ASX ANNOUNCEMENT

Actinogen announces achievement of clinically and statistically significant superiority of Xanamem® over placebo on depression in XanaCIDD phase 2a trial without meeting the primary endpoint of a cognition "Attention Composite"

There was a clinically meaningful and persistent improvement in depression measured by the key secondary endpoint of MADRS.[1] The primary endpoint of superiority to placebo in a cognitive "attention composite" of three Cogstate computerized tests was not met with large improvements seen in both Xanamem and placebo groups. Xanamem was safe and well tolerated.

Sydney, 12 August 2024. Actinogen Medical ASX: ACW ("ACW" or "the Company") announces that Xanamem treatment had clinically and statistically significant ($p < 0.05$) benefits on depression in its phase 2a XanaCIDD trial of Xanamem in patients with cognitive dysfunction and major depressive disorder (MDD). This outcome indicates potential modification of the underlying biology of depression as a result of inhibition of tissue cortisol synthesis – a completely novel mechanism for the treatment of depression. The trial did not meet the primary endpoint of improving the "Attention Composite" in the context of an unexpectedly large improvement in the placebo group.

Management and US psychiatry trials expert, Dr Steven Targum MD, will discuss the attached slide presentation at a webinar at 11am (AEST) today. Click here to register and attend.[2] Dr Targum is a fellow of the American Psychiatric Association and has published more than 170 peer-reviewed articles.

Key XanaCIDD trial findings and their implications are:

- Xanamem was safe and well-tolerated with a promising safety profile consistent with prior trials
- MADRS depression score improvement in all 165 patients favoured Xanamem over placebo. These clinically significant benefits (Cohen's d (Cd) > 0.2) in change from baseline was observed at the end of 6 weeks of treatment (1.5 points, Cd = 0.24, p = 0.11) and were statistically significant four weeks after the end of treatment (2.7 points, Cd = 0.43, p = 0.02). The placebo group improvement from baseline of 26% was within the expected range for trials of this type
- Greater Xanamem benefit on MADRS scores was evident in the pre-specified group of 81 patients with less severe depression: at the end of treatment (3.6 points, Cd = 0.88, p = 0.02) and four weeks later (3.6 points, Cd = 0.87, p = 0.03). The large clinically and statistically significant benefits in this responder population are particularly notable and the characteristics of the group will be fully explored to inform future trials

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[1] MADRS: The Montgomery-Asberg Depression Rating Scale is a structured psychiatric interview evaluating MDD symptoms

[2] Or paste the following link into your browser: https://actinogenmedical.zoom.us/webinar/register/WN_mrZOSz2YSsaMGVnpvAQxYQ

- Greater Xananem benefit on MADRS scores was also evident in a smaller pre-specified group of 31 patients taking the drug as monotherapy, that is, without other anti-depressant medication: clinically significant at the end of treatment (4.3 points, Cd = 0.64, p = 0.06) but not four weeks after treatment
- The trial did not meet the primary endpoint of an "attention composite" of three Cogstate computerized tests measuring attention and working memory with similar and large improvements in performance observed. Mean improvements in the Xanamem and placebo groups were 0.3 and 0.4 z-score points, respectively (p not significant). The unexpectedly large placebo mean improvement may have impaired the ability of the trial to observe any short-term pro-cognitive effects of Xanamem
- The Cogstate Attention Composite is not used in the XanaMIA Alzheimer's disease trial. In XanaMIA key endpoints focus on a broader range of tests validated in the Alzheimer's field including a 7-point cognitive composite, the Clinical Dementia Rating Scale – Sum of Boxes functional scale and the Amsterdam Activities of Daily Living scale.

Dr Dana C Hilt, Actinogen's Chief Medical Officer, said:

"This encouraging result on depression is very positive to the whole Xanamem program and confirms 10 mg daily is an active clinical dose with the ability to potentially modify underlying biological processes in the brain. We will continue to examine these topline data in detail and the larger dataset to better understand the complete results and determine next steps for the depression program. The unexpected cognition placebo effect appears to have impaired the ability of Xanamem to show the pro-cognitive effects that we have observed in three previous studies.

"Our on-going XanaMIA phase 2b trial in biomarker-positive patients with mild to moderate Alzheimer's disease continues to enrol and remains on-track to deliver initial results in the middle of next year. I believe the results on acute symptomatic cognitive enhancement in XanaCIDD do not alter the chances of success for Xanamem in Alzheimer's disease where cortisol is implicated in the underlying biology of long-term disease progression reflected as functional and cognitive decline."

Dr Steven Gourlay, Actinogen's CEO said:

"The excellent safety profile of Xanamem was again demonstrated in this trial and the significant treatment benefits seen in depression are encouraging for both the depression and Alzheimer's disease programs. We believe the trial confirms the ability of Xanamem 10 mg daily to safely provide benefit to patients by inhibiting the synthesis of the "stress hormone" cortisol in the brain.

"The Actinogen team has done an outstanding job to deliver this trial aimed at acute symptom improvement in depressed patients suffering from cognitive dysfunction. Our primary objective remains the current XanaMIA Phase 2b trial designed to measure Xanamem's ability to slow or halt Alzheimer's disease progression over 36 weeks."

