms the trial cleared the pre-specified efficacy futility hurdle and unblinded safety review, materially de-risking the program as it moves toward final results in November

Xanamem has a clear path to Alzheimer's approval

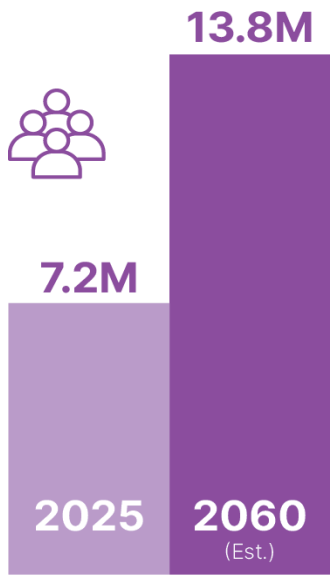
Phase 2b/3 trial on track, FDA Sep 2026 agreement streamlines development

- Recent FDA agreement confirms development pathway to US marketing approval using one additional pivotal trial of 10 mg vs. placebo and open-label safety studies
- Clear guidance on manufacturing, ancillary studies
- Major milestones in near-term of on-going XanaMIA pivotal clinical trial:
  - ✓ Full enrolment in US and Australia in December 2025
  - ✓ Excellent safety profile, positive first Data Monitoring Committee (DMC) safety review
  - ✓ Positive second DMC review with unblinded interim analysis result confirms the trial cleared the pre-specified efficacy futility hurdle and unblinded safety review
  - ✓ On-track for final results in November 2026
- Phase 3 planning commencing in parallel with discussions re potential partnerships
- EMA scientific advice schedule for Q2 2026

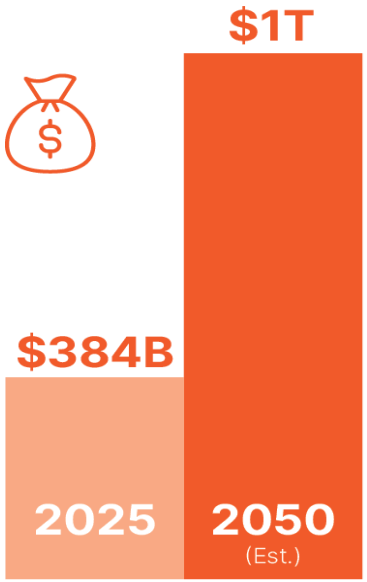
Alzheimer's disease market is large and growing

Growing Alzheimer's Disease market – U.S.

Large, unsatisfied and growing market



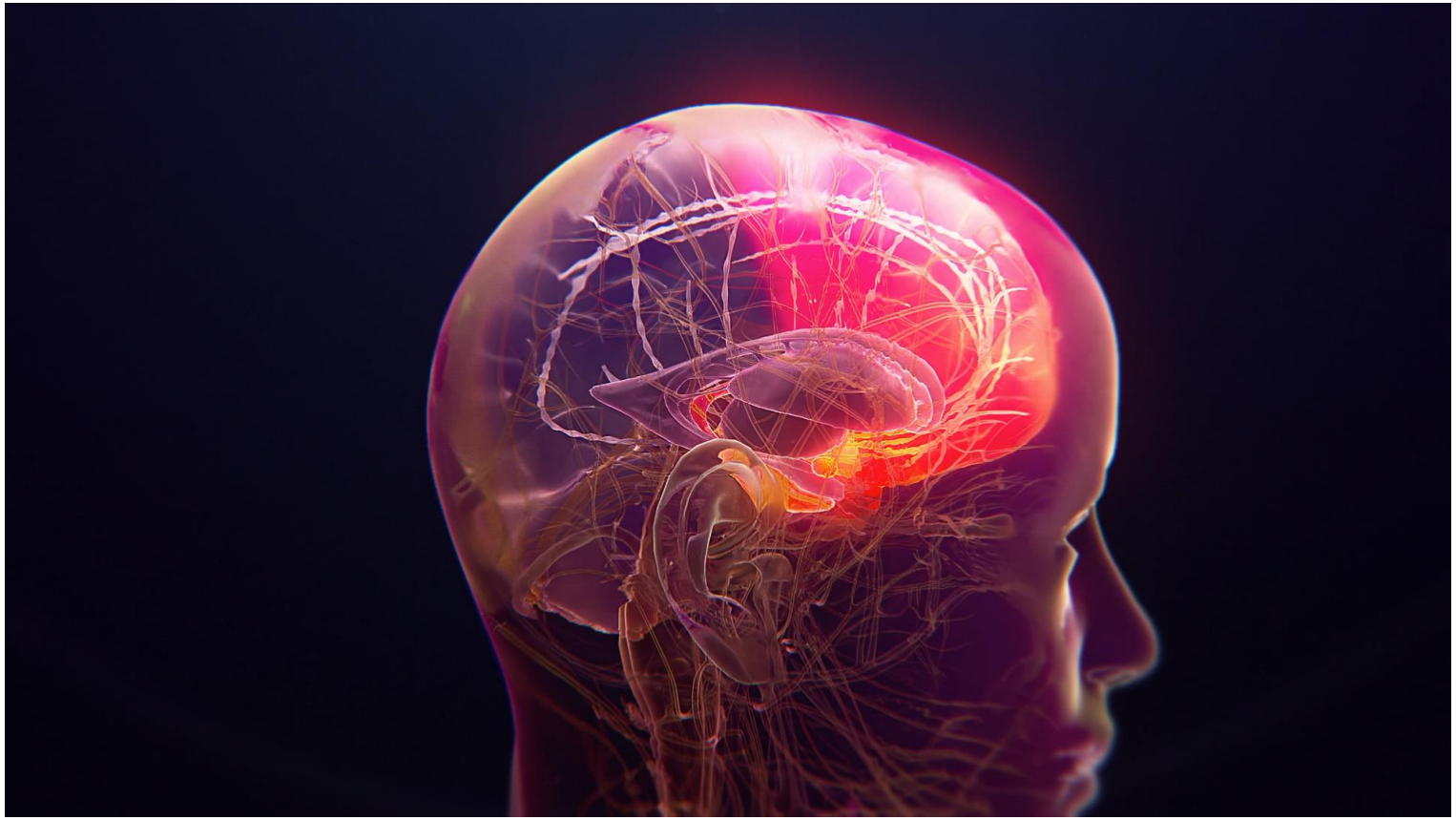
Number of patients (65+ years old)



