Actinogen

Advancing Xanamem® in Alzheimer's Disease

Fully enrolled phase 2b/3 study | Topline data November 2026

Independent DMC recommended study continue unchanged (January 2026)

Corporate Presentation

May 2026

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Corporate summary and investment highlights

Independent interim validation achieved | Topline phase 2b/3 results November 2026

Validated mechanism with differentiated oral profile

- Xanamem is a novel oral therapy targeting elevated brain cortisol, a well-established contributor to Alzheimer's disease
- Oral administration and favorable safety profile support broad use

NEXT MAJOR VALUE INFLECTION
Phase 2b/3 topline results
November 2026

Biomarker-enriched pivotal trial with independent validation

- Phase 2b/3 XanaMIA study (n=247) fully enrolled; topline results expected November 2026
- January 2026 independent Data Monitoring Committee recommended the study continue unchanged following unblinded interim review

Regulatory pathway to NDA submission

- Current phase 2b/3 study expected to form part of registrational package
- FDA agreement on streamlined pathway to NDA approval with only one additional pivotal trial and standard 1500-person safety database – EMA scientific advice pending

Strong capital position

- Company funded beyond November 2026 topline readout
- Resources focused on execution of the Phase 2b/3 XanaMIA trial and preparation for 2027

Experienced leadership

Proven experience in clinical development, manufacturing, regulatory & commercialization

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Chairman
MBBS; MBA

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MBBS; FRACP; PhD; MBA

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MD

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Chief Financial Officer
BComm, LLB

Andrew Udell
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MBA

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VP Clinical Operations
RN, M Health Law

Fujun Li
Head of Manufacturing
PhD

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

Independent interim review: trial continues unchanged

Interim safety and futility review

Recommendation:

- Continue the XanaMIA trial without modification

Interim review process:

- Independent Data Monitoring Committee chaired by Alzheimer's disease trials expert Dr Hans Moebius
- The Committee was not authorized to recommend early stopping for efficacy in order to preserve the trial's statistical integrity
- The Committee confidentially reviewed treatment group data on:
  - ✓ Safety data from all enrolled participants (n=247)
  - ✓ Interim efficacy data representing approximately 37% of the expected final dataset across scheduled timepoints including 52 participants with Week 36 (end of treatment) data

Independent interim review delivers a positive continuation decision, clearing safety and futility criteria ahead of November 2026 topline results

Open-label extension enhances long-term dataset

Long-term safety and efficacy durability extension to Phase 2b/3

Design

- All participants offered active Xanamem 10mg after completion of double-blind phase
- Initiated March 2026 with high initial enrolment

Data contribution

- ≥12 months additional safety exposure
- Longitudinal assessment of CDR-SB, cognition, and activities of daily living
- Observational comparison of early vs delayed treatment initiation
- Potential to show durability of benefit

Strategic impact

- Expands cumulative safety database
- Supports regulatory engagement
- Informs durability of clinical effect

Xanamem: Well defined path to U.S. approval

FDA alignment confirms streamlined late-stage development pathway

Current study

- Phase 2b/3 XanaMIA study (n=247) expected to form part of registrational package
- Open-label phase has commenced with high uptake from main trial participants

Remaining clinical requirements

- One additional single-dose phase 3 trial (10 mg vs placebo) likely required[1]
- Open-label safety studies
- Limited number of clinical pharmacology studies

Regulatory engagement

- FDA alignment achieved September 2025
- Clear guidance on clinical, manufacturing and ancillary studies
- EMA scientific advice scheduled Q2 2026

1. FDA and EMA may accept a single pivotal trial plus adequate supportive evidence for approvals under certain circumstances

Near-Term Catalysts Through XanaMIA Readout

Milestone	Likely Timing
Positive interim analysis XanaMIA AD trial of all available data (weeks 12, 24 & 36)	Completed
XanaMIA AD open-label extension (OLE) commences & reports initial enrolment data	Completed
XanaCIDD MDD peer-reviewed journal publication	Q2 2026
EMA Scientific Advice meeting for AD	Q2 2026
BIO conference in San Diego	Q2 2026
Clinical Trials Science Forum	Q3 2026
AAIC AD conference in London	Q3 2026
Bioshares conference Queenstown	Q3 2026
Canaccord biotech conference	Q4 2026
Last participant assessment visit in XanaMIA pivotal trial	Oct 2026
Final topline results, XanaMIA AD trial	Nov 2026
Topline results presentation at major AD scientific meeting	TBD