Details of the design of the XanaCIDD phase 2a trial in patients with CI and MDD:

- Randomized, double-blind, exploratory, proof-of-concept, placebo-controlled, parallel group, six-week trial in 167 patients with persistent MDD and measurable cognitive impairment at baseline (165 patients had at least one efficacy assessment)
- Xanamem 10mg or placebo was added to the existing stable anti-depressant therapy (n = 134), or used as monotherapy in patients with a previous history of anti-depressant treatment (n = 31)
- The primary endpoint was the computerized Cogstate "Attention Composite" test battery, measuring attention and working memory. This measure was shown to be a sensitive measure of short-term

Xanamem cognition benefit in the prior XanaMIA Part A and XanaHES trials[3] conducted in cognitively normal, older volunteers. In the XanaMIA Part A trial, a placebo improvement of approximately 0.15 points was observed

- The key secondary endpoint was the MADRS which is a structured psychiatric interview evaluating MDD symptoms. The MADRS is the commonly used endpoint for major MDD trials and regulatory approvals of anti-depressant medications. Improvements in placebo groups of 20-40% are commonplace. Approved anti-depressants typically report average MADRS improvements of ~2 to 3 points over placebo groups[4]
- The three subgroups pre-specified for efficacy analyses were patients with or without background anti-depressant therapy, patients with higher vs. lower levels of baseline depression, and patients with higher vs. lower levels of baseline cognitive dysfunction
- Other secondary endpoints remain the subject of on-going analysis include an executive function cognitive composite, a memory function cognitive composite, proportions of responders and global clinical assessment scores.

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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.

Actinogen is currently developing its lead compound, Xanamem, 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.

[3] Attention and working memory, sometimes characterized as the ability to focus, is a critical and essential component of cognitive ability
[4] Hengartner MP, Jakobsen JC, Sørensen A, Plöderl M (2020) Efficacy of new-generation antidepressants assessed with the Montgomery-Asberg Depression Rating Scale, the gold standard clinician rating scale: A meta-analysis of randomised placebo-controlled trials. PLOS ONE 15(2): e0229381. https://doi.org/10.1371/journal.pone.0229381

Current Clinical Trials

The **XanaCIDD Phase 2a cognition & depression trial** is a double-blind, six-week proof-of-concept, placebo-controlled, parallel group design trial in 167 patients. Participants are evenly randomized to receive Xanamem 10 mg once daily or placebo, in some cases in addition to their existing antidepressant therapy, and effects on cognition and depression are assessed. Positive topline results on depression were announced 12 August CY2024.

The **XanaMIA Phase 2b Alzheimer's disease trial** is a double-blind, 36-week treatment, placebo-controlled, parallel group design trial in 220 patients with mild to moderate AD and progressive disease, determined by clinical criteria and confirmed by an elevated level of the pTau181 protein biomarker in blood. Patients receive Xanamem 10 mg or placebo, once daily, and effects on cognition, function and progression of Alzheimer's disease are assessed. Thus, Xanamem is being assessed in this trial for its potential effects as a both a cognitive enhancer and a disease course modifier. Initial results from an interim analysis of the first 100 participants are anticipated in mid 2025.

About Xanamem

Xanamem's novel mechanism of action is to block the production of cortisol inside cells through the inhibition of the 11β-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 11β-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® is a trademark of Actinogen Medical.

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XanaCIDD phase 2a proof-of-concept trial of cognitive impairment and depression

Clinically & statistically significant Xanamem® benefits in depression without meeting the primary endpoint of a cognition "Attention Composite"

Dr Dana Hilt MD, CMO

Dr Steve Targum, MD, psychiatrist & independent depression expert

Dr Steve Gourlay, MBBS PhD, CEO

Xanamem® topline results webinar 12 August 2024

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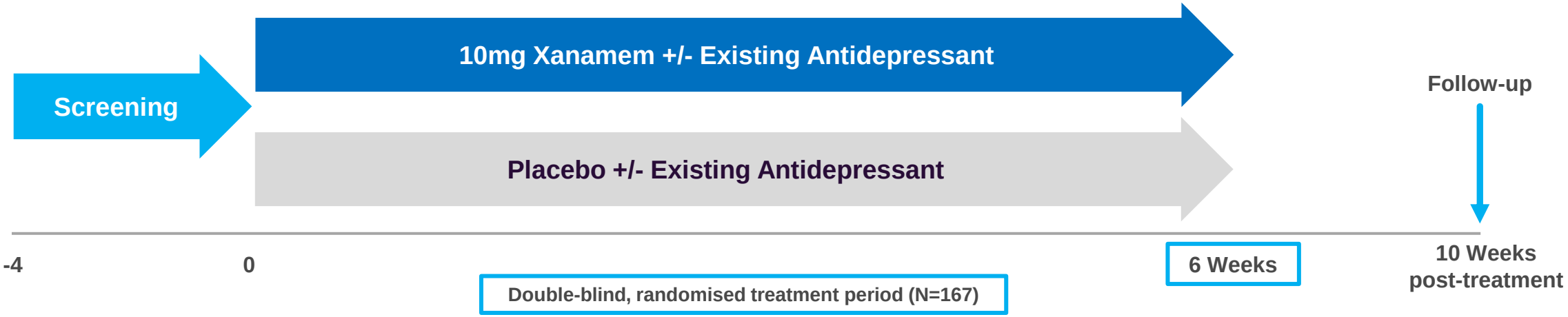
XanaCIDD topline summary