Cost to treat (USD)

Sources: U.S. burden of Alzheimer's disease, related dementias to double by 2060 | CDC Online Newsroom | CDC, US Alzheimer's Prevalence Surpasses 7 Million and The Cost of Dementia in 2025 - April 23, 2025 - USC Schaeffer

Xanamem's unique mechanism of action



Click here for animation video

Highlights of Alzheimer's treatment landscape

Oral Xanamem is leading the charge with a potential game-changing new mechanism

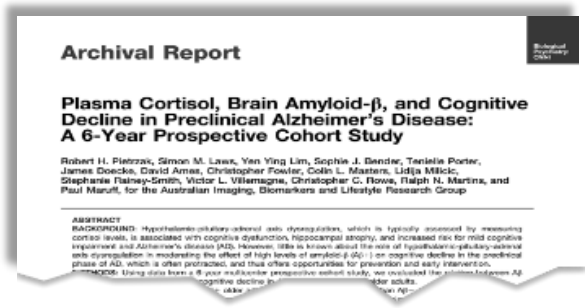
Mechanistic	Admin	Comments
Older drugs - boosting acetylcholine or glutamate	Oral	• Marketed since '90s/'00s, symptomatic only. Gastrointestinal side effects.
Anti-amyloid protein immunotherapies	IV/SubQ	• Marketed with challenges including variable reimbursement (e.g. not Aust.). Safety concerns including infusion reactions, brain swelling / bleeding - MRI monitoring required
Second-gen anti-amyloid with "brain shuttle"	IV/SubQ	• Late-stage trials e.g. Roche's trontinemab. Likely to be safer than first-gen due to less binding to vascular wall amyloid
Xanamem (emestedastat) control of elevated brain cortisol	**Oral**	• **Mid-first pivotal, phase 2b/3 trial (n=247). Promising safety to date (n~500), can be combined with older drugs. Once daily pill**
Blarcamesine SIGMAR1 antagonist to block autophagy	Oral	• One phase 2b/3 trial, regulatory approval recently rejected by EMA. Dizziness, increased rate serious side effects vs. placebo
Anti-amyloid formation or toxicity	Oral	• Most failed phase 2, some on-going trials in patient subgroups.
Anti-tau protein immunotherapy	IV/SubQ	• All trials have failed to date, more on-going

Why does the Company have confidence in a positive phase 2b/3 trial outcome?

