Topline Results from the Phase 2b PRImus-AD Trial: Safety and Efficacy of Oral PRI-002 in Early AD

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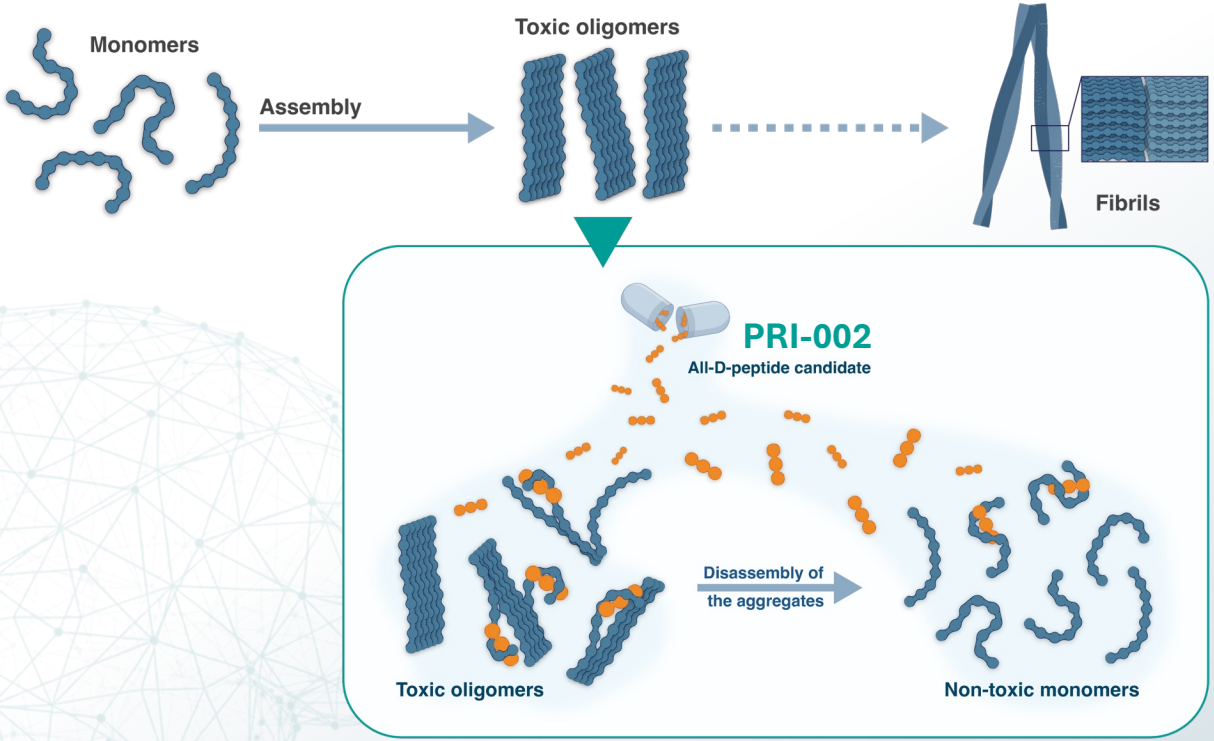
Disclosures