XanaCIDD trial design and methods

Phase 2, double-blind, proof-of-concept controlled trial to assess safety and efficacy



Primary Endpoint	Key Secondary Endpoints
• **Cogstate Cognitive Test Battery Attentional Composite** (attention and working memory)	• Montgomery-Åsberg Depression Rating Scale (**MADRS**) • Executive Function Cognitive Composite • Memory Function Cognitive Composite

Results summary

- The trial was well-conducted, with excellent data quality, no major differences between Australia and the UK or at high enrolling clinical sites
- Xanamem was safe and well tolerated
- No serious adverse events thought related to Xanamem have occurred in any trial to date
- Clinically and statistically significant treatment benefits of Xanamem were seen on depression either at the end of treatment (EOT) and/or at follow up four weeks post-treatment (PT)
- No treatment benefit greater than placebo observed in the primary cognition endpoint (Attention Composite):
    - A large and unexpected placebo effect size improvement of 0.4 points was observed in the primary endpoint of the Attention Composite at the EOT vs. 0.3 points for Xanamem

* Notes on clinical significance: Cd > 0.2 means “possible” Cd > 0.5 means “large” and/or absolute group difference of 4-5 MADRS points (as for many approved anti-depressants)

Clinically and statistically significant benefits over placebo on MADRS depression scale

- Xanamem treatment performed better than placebo, to a clinically, and in many cases, statistically significant extent, on the key secondary endpoint of depression (MADRS score) overall and in key pre-specified subgroups:
  - ✓ In all patients (n=165) a trend toward benefit was seen at the EOT visit and a clinically and statistically significant benefit four weeks post-treatment
  - ✓ Clinically and statistically significant improvements were seen in the 81 patients with less severe depression (MADRS < 26) at both the EOT visit and four weeks post-treatment
  - ✓ The numerically greatest improvement at the EOT was seen in a smaller group of 31 patients who were not taking anti-depressants i.e. using Xanamem as monotherapy

* Notes on clinical significance: Cd > 0.2 means “possible” Cd > 0.5 means “large” and/or absolute group difference of 4-5 MADRS points (as for many approved anti-depressants)

XanaCIDD topline results detail

XanaCIDD statistical methods

Statistical considerations reflect industry standard for proof-of-concept trials

- Primary endpoint of the Attention composite was analyzed using a standard Mixed Model for Repeated Measures (MMRM)
- Secondary endpoints (including depression by MADRS) were analyzed in the same way
- Four pre-specified subgroups were country (Australia/UK), current anti-depressant therapy (yes/no), baseline depression severity (lower/higher) and degree of cognitive impairment (lower/higher)
- p values are 1-sided hypothesis tests unless stated otherwise
- Effect sizes were calculated using the Cohen's d (Cd) statistic representing the effect as a % of the baseline population variability or standard deviation. This metric is frequently used in the cognition field[1] and is useful in depression[2]:
  - **> 0.2** = Potentially clinically meaningful effect size
  - **≥ 0.3** = Clinically meaningful effect size
  - **≥ 0.5** = Large and clinically meaningful effect size