1. Very strong cortisol scientific rationale in Alzheimer's
2. Human PET study showing high brain target engagement (n = 40)
3. Large clinical benefit in pTau biomarker-positive Alzheimer's patients (n = 34)
4. Clinically important activity of Xanamem on depression in phase 2 (n = 165)
5. Evidenced-based trial design & patient selection (n=247)

1. Very strong cortisol scientific rationale in Alzheimer's

- Compelling evidence provided by the Australian Imaging, Biomarker & Lifestyle Study of Ageing (AIBL) study (2017)[1]
  - ✓ Higher plasma cortisol leads to a much greater risk of developing AD
  - ✓ Accelerated effect of Aβ+ on decline in global cognition, episodic memory, and attention
- Individuals with the APOE-ε4 allele have higher CSF cortisol[2]
- Multiple other studies support the association between cortisol and AD development and progression[3-6]
- High cortisol and low folate predict probable Alzheimer's disease after age 75[7]
- Higher CSF cortisol levels in AD patients are associated with more rapid clinical worsening and cognitive impairment[8,9]

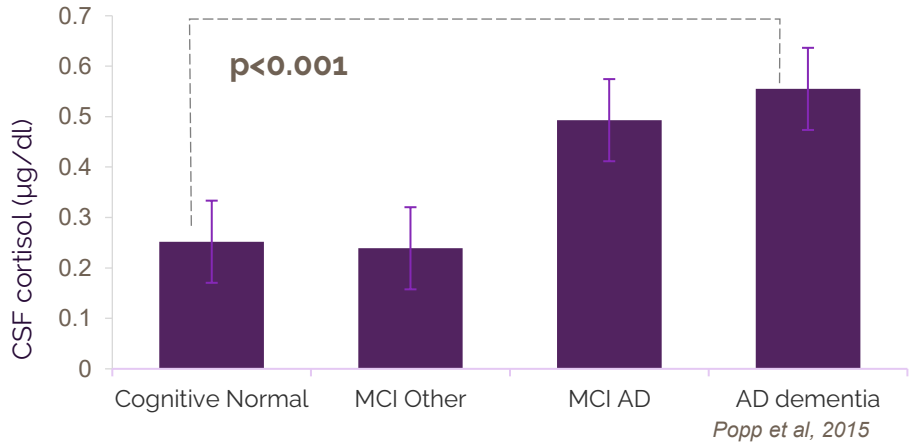

Archival Report

Plasma Cortisol, Brain Amyloid-β, and Cognitive Decline in Preclinical Alzheimer's Disease: A 6-Year Prospective Cohort Study