- **Oliver Peters** is a part-time employee at Priavoid GmbH and Charité Universitätsmedizin Berlin and has received research funding or consultancy fees or speech honoraria from pharmaceutical companies involved in the manufacturing and marketing of drugs for Alzheimer's disease including : Alector, Biogen, Eisai, Eli Lilly, Genentech, Grifols, Noselab, Novartis, Pharmatrophix, Predemtec, Priavoid, Prinnovation, Probiodrug, Roche Pharma, Roche Diagnostics, Schwabe and Vivoryon.
- **Dagmar Jürgens:** no disclosures (employee of Priavoid GmbH).
- **Gerhard Tischler** is an employee of PRInnovation GmbH and has received reimbursement from PRInnovation GmbH. Gerhard Tischler reports a relationship with Priavoid GmbH that includes; equity or stocks.
- **Tina Bartsch** was an employee of PRInnovation and is now an employee of Priavoid GmbH.
- **Lorenzo Bulli:** no disclosures (employee of PRInnovation GmbH)
- **Katja Lindner**: no disclosures (employee of PRInnovation GmbH).
- **Julie-Anne Gabelich**: no disclosures (employee of PRInnovation GmbH).
- **Julia Post-Schulz:** no disclosures (employee of PRInnovation GmbH)
- **Gunther Kauselmann:** no disclosures (employee of Priavoid GmbH).
- **Knut Adermann:** no disclosures (employee of Priavoid GmbH).
- **Kathrin Zeiger**: no disclosures (employee of PRInnovation GmbH).
- **Alexander Brener** is an employee and board member of PRInnovation GmbH and reports a relationship with Priavoid GmbH that includes; equity or stocks. Alexander Brener holds a patent issued in his name.
- **Dieter Willbold** is an employee of Priavoid GmbH. He is co-inventor of patents concerning PRI-002. He is co-founder of Priavoid GmbH and attyloid GmbH.

Priavoid's Detangler Approach

Aiming to address the underlying biology of neurodegenerative diseases

Visit our poster **P017** to learn more about our compounds' MoA



PRI-002:

- Specifically targets neurotoxic Aβ oligomers
- Dissolves oligomers into non-toxic monomers
- All-D-peptide: Less immunogenic and orally available

Favorable Safety and Initial Efficacy Signs in Phase 1b

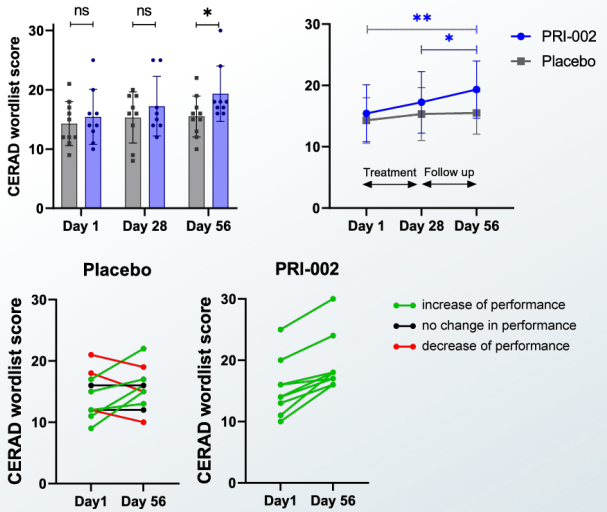
Oral PRI-002 treatment in patients with MCI or mild AD: a randomized, double-blind Phase 1b trial*

nature communications

- 19 patients, 1:1 randomization, treatment duration of 4 weeks

Summary of adverse events

	Placebo (*n* = 10)	PRI-002 (*n* = 9)	Total (*n* = 19)
Overall incidence of Adverse Events (AEs)			
Number of subjects with at least one AE (%)	8 (80%)	5 (56%)	13 (68%)
Mild (grade 1)	26	14	40
Moderate (grade 2)	1	2	3
Severe (grade 3)	0	0	0
AEs probably or possibly related to study treatment			
Number of subjects with at least one treatment-related AE (%)	1 (10%)	1 (11%)	2 (10.5%)
Mild (grade 1)	1	4	5
Moderate (grade 2)	0	2	2
Severe (grade 3)	0	0	0



- PRI-002 overall well-tolerated, no ARIA
- Early efficacy signs in CERAD score
- Improvement of synaptic plasticity by reducing neurotoxic oligomers support MoA

*Kutzsche J, et al. Nature Communications. 2025;16(1). doi:10.1038/s41467-025-59295-z