1. Cohen et al. 1992 2. Nordhal-Hansen et al. 2024

Typical, broad, moderate depression trial population

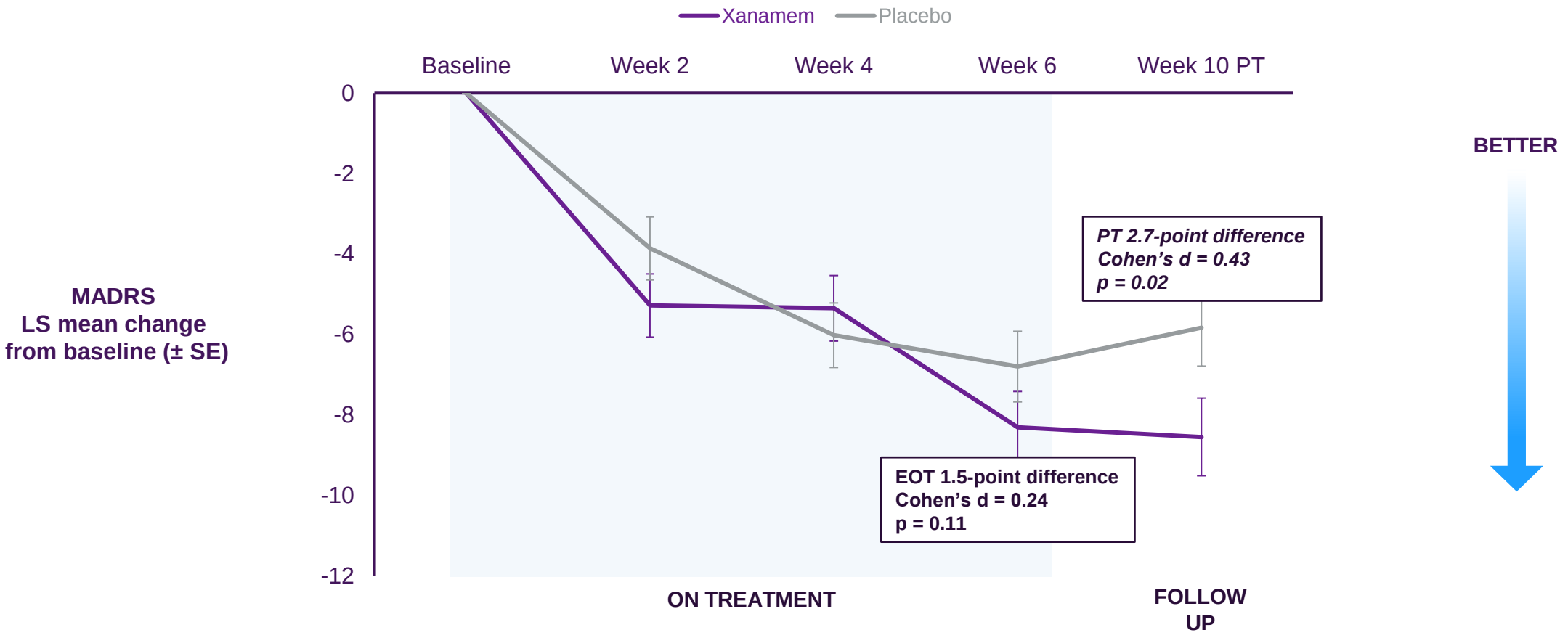
All patients on or previously treated with anti-depressants

	Xanamem (n=82)	Placebo (n=83)
Mean age (std dev)	49 (13)	49 (15)
% female	63	61
Mean HAM-D depression score (std dev)	21 (3)	21 (3)
Mean MADRS (std dev)	24 (6)	26 (7)
% on anti-depressant therapy	77%	84%
Mean cognition – Attention Composite (std dev)	0.11 (0.77)	-0.10 (0.98)

*HAMD assessed at screening

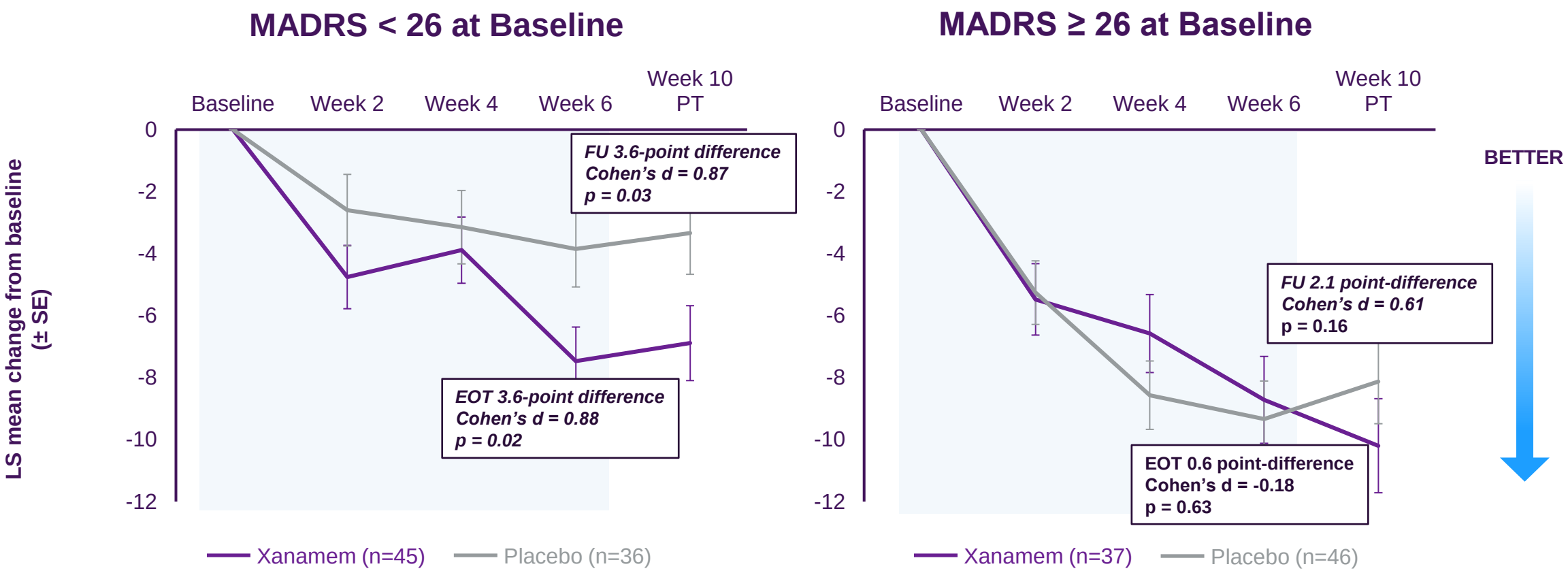
Xanamem benefit at Week 6 & 10

All randomized participants (n = 165)