aibl

The Australian Imaging, Biomarkers and Lifestyle Flagship Study of Ageing

MEAN CSF CORTISOL LEVELS

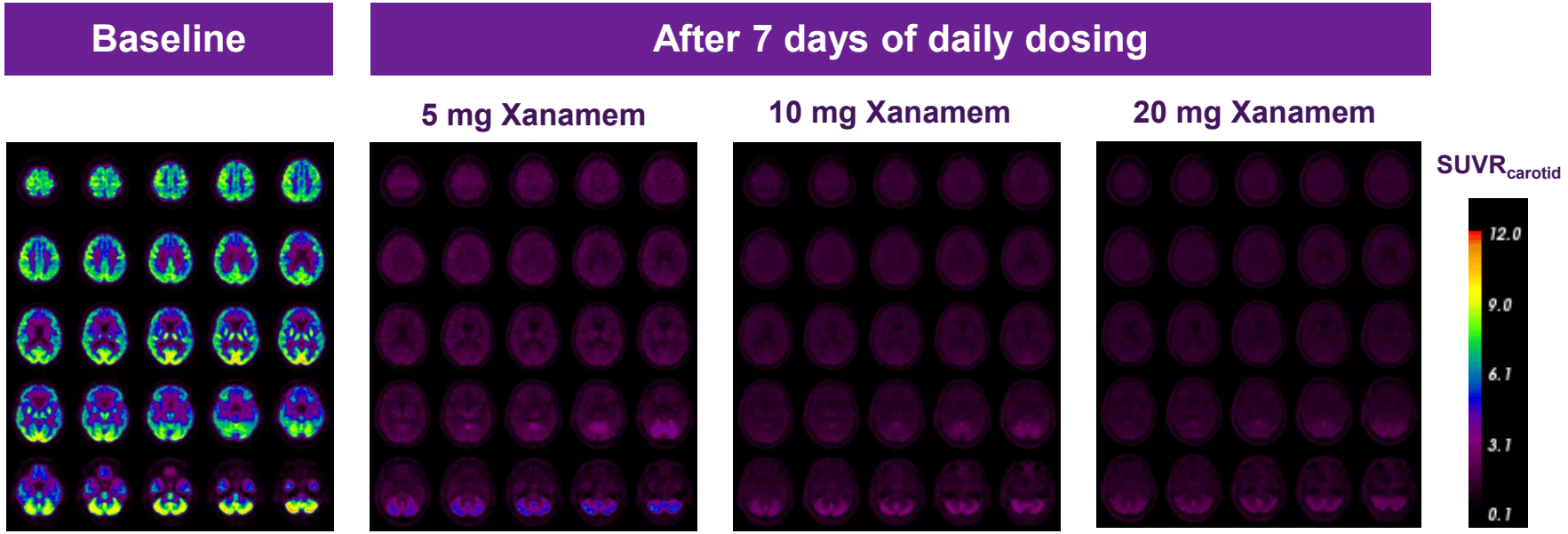


Popp et al, 2015

[1] Pietrzak et al., 2017, Biol Psychiatry: Cognitive Neuroscience and Neuroimagery, [2] Lupien et al., 1998, Nat Neurosci 1:69–73; [3] Geerlings et al., 2015, Neurology 85: 1-8; [4] Lehallier et al., 2016, JAMA Neurology 73(2), 203-212; [5] Popp et al., 2015, Neurobiol. Aging 36:601–607; [6] Ennis et al., 2017, Neurology 88(4):371-378; 2:45-52; [6] Lupien et al., 2009, Nat Rev Neurosci 10:434–445; [7] Hinterberger et al., J Am Ger Soc 2013 61(4):648-651; [8] Cernansky et al., 2006, Am J Psychiatry 163:2164-2169; [9] Kornhuber & Jensen, 2015, Neurobiol Aging 36:601-607;

2. Human PET study shows full target engagement

Other 11β-HSD1 enzyme inhibitors have not achieved adequate brain levels



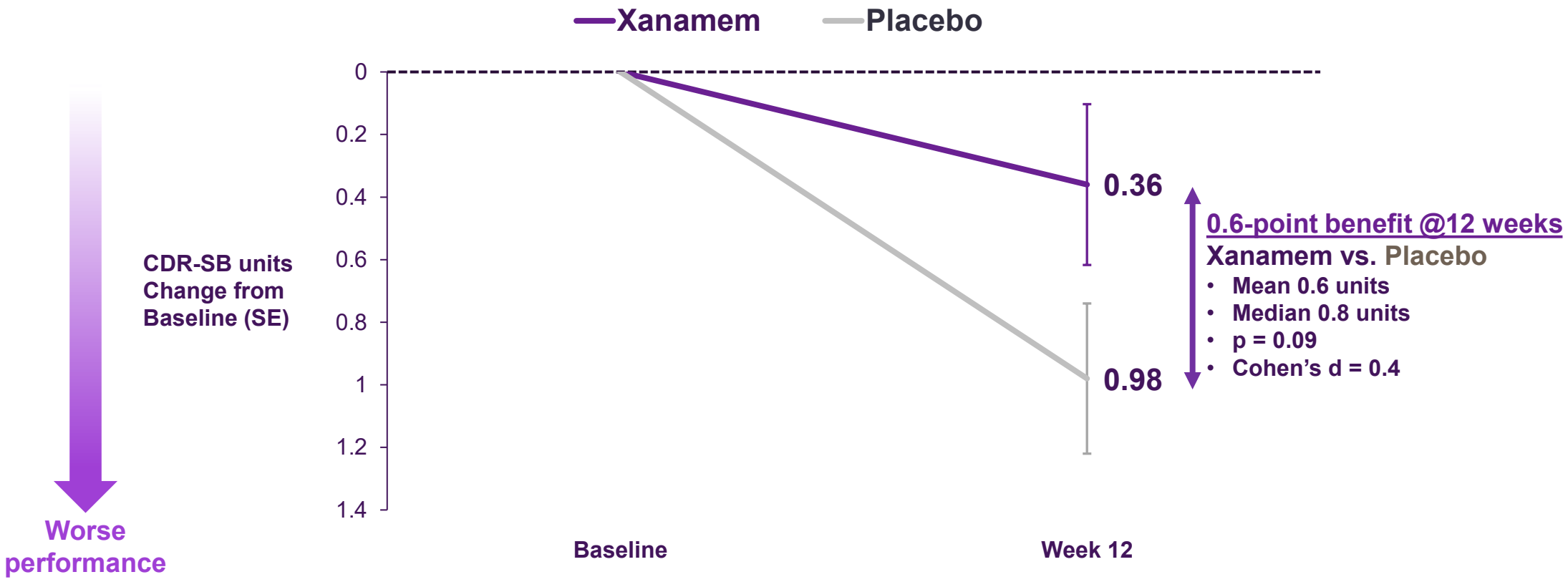
Xanamem extensively binds to the 11β-HSD1 enzyme throughout the brain, with high post-treatment effects (absence of color) after 7 days at all doses, slightly less at a 5 mg dose.