PRImus-AD: Study Design

Common Close Design treatment duration from 48 to 96 weeks

Placebo vs 300 vs 600 mg/day

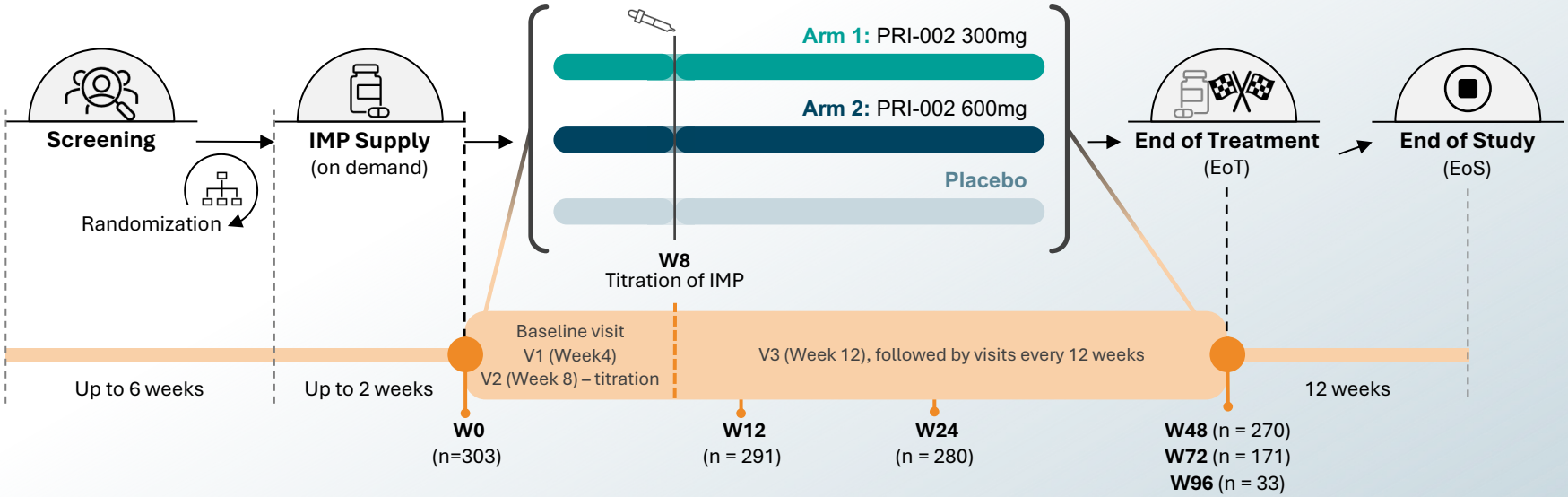
Visit our poster **P021** to learn more about our study design

Primary endpoints: Safety, CDR-SB at week 48

Secondary endpoints: ADAS-Cog13, ADCS-ADL, MMSE

38 Study sites in 6 EU countries

Recruitment target achieved in time



Demographics and Baseline Characteristics

Parameters		Overall (n = 303)	Placebo (n = 100)	300 mg (n = 100)	600 mg (n = 103)
Age at screening (y)	Mean (SD)	70.3 (6.5)	70.7 (6.7)	69.5 (6.3)	70.8 (6.6)
Sex	Female Male	159 (53%) 144 (48%)	52 (52%) 48 (48%)	54 (54%) 46 (46%)	53 (52%) 50 (49%)
Disease stage	MCI Mild Dementia	154 (51%) 149 (49%)	51 (51%) 49 (49%)	51 (51%) 49 (49%)	52 (51%) 51 (50%)
Confirmation of diagnosis	CSF Biomarker Profile PET	227 (75%) 76 (25%)	80 (80%) 20 (20%)	72 (72%) 28 (28%)	75 (73%) 28 (27%)
APOE e4 status	Non-carrier Heterozygous Homozygous	95 (31%) 143 (47%) 65 (22%)	31 (31%) 48 (48%) 21 (21%)	31 (31%) 48(48%) 21 (21%)	33 (32%) 47 (46%) 23 (22%)
CDR-SB	Mean (SD)	3.4 (1.5)	3.3 (1.4)	3.4 (1.6)	3.4 (1.5)
ADAS-Cog13	Mean (SD)	28.1 (8.0)	27.7 (7.2)	28.0 (8.5)	28.5 (8.3)
ADCS-ADL	Mean (SD)	39.3 (7.3)	39.6 (7.0%)	38.9 (7.6)	39.5 (7.4)
MMSE	Mean (SD)	24.5 (3.0)	24.3 (2.9)	24.6 (2.8)	24.4 (3.2)
CDR-G	0 Mean (SD) 0.5 Mean (SD) 1 Mean (SD) 2 Mean (SD)	1 (0.3%) 239 (79%) 62 (21%) 1 (0.3 %)	0 (0%) 79 (79%) 21 (21%) 0 (0%)	1 (1.0%) 78 (78%) 20 (20%) 1 (1.0%)	0 (0%) 82 (80%) 21 (20%) 0 (0%)