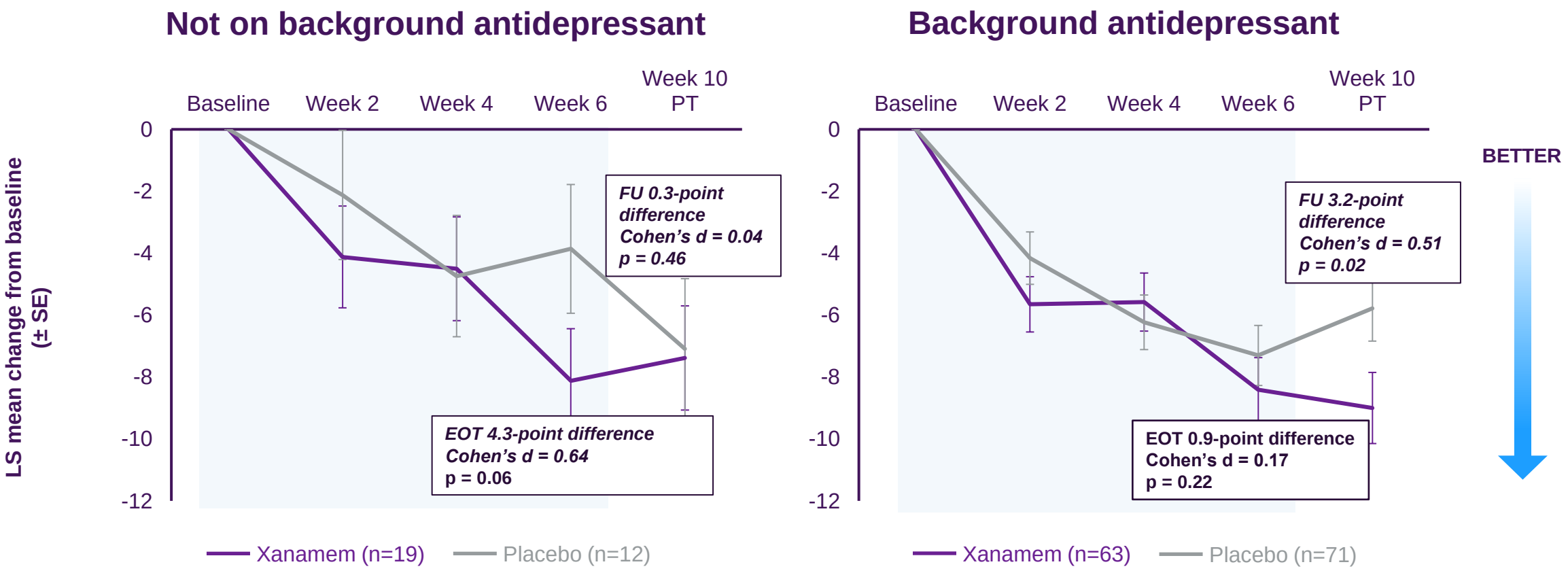


Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale

Persistent, statistically significant anti-depressant effect in patients with less severe depression