Strong physician interest and demand for Xanamem

Global Alzheimer's therapeutic market expected to exceed $20B by 2030

Quantitative survey of 91 U.S. neurologists treating Alzheimer's disease (June 2025)

Respondents each manage ~250 AD patients on average

Rapid adoption expected

~80% expect to prescribe within 6 months

- 13% within first month
- 41% within three months

Early uptake anticipated among high-volume AD prescribers

Significant market share potential

~50% projected peak share

- 43% estimate 31–50% peak share
- 14% estimate >50% peak share

Broad eligibility supports substantial utilization

Leading role in management

92% anticipate leading role

- 30% expect top-two agent
- 0% indicate no role

Oral profile and safety drive enthusiasm

Xanamem positioning in Alzheimer's disease

Oral profile and safety address key limitations of existing therapies

Current therapy limitations

- Anti-amyloid injectables require infusions and extensive MRI monitoring
- ARIA (brain swelling) risk concerns
- Focus on very early AD/MCI
- Administration complexity constrains uptake
- Existing oral therapies offer limited efficacy

Xanamem differentiation

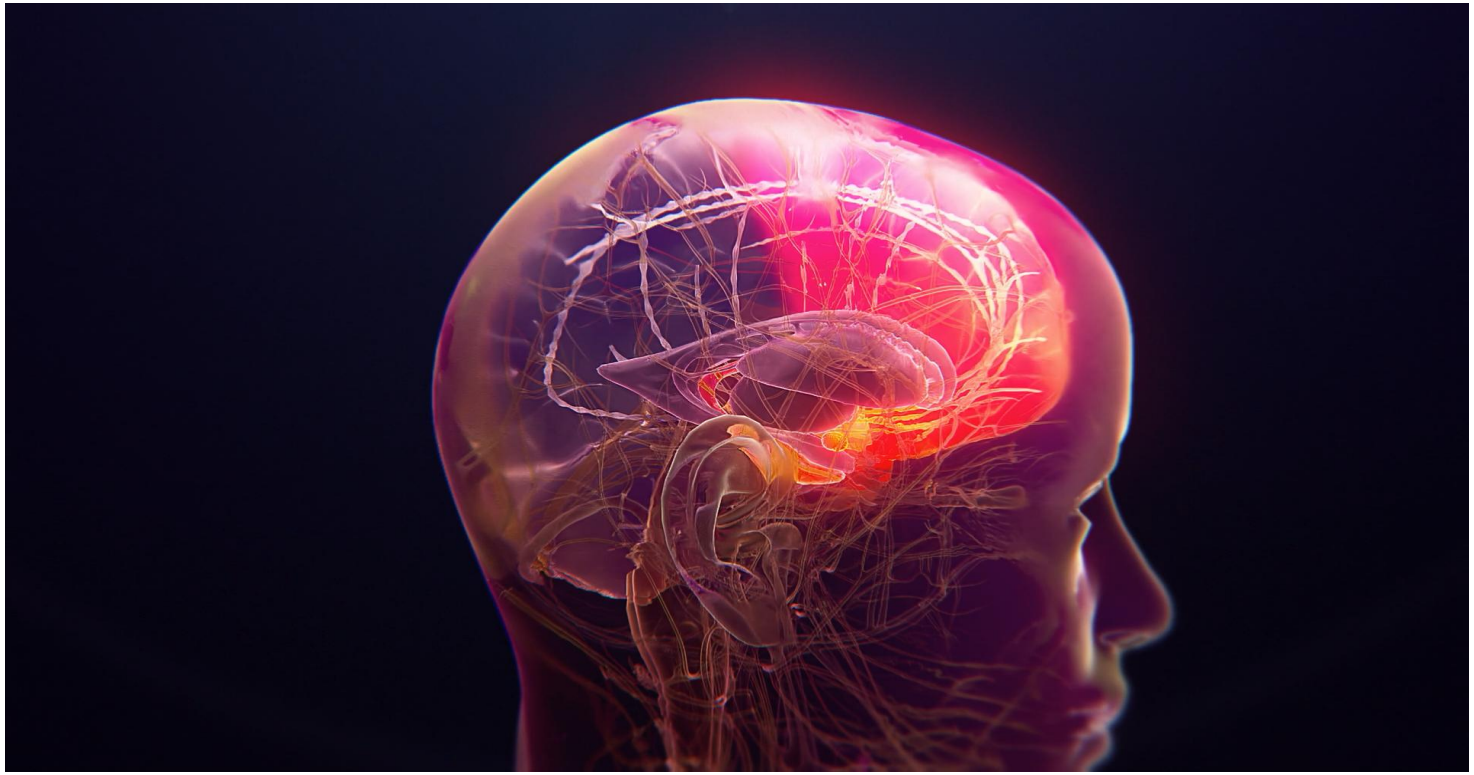
- Once-daily oral therapy
- No ARIA risk observed to date. No MRI monitoring
- Broad eligibility across mild to moderate AD
- Combination-friendly with other treatments
- Viewed as potential first-line therapy