Primary Safety Outcome

Adverse Events at 48 Weeks

		Placebo (n = 100)	300mg (n = 100)	600mg (n = 103)
Any Treatment Emergent Adverse Event (TEAE)		77.0%	80.0%	71.8%
Any serious TEAE		8.0%	9.0%	8.7%
TEAE by relationship	Related Not Related	30.0% 72.0%	23.0% 72.0%	18.4% 64.1%
SAE by relationship	Related Not Related	0% 8.0%	0% 9.0%	0% 8.7%
TEAE leading to study drug discontinuation, interruption or dose adjustment		13.0%	3.9%	13.0%
Deaths until week 48 (n) *		1	1	1
Deaths from week 48-EoS (n)**		1	2	0

- There were no significant trends in changes over time or shifts from baseline for any of the TEAS, SAEs or deaths and no notable differences between groups over 48 weeks

*Cause of death: placebo: dementia Alzheimer's type; 300 mg: craniocerebral injury; 600 mg: lung neoplasm
**Cause of death: placebo: cerebrovascular accident; 300 mg: influenca, aspiration;

Primary Safety Outcome

Adverse Events at 48 Weeks

AEs* of Special Interest	Placebo (n=100)	300mg (n=100)	600mg (n=103)
ARIA-E	1.0%	2.0%	0%
ARIA-H	5.0%	8.0%	11.7%
Clinical AEs (>5%)			
Headache	12.0%	5.0%	2.9%
Dizziness	5.0%	6.0%	6.8%
Nausea	4.0%	11.0%	3.9%
Vomiting	4.0%	6.0%	1.0%
Depression	4.0%	5.0%	1.9%
Arthralgia	7.0%	7.0%	4.9%
Fall	8.0%	7.0%	5.8%
Paraclinical/Laboratory AEs (>5%)			
Blood lactate dehydrogenase	3.0%	5.0%	4.9%
Lymphopenia	2.9%	1.0%	5.8%
Hypertension	3.0%	6.0%	5.8%

* Classification by Primary Investigator

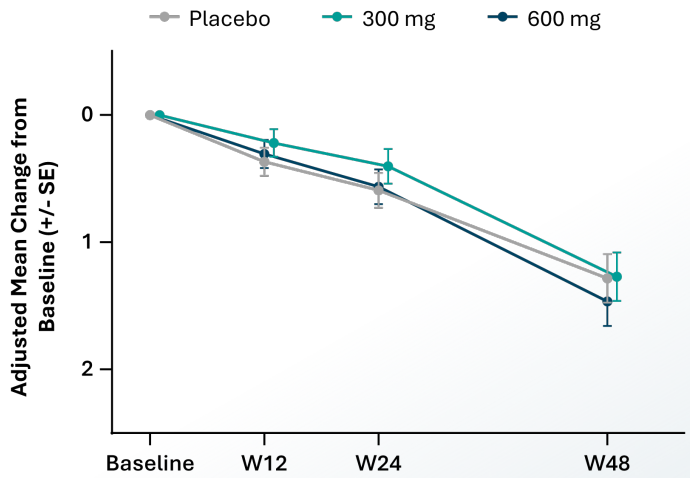
Visit our poster **P020** to learn more about our safety data