This is consistent with full hormonal pharmacodynamic activity seen in clinical trials with doses as low as 5 mg.

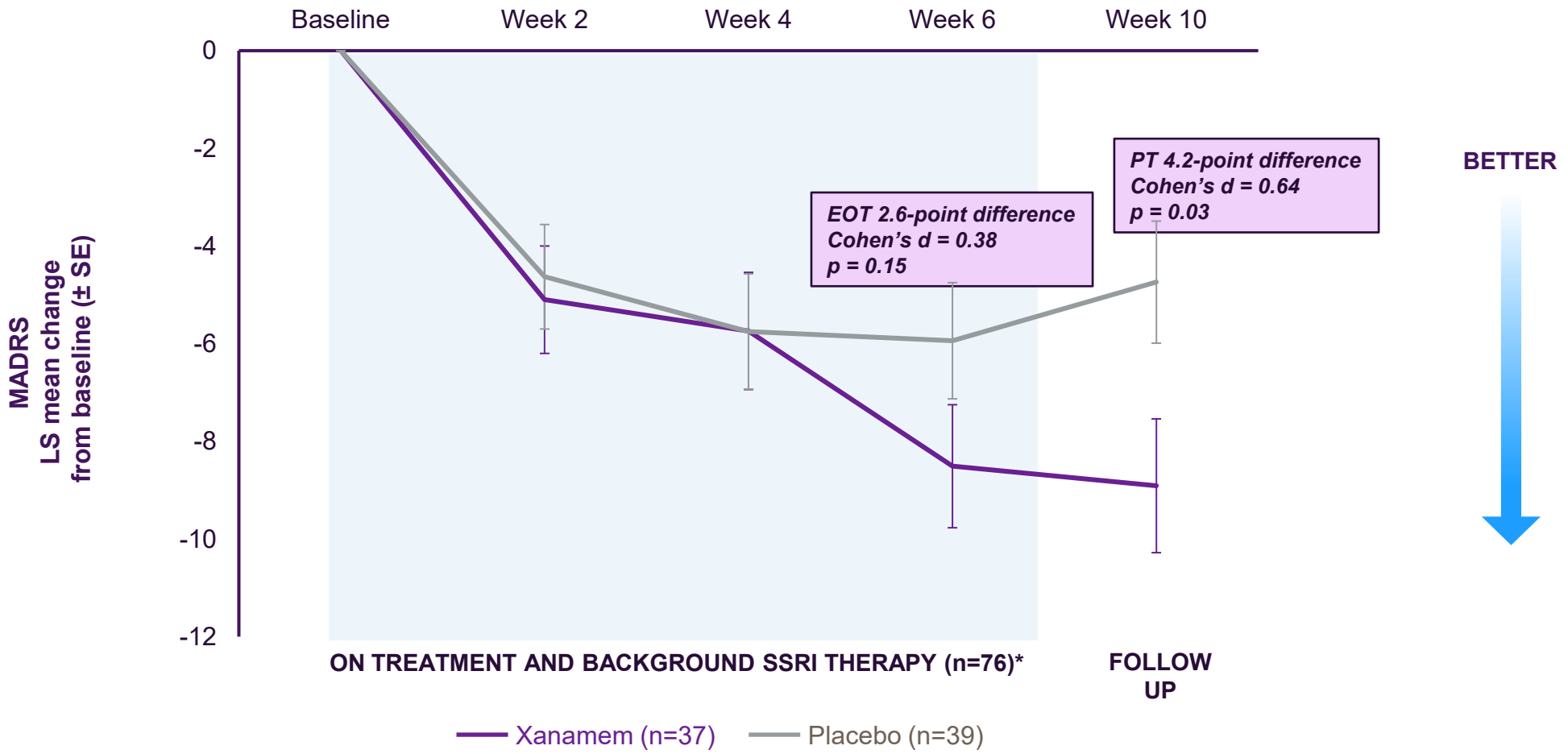
Journal of Alzheimer's Disease 97 (2024) 1463–1475
Brain 11-Hydroxysteroid Dehydrogenase Type 1 Occupancy by Xanamem™ Assessed by PET in Alzheimer's Disease and Cognitively Normal Individuals
Victor L. Villemagne, Vincent Dor, Lee Chong, Michael Kassiou, Rachel Mulligan, Azadeh Feizpour, Jack Taylor, Miriam Roesner, Tamara Miller and Christopher C. Rowe