Positioned for phase 2b/3 success

Targeting elevated brain cortisol in Alzheimer's disease

Xanamem selectively inhibits brain 11β-HSD1 while preserving adrenal cortisol function

Elevated brain cortisol is associated with cognitive decline and neurodegeneration

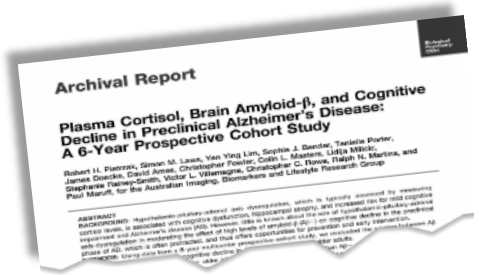


Watch MOA animation

Elevated brain cortisol and Alzheimer's progression

Human observational and biomarker data support cortisol as a disease driver

- Higher plasma cortisol associated with increased AD risk (AIBL study)
- Cortisol accelerates cognitive decline and interacts with Aβ pathology
- APOE-ε4 carriers exhibit higher CSF cortisol levels
- Elevated CSF cortisol correlates with more rapid clinical worsening

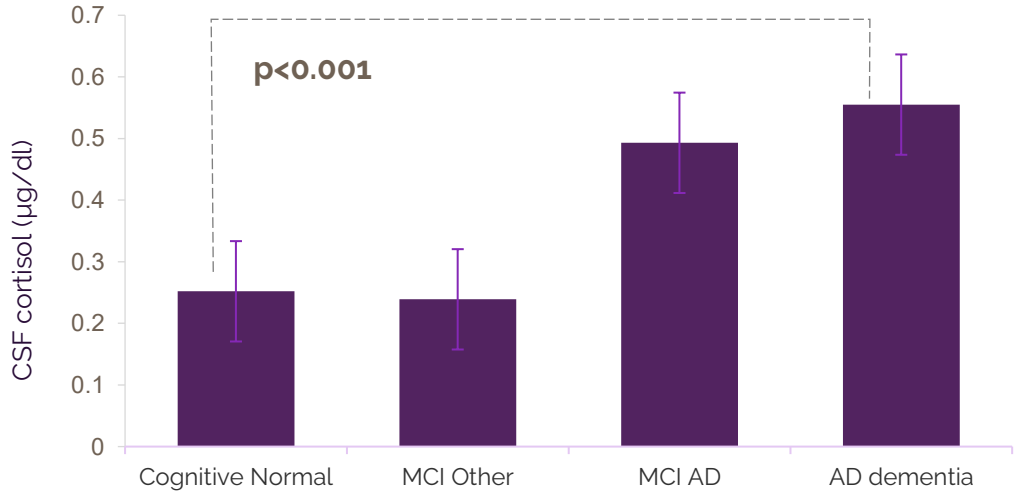

Archival Report

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

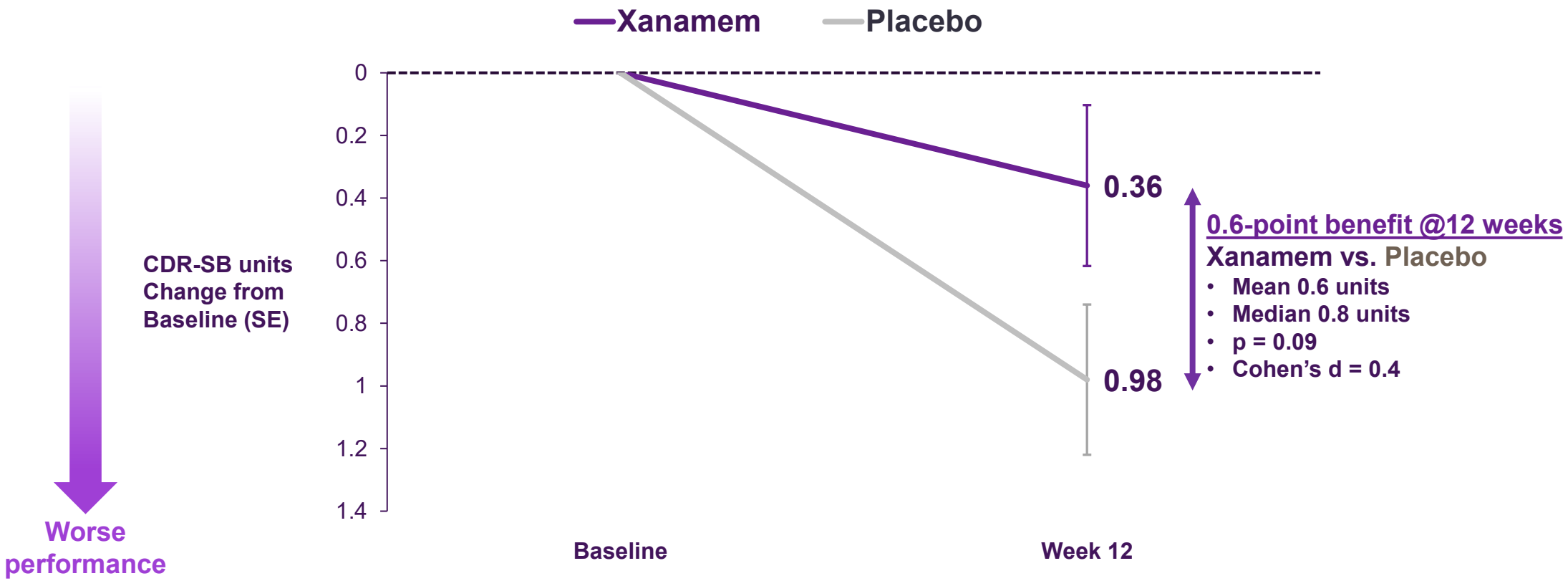


Popp et al, 2015

[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;

Xanamem: CDR-SB slowed in pTau-positive Alzheimer's

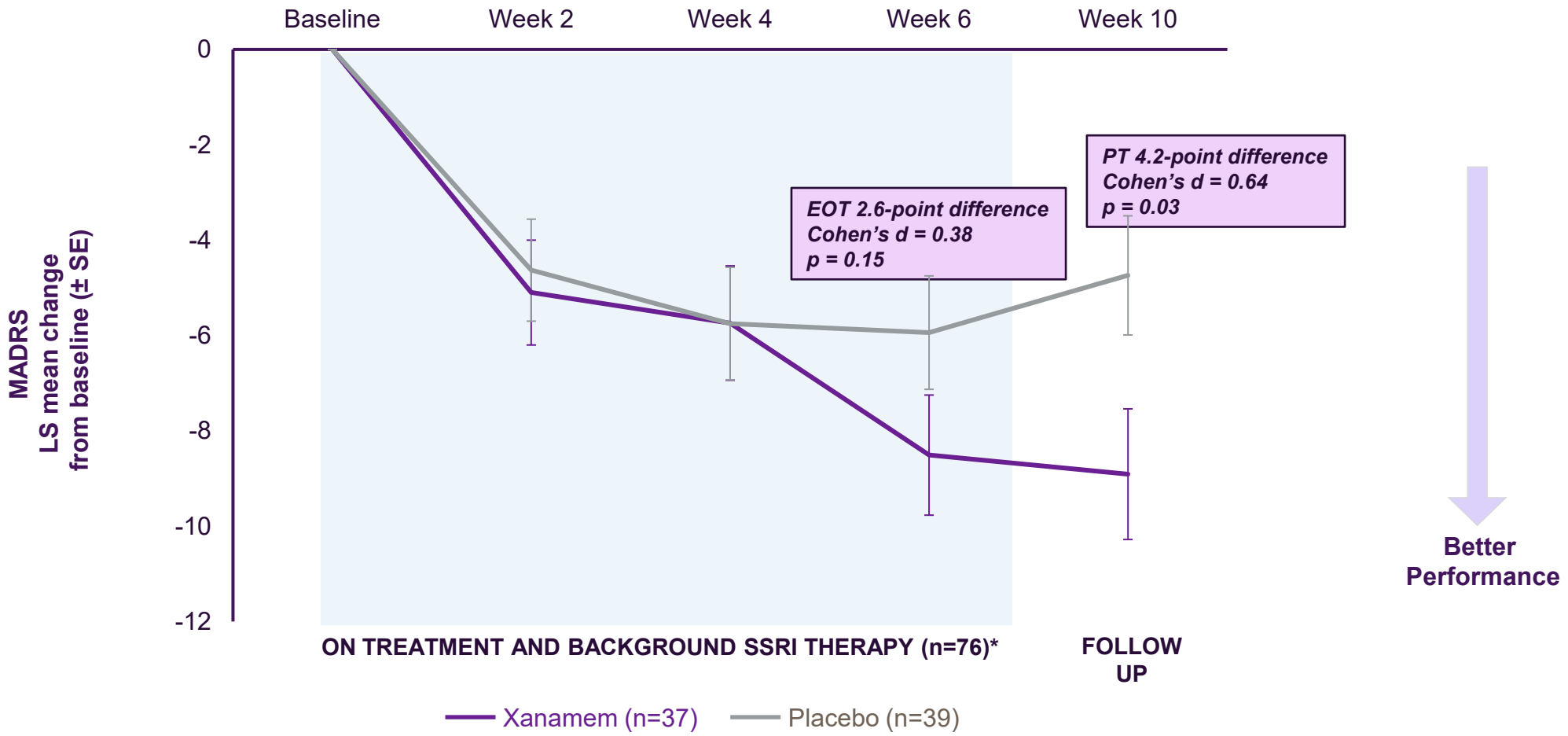
Phase 2a study showed slowing of decline over 12 weeks (n=34)