- The most common side effects were headache, dizziness and nausea
- There were no significant trends in changes over time or shifts from baseline for any of ECG or vital sign parameters and no notable differences between groups

Primary Efficacy Outcome CDR-SB

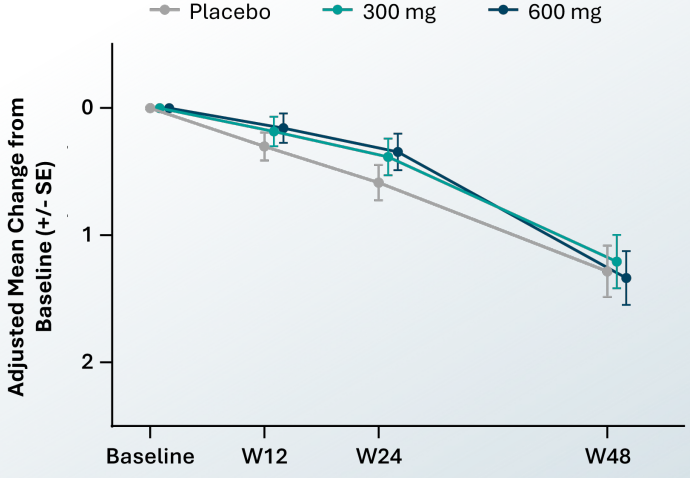
48 weeks, MMRM-based estimated mean

mITT



Placebo	99	96	93	88
300 mg	99	97	94	90
600 mg	101	94	93	86

PP



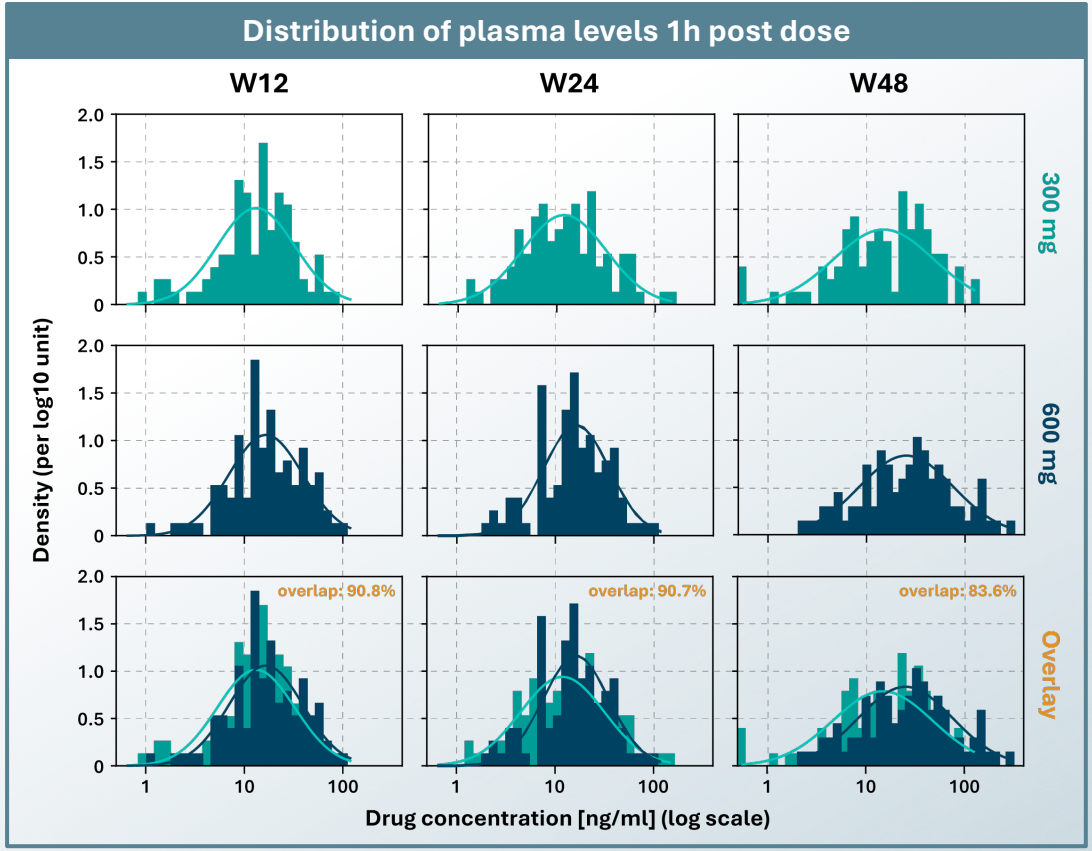
Placebo	86	86	85	85
300 mg	80	80	79	79
600 mg	78	76	78	77