3. Large Xanamem benefit in high pTau181 patients

Phase 2a biomarker study: major slowing of CDR-SB decline over 12 weeks (n=34)



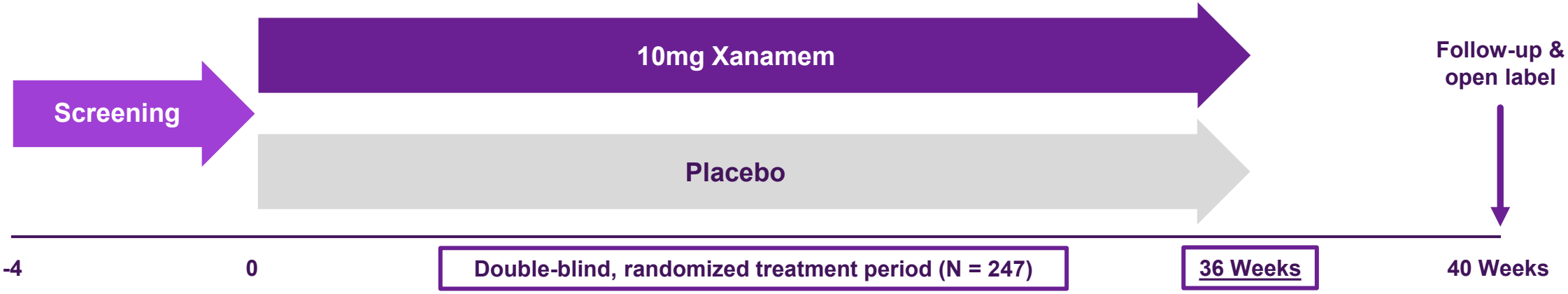
4. Durable activity of Xanamem 10 mg daily on depression in phase 2



Abbreviations: SSRI, selective serotonin reuptake inhibitor.
*Planned phase 3 population

5. Evidence-based trial design & patient selection

Positive XanaMIA phase 2b/3 interim analysis outcome achieved, topline final results Nov 2026



Key Inclusion Criteria	Primary Endpoint	Key Secondary Endpoints	Implementation
• **Blood pTau biomarker positive** • Mild-moderate Alzheimer's by NIA-AA criteria	• **CDR-SB (functional and cognitive measure) @36 weeks**	• Cognitive Test Battery (7 cognitive measures well-validated in the Alzheimer's field) • Amsterdam Activity of Daily Living (functional measure)	• Full enrolment at 15 Australian & 20 US sites • Positive XanaMIA phase 2b/3 interim analysis outcome achieved (unblinded efficacy futility & safety on all available data) • Final topline results Nov 2026

NIA-AA=National Institute of Aging - Alzheimer's Association; **CDR-SB** Clinical Dementia Rating Scale – Sum of Boxes