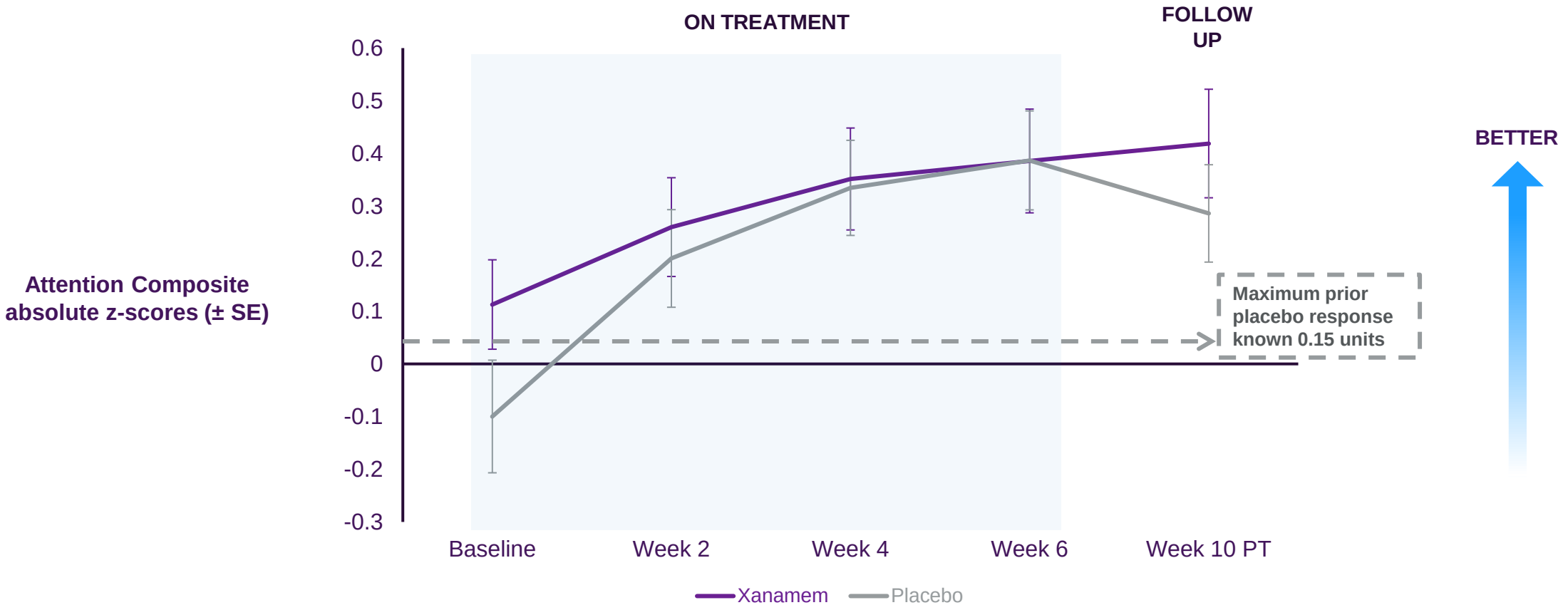


Potential anti-depressant effect in patients on or off another anti-depressant medication



Large placebo effect on the attention composite

Both Xanamem and placebo improved greatly over 6 weeks, p = not significant



Excellent safety profile consistent with prior trials

Summary of Treatment-Emergent Adverse Effects (TEAE)

	Xanamem N = 82	Placebo N = 83	Overall N = 165
Any TEAE	69 (84.1%)	67 (80.7%)	136 (82.4%)
TEAE related to trial drug	27 (32.9%)	24 (28.9%)	51 (30.9%)
Serious adverse event	0	1 (1.2%)	1 (0.6%)
Treatment-related TEAE leading to discontinuation or interruption of trial drug	3 (3.7%)	1 (1.2%)	4 (2.4%)
TEAEs with incidence ≥ 5% overall			
Headache	11 (13.4%)	16 (19.3%)	27 (16.4%)
Fatigue	6 (7.3%)	5 (6.0%)	11 (6.7%)
Nasopharyngitis	4 (4.9%)	6 (7.2%)	10 (6.1%)
Upper respiratory tract infection	5 (6.1%)	5 (6.0%)	10 (6.1%)

XanaCIDD conclusions & implications

Encouraging data on depression & safety

- Xanamem was safe and well tolerated; no significant safety issues were observed
  - There was no clear pattern of treatment-related adverse effects related to Xanamem
  - Safety profile consistent with prior trials
- No treatment effect observed in the primary cognition endpoint (Attention Composite)
  - A large and unexpected placebo effect was observed in the Attention Composite and other measurements of cognition which may have obscured any drug treatment effect
- Clinically and in many analyses statistically significant treatment benefits were seen on depression
  - Key secondary endpoint, MADRS, at EOT and four weeks of post-treatment follow up
- Persistence of Xanamem beneficial effects for at least four weeks after the end of treatment suggests some underlying biological modification may have occurred
- Trial data will be further explored in the coming weeks and reviewed with depression experts to evaluate paths forward for Xanamem in depression (QC is preliminary & on-going)

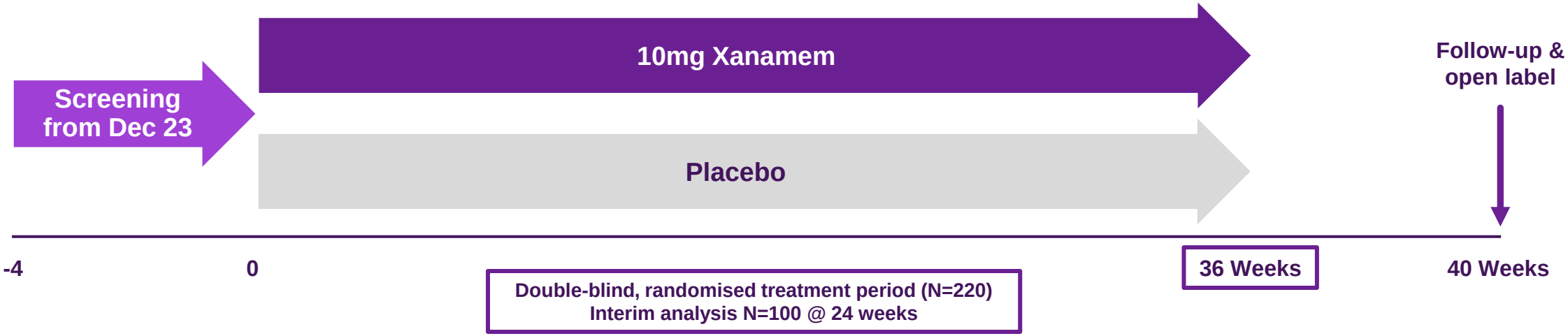
Positive implications of XanaCIDD for Alzheimer's