Journal of Alzheimer's Disease 100 (2024) 139–150
Plasma pTau181 Predicts Clinical Progression in a Phase 2 Randomized Controlled Trial of the 11-HSD1 Inhibitor Xanamem® for Mild Alzheimer's Disease
Jack Taylor, Mark Jaros, Christopher Chen, John Harrison and Dana Hilt

Durable activity in phase 2 depression study

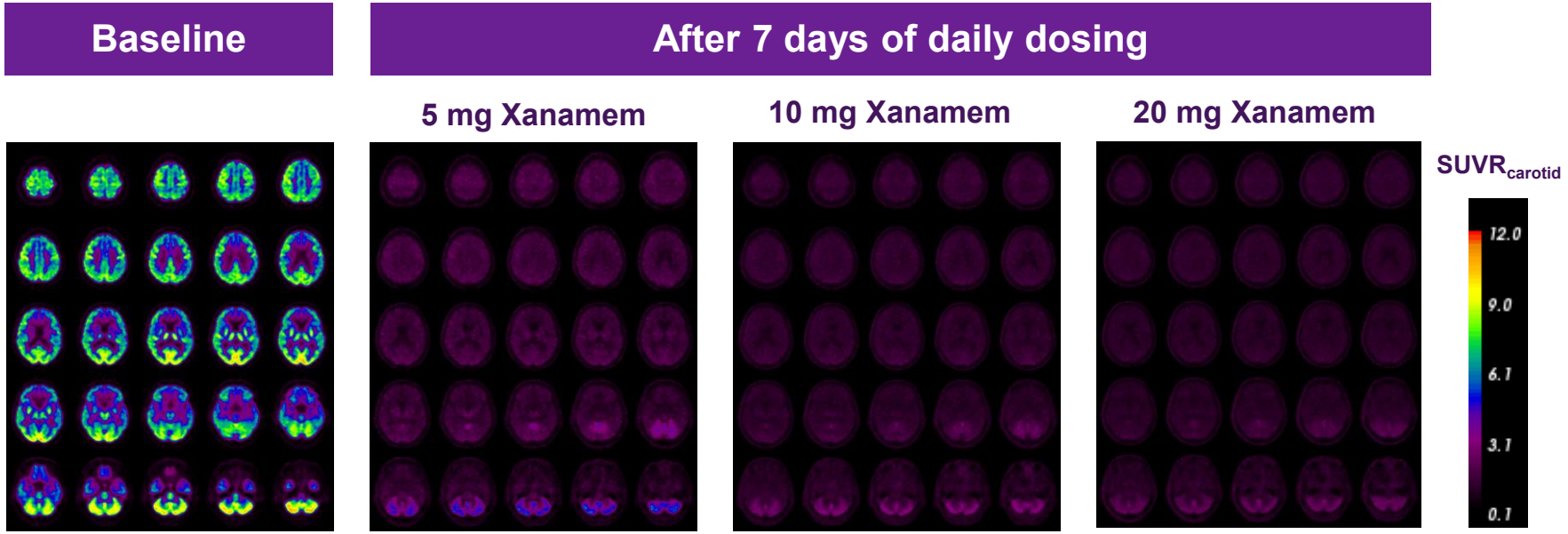
10 mg demonstrated separation from placebo overall and on background SSRI therapy