XanaMIA trial open-label phase

Open-label phase commences Q1 2026

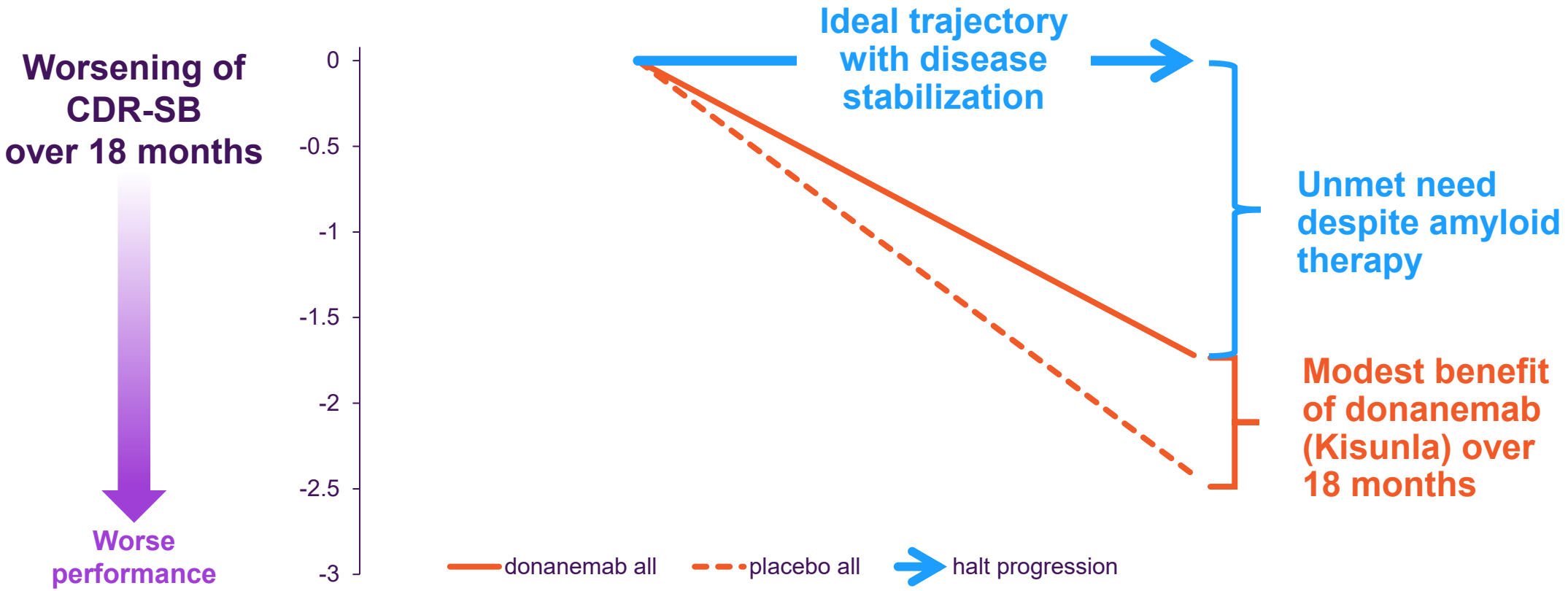
- Active Xanamem 10 mg offered to all current and prior XanaMIA phase 2b/3 trial participants irrespective of any gaps between completing the main trial and OLE availability
- No placebo control group
- Provides longer term safety data for at least 12 months and observational data on key efficacy endpoints such as the CDR-SB, cognition and activities of daily living
- Able to be reported at regular intervals e.g. every 6 months
- Will enable characterisation and comparison of efficacy endpoints trajectories between the group that got Xanamem in the main trial and then continue with Xanamem vs. placebo then Xanamem

Strategic insights about commercialization and partnering in AD

1. Anti-amyloid infusions have a borderline risk-benefit profile and are expensive
2. Xanamem is being developed with a better risk-benefit and ease-of-use profile aimed at stabilizing the disease safely
3. Desired Xanamem benefits include multiple aspects of cognition and life functioning – ideally to halt Alzheimer's decline completely
4. XanaMIA trial is a catalyst for commercial and partnering interest

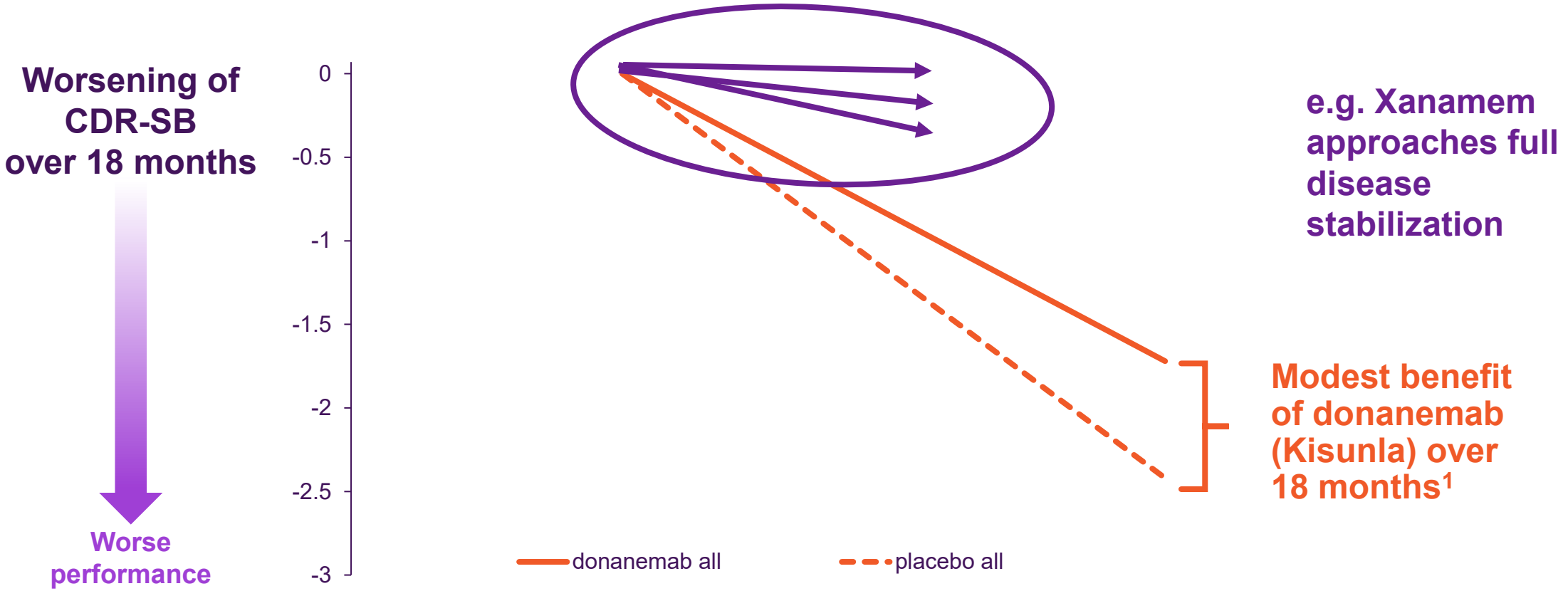
1. Anti-amyloid drugs only modestly slow disease