XanaMIA phase 2b – a 36-week trial in patients with biomarker-positive Alzheimer's disease

- Evidence of durable benefit on depression from control of brain cortisol validates Xanamem's mechanism of action at a 10 mg daily dose
- Two different trials based on the same cortisol mechanism:
  - XanaCIDD was an exploratory or proof-of-concept trial aimed at acute symptom improvement (6-weeks) in depressed patients with cognitive dysfunction
  - XanaMIA will measure the Xanamem's ability to slow or halt Alzheimer's disease progression (36-weeks) in biomarker positive patients with mild to moderate disease
- XanaMIA is a confirmatory Phase 2b AD trial whose design is based on functional and cognitive Xanamem benefit
  - Previous large clinical benefits observed in biomarker-positive patients with Alzheimer's
  - Previous positive animal model effects for 11β-HSD1 inhibition in Alzheimer's models
  - Now positive effects shown on depression

XanaMIA confirmatory phase 2b trial in Alzheimer's

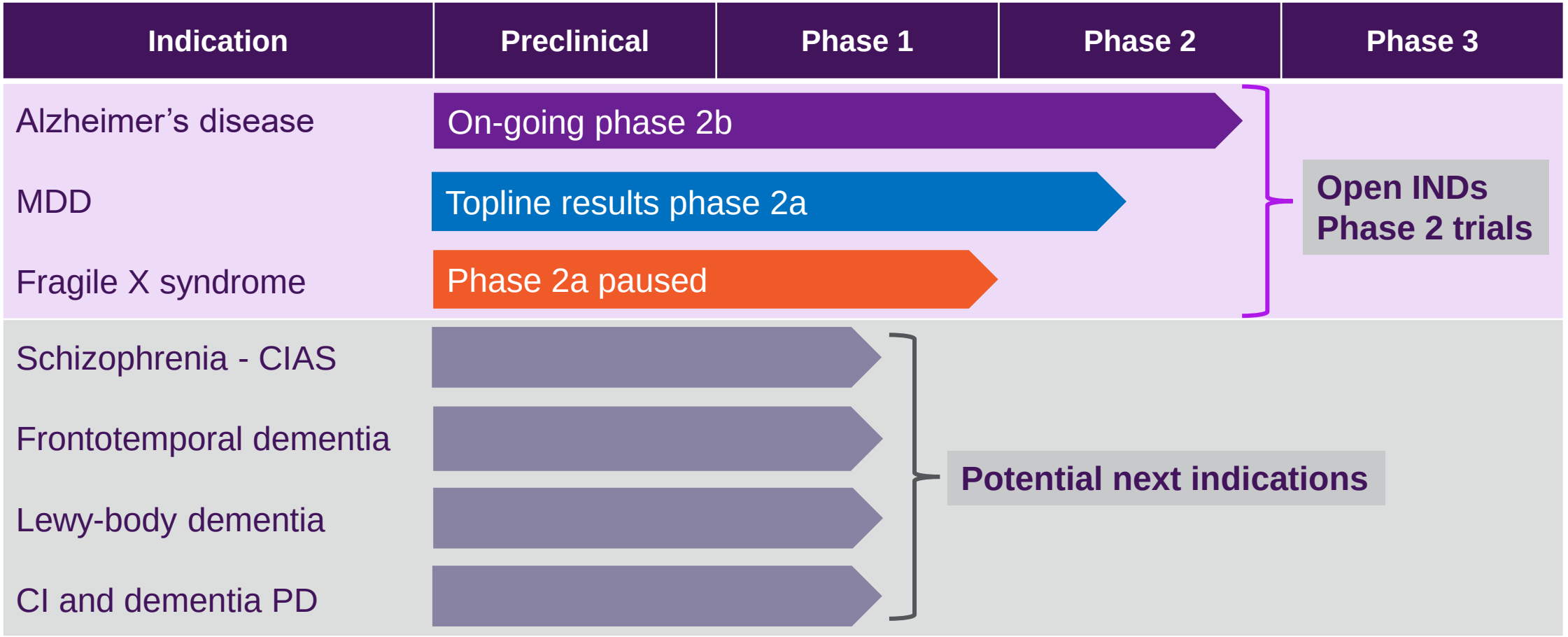
Initial, interim results in mid 2025, final results mid 2026



Key Inclusion Criteria	Primary Endpoint	Key Secondary Endpoints	Implementation
• Blood pTau biomarker positive • Mild-moderate Alzheimer's by NIA-AA criteria	• Cognitive Test Battery (7 cognitive measures, Cogstate tests not used)	• CDR-SB (functional and cognitive measure) • Amsterdam Activity of Daily Living (functional measure)	• Enrolment at 15 Australian sites • Expanding to US • Interim analysis when 100 people complete 24 weeks