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

Xanamem achieves high brain target occupancy

Human PET imaging confirms brain 11β-HSD1 engagement



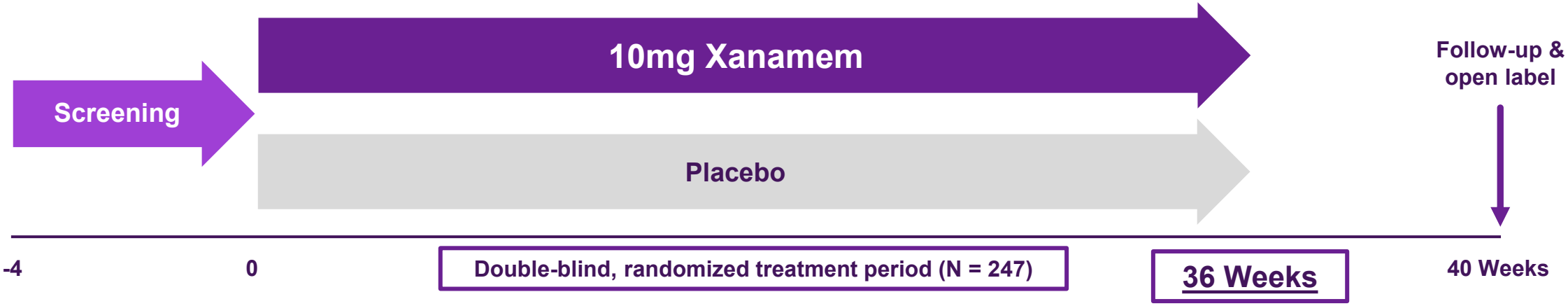
Reduction in tracer signal (loss of color) indicates high 11β-HSD1 occupancy -

Strong occupancy observed across evaluated clinical doses

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

Rigorous phase 2b/3 trial positioned for success

Fully enrolled (n=247) across U.S. and Australia; topline results November 2026



Population	Primary Endpoint	Key Secondary Endpoints	Execution
• Blood pTau biomarker positive • Mild-moderate AD (NIA-AA criteria)	• CDR-SB at 36 weeks (functional and cognitive measure)	• Cognitive Test Battery • Amsterdam Activity of Daily Living	• **Fully enrolled (n=247)** • Independent DMC interim review recommended trial continuation • **Topline results November 2026**

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

Summary: positioned for phase 2b/3 success

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Clear Biological Rationale	Demonstrated Brain Target Engagement	Clinical Signal in Enriched Alzheimer's Population	Consistent CNS Activity Across Indications	Rigorous, Fully Enrolled Phase 2b/3 Trial
Elevated brain cortisol implicated in cognitive decline and neuronal injury	High 11β-HSD1 occupancy confirmed by human PET imaging	CDR-SB slowing in pTau positive patients over 12 weeks	Durable separation from placebo in Phase 2 depression study	247 patients; interim continuation; November 2026 readout

Strategic implications for commercialization and partnering

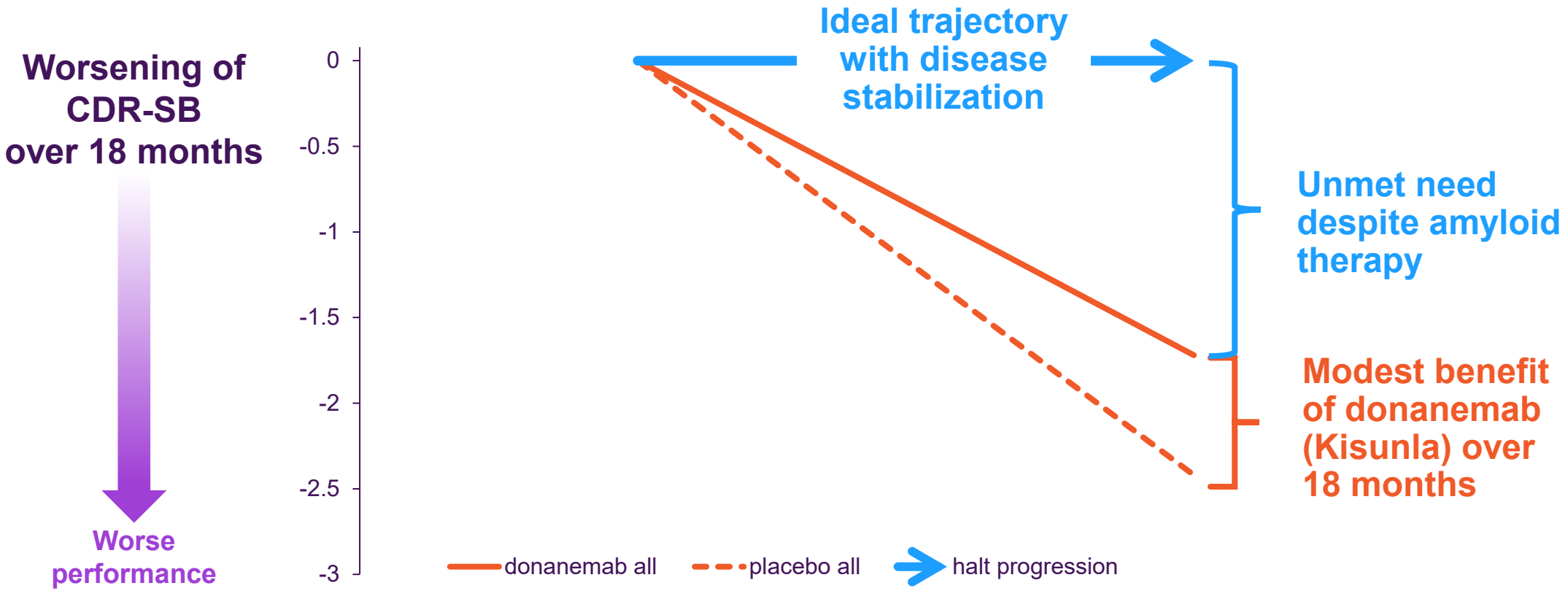
AD treatment landscape: meaningful limitations persist