Ideally patients with AD would not worsen on treatment at all



Drugs targeting other mechanisms like Xanamem are needed

2. Potential for Xanamem to beat existing approved treatments on CDR-SB primary endpoint



If results are good, Xanamem could be many times more effective than other drugs

1. Sims et al. JAMA 2023 336(6):512-527

3. Well-established safety and potential to see consistent benefit on key secondary efficacy measures

Safety

- **Well-tolerated**
- **No serious adverse events related to Xanamem in whole program to date (n ~ 500)[1]**

Key secondary endpoints

- **Cognition**
- **Activities of daily living**

1. No serious adverse events related to Xanamem have been reported across all clinical trials to date; various other safety data are reported in peer reviewed publications (see https://actinogen.com.au/xanamem/)

4. XanaMIA catalyst for commercial & partnering events

We know the commercial opportunity is huge:

- US Neurologists treating AD embrace the idea of a safe and effective, oral drug and indicate that uptake would be rapid in the first year – anti-amyloid injectables have low market appeal
- Xanamem could easily move to first line therapy and displace many existing treatments
- Combinability with other small molecules and biologics a major plus
- Multiple potential commercialization partners are reviewing data in our dataroom

We are planning for:

- Completing one or more regional partnership deals if terms are favourable
- Final results that excite multiple, global partnership bids
- Final results that enable regulators to seriously consider expedited approvals

Summary

Building momentum toward Alzheimer's results

Numerous value-add near-term milestones

- **Experienced team with proven track records**
- **On-track with XanaMIA pivotal trial for mild-moderate Alzheimer's disease**
  - ✓ Full enrolment of 247 participants in XanaMIA achieved
  - ✓ Positive interim analysis results January 2026, topline final results November 2026
- **Highly positive market research with about 100 US Alzheimer's physicians**
  - ✓ And 80% of physicians would prescribe Xanamem in the first 6 months from launch
- **FDA agreement on streamlined path to Xanamem approval (EMA Q2 2026)**
  - ✓ One other pivotal trial of 10 mg vs. placebo, 1500 patients in total
- **IP portfolio strengthened with the prosecution of multiple new patents**
- **Growing partnership awareness and interest in the program**
- **Company funded beyond topline results in November 2026**

Multiple near-term milestones in coming year

Milestone	Likely Timing
Positive interim analysis XanaMIA AD trial of all available data (weeks 12, 24 & 36)	Achieved
XanaCIDD MDD peer-reviewed journal publication	Q1/2 26
XanaMIA AD open-label extension (OLE) commences	Q1 26
ADPD AD conference in Copenhagen	Q1 26
EMA Scientific Advice meeting for AD	Q2 26
Clinical Trials Science Forum – streamlined pathways to Xanamem marketing approvals	Q2 26
BIO conference in San Diego	Q2 26
AAIC AD conference in London	Q3 26
Last patient completes 36-week treatment, 4-week follow-up	Oct 26
Final topline results, XanaMIA AD trial	Nov 26
XanaMIA topline results presentation at key AD scientific meeting	Nov 26

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