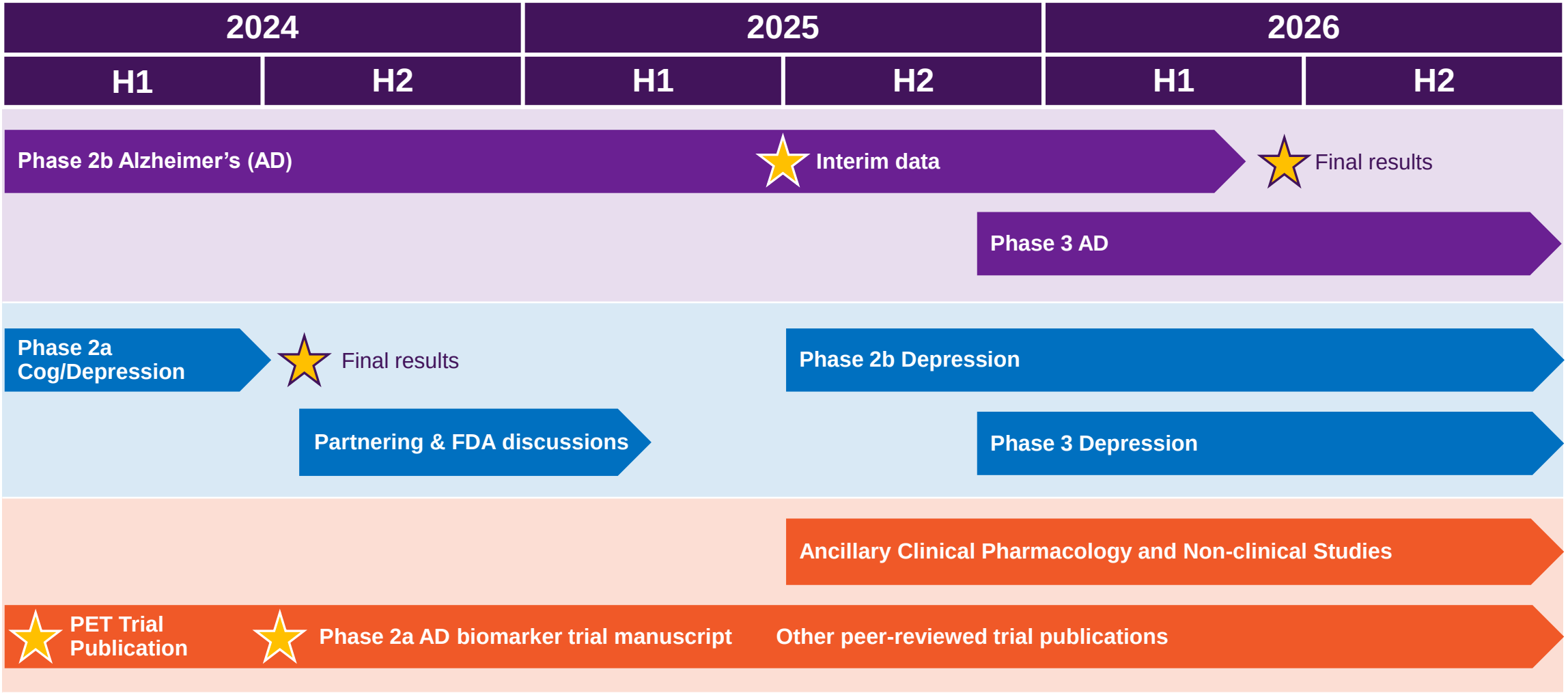
NIA-AA=National Institute of Aging - Alzheimer's Association; CDR-SB Clinical Dementia Rating Scale – Sum of Boxes

Xanamem pipeline unchanged



MDD: Major depressive disorder; **CIAS:** Cognitive impairment associated with schizophrenia; **CI:** Cognitive impairment; **PD:** Parkinson's disease

Two promising phase 2 clinical programs



Positive momentum for the Xanamem program

- Xanamem has an excellent safety/tolerability profile with more than 380 people treated
- Evidence of significant Xanamem activity on depression is encouraging and will be further explored in the coming weeks as additional data become available
- Persistent anti-depressant effects suggest activity on underlying biological brain processes
- Xanamem's safety and positive activity on depression at 10 mg daily further supports use of the 10 mg dose level in patients with Alzheimer's disease in the on-going XanaMIA phase 2b trial
- The XanaMIA phase 2b trial will continue to enrol patients in Australia while expanding to new US sites in order to deliver the interim analysis of the first 100 patients by mid 2025
- Cash runway through late 2025 with existing and accrued funds supports plan

References

1. Cohen, J. (1992). A power primer. *Psychological Bulletin, 112*(1), 155–159. https://doi.org/10.1037/0033-2909.112.1.155
2. Hengartner MP, Jakobsen JC, Sørensen A, Plöderl M (2020) Efficacy of new-generation antidepressants assessed with the Montgomery-Asberg Depression Rating Scale, the gold standard clinician rating scale: A meta-analysis of randomised placebo-controlled trials. PLOS ONE 15(2): e0229381. https://doi.org/10.1371/journal.pone.0229381

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