Plasma exposure

PK at 12, 24 and 48 weeks –

1 h post dose for both treatment arms

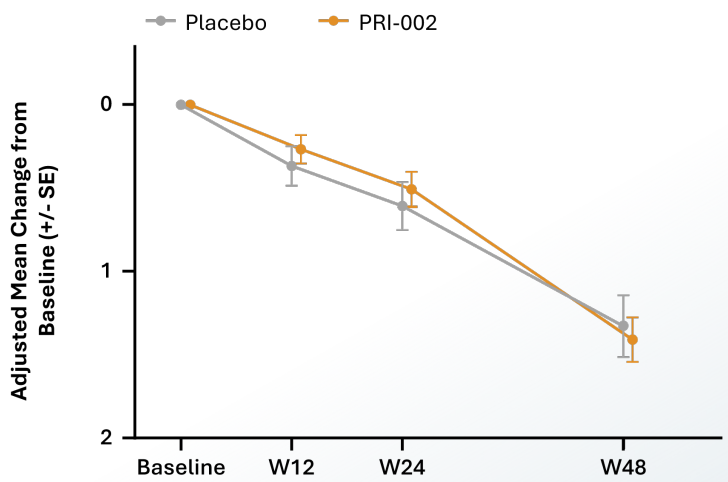
- Drug levels in plasma after 12w, 24w and 48w of daily oral treatment
- Largely overlapping plasma levels between 300 mg and 600 mg groups allow for a pooled analysis of the clinical outcomes



Primary Efficacy Outcome CDR-SB

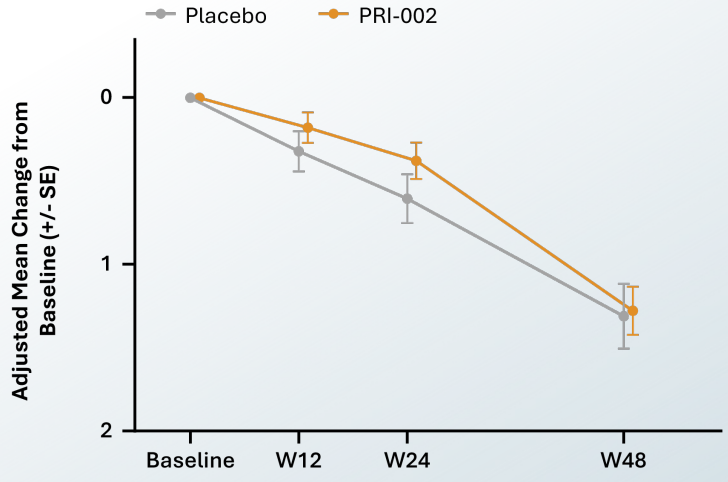
Pooled verum, 48 weeks, MMRM-based estimated mean