Recent advances have not eliminated meaningful clinical and practical barriers

Mechanistic	Admin	Comments
Older drugs - boosting acetylcholine or glutamate	Oral	• Symptomatic benefit only • Gastrointestinal tolerability limitations
Anti-amyloid protein immunotherapies	IV/SubQ	• Modest slowing of decline • ARIA risk and MRI monitoring; variable reimbursement
Second-gen anti-amyloid with “brain shuttle”	IV/SubQ	• Late-stage trials aimed at improved vascular safety
Xanamem (emestedastat) control of elevated brain cortisol	**Oral**	• **Phase 2b/3 pivotal trial (n=247)** • **Oral, once-daily; no ARIA observed** • **Combination-compatible**
Blarcamesine SIGMAR1 antagonist to block autophagy	Oral	• Phase 2b/3 trial; EMA rejection • CNS tolerability concerns reported
Anti-amyloid formation or toxicity	Oral	• High historic attrition • Subgroup strategies under evaluation
Anti-tau protein immunotherapy	IV/SubQ	• Multiple trial failures to date • Development ongoing

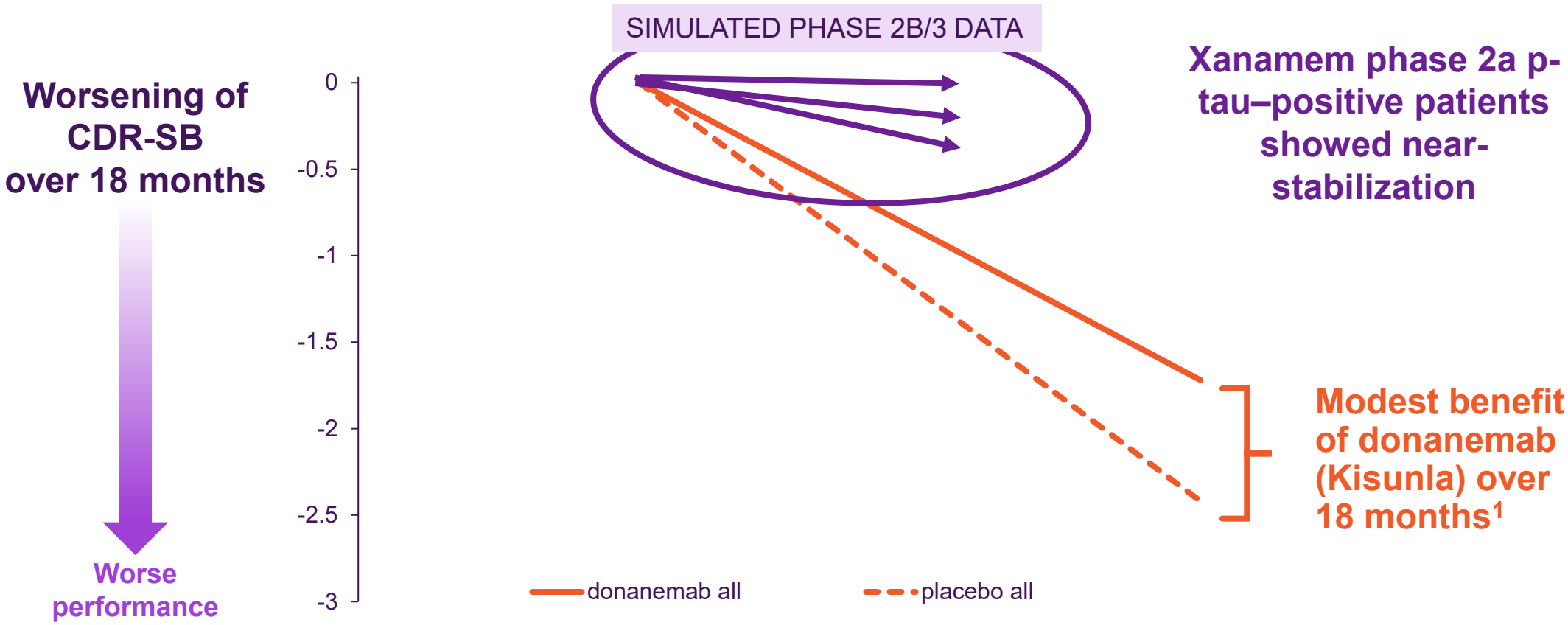
Anti-amyloid therapies modestly slow decline