mITT



	Baseline	W12	W24	W48
Placebo	99	96	93	89
PRI-002	200	191	187	178

PP

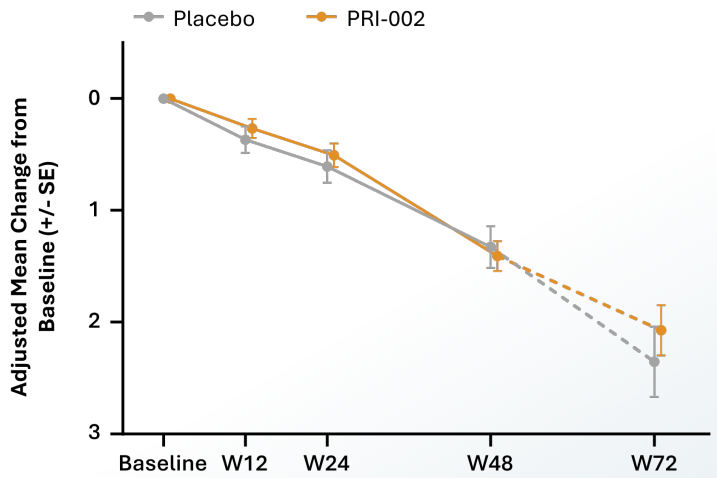


	Baseline	W12	W24	W48
Placebo	86	86	85	86
PRI-002	158	156	157	158

Efficacy Outcome CDR-SB

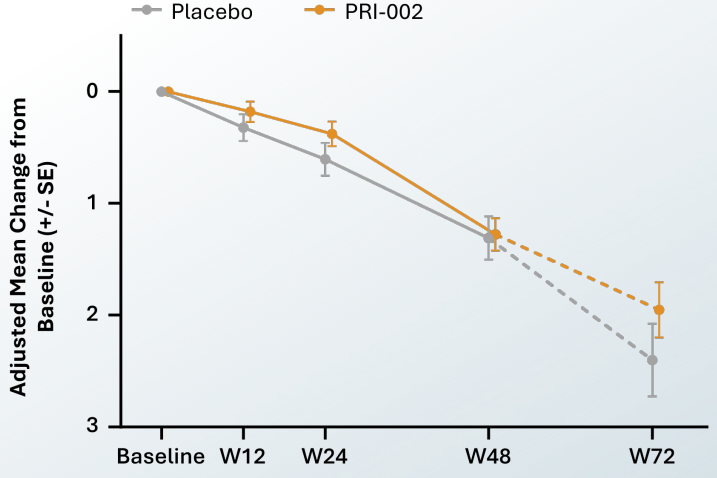
Pooled verum, 72 weeks, MMRM-based estimated mean