Disease stabilization represents an important therapeutic aspiration



Additional therapeutic mechanisms remain an important area of investigation

Potential for Greater Magnitude of Effect on CDR-SB



Xanamem may stabilize or slow CDR-SB progression more than other therapies

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

Well-established safety and consistent benefit across key secondary measures

Safety

- Well-tolerated across clinical program
- No serious adverse events related to Xanamem reported to date (n ~ 500)[1]
- No ARIA signal observed

Key secondary endpoints

- Cognition (validated cognitive measures)
- Activities of daily living (functional measures)

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 Actinogen – Xanamem® (emestedastat)/)

XanaMIA as a near-term catalyst for commercial and partnering acceleration

Commercial opportunity drivers include:

- U.S. neurologists demonstrate strong interest and demand for a safe, effective oral option
- Anti-amyloid injectables face adoption constraints related to administration and monitoring
- Oral profile and safety enable broad patient eligibility
- Combination potential expands first-line and adjunct positioning flexibility

Strategic execution priorities include:

- Advancing selective regional partnerships where terms are favorable
- Phase 2b/3 data positioned to drive global partnering discussions
- Proactive engagement with regulators regarding potential expedited pathways

Summary: commercial and partnering implications

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Structural Limitations of Anti-Amyloid

Infusion burden, ARIA risk, and cost limit broad adoption

Differentiated Oral Profile

Xanamem is positioned with a favorable risk-benefit and ease-of-use profile

Potential for Meaningful Stabilization

Targeting elevated brain cortisol may enable functional impact beyond modest slowing

XanaMIA as a Value Catalyst

Phase 2b/3 readout is positioned to accelerate commercial and strategic partnering activity

Summary

XanaMIA positioned as a registration catalyst

Operational execution and regulatory alignment ahead of pivotal Alzheimer's data

- **On-track with XanaMIA pivotal trial in patients with mild-to-moderate AD**
  - ✓ Full enrolment of 247 participants achieved
  - ✓ Positive interim analysis Jan 2026; topline results expected Nov 2026
  - ✓ Structured as a registrational study aligned with FDA guidance

- **Executing on streamlined development path for Alzheimer's disease**
  - ✓ Open-label extension XanaMIA trial phase opened in March 2026
  - ✓ Next pivotal trial in planning - to commence in 2027
  - ✓ EMA scientific guidance due in Q2
  - ✓ Manufacturing and pre-commercialization activities on-track
  - ✓ Ancillary clinical pharmacology trials to start in 2027

Commercial and strategic strength ahead of readout

Leadership, market validation, lifecycle protection, and financial readiness

- **Experienced leadership team with proven track records across development, approval, commercialization, and strategic transactions**
- **Strong physician demand across ~100 U.S. Alzheimer's specialists**
  - ✓ ~80% indicate intent to prescribe within first 6 months of launch
- **Composition of matter protection to 2036 in most markets[1]**
  - ✓ Additional patents extend protection into the 2040s
  - ✓ Regulatory data exclusivity of at least 5 years from marketing approval dates support protection from generic competition in most countries
- **Increasing strategic partnering engagement**
- **Funded beyond November 2026 topline readout**

1. Patent protection extensions for the initial composition of matter patent (2031) of between 5 and 10 years apply in nearly all countries

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