mITT



	Baseline	W12	W24	W48	W72
Placebo	99	96	93	89	55
PRI-002	200	191	187	178	109

PP

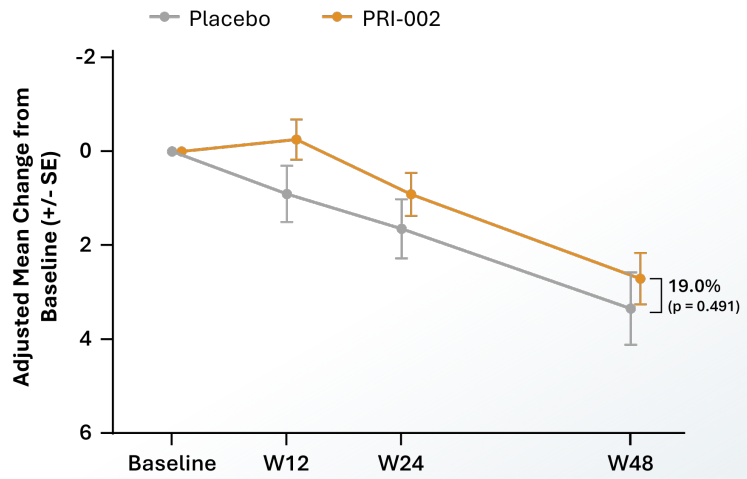


	Baseline	W12	W24	W48	W72
Placebo	86	86	85	86	54
PRI-002	158	156	157	158	95

Secondary Efficacy Outcome ADAS-Cog13

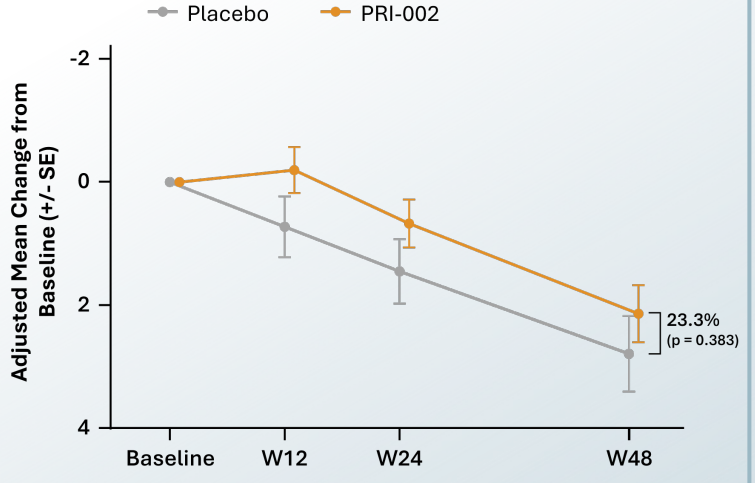
Pooled verum, 48 weeks, MMRM-based estimated mean

mITT



	Baseline	W12	W24	W48
Placebo	98	90	91	84
PRI-002	196	187	180	173

PP

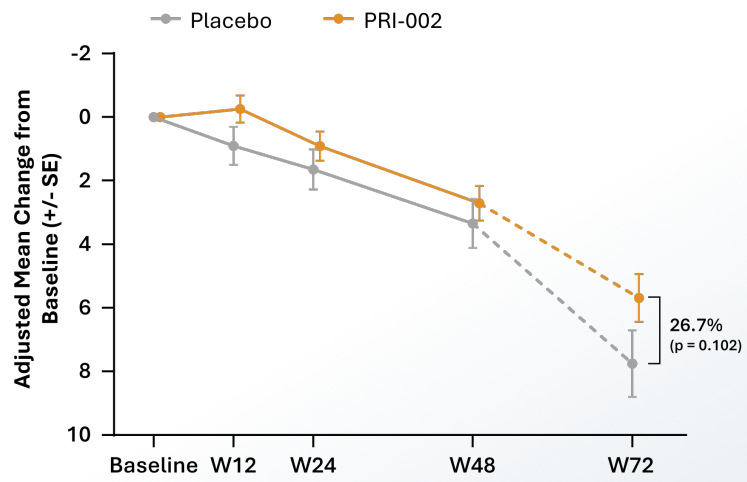


	Baseline	W12	W24	W48
Placebo	86	81	83	82
PRI-002	158	151	151	152

Secondary Efficacy Outcome ADAS-Cog13

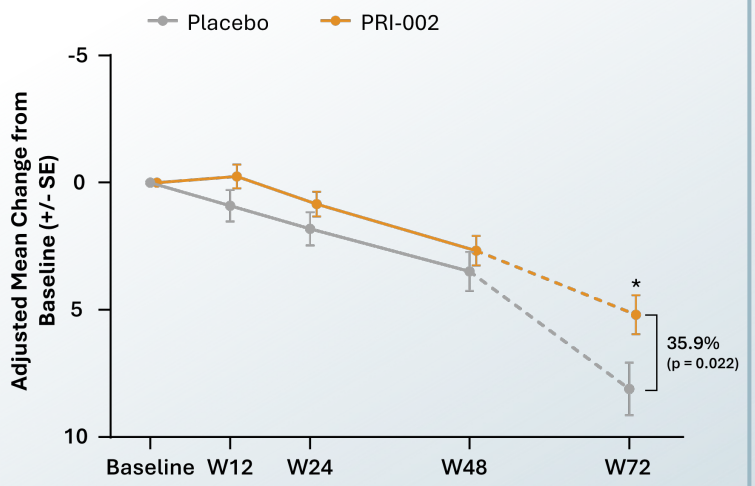
Pooled verum, 72 weeks, MMRM-based estimated mean

mITT



	Baseline	W12	W24	W48	W72
Placebo	98	90	91	84	52
PRI-002	196	187	180	173	107

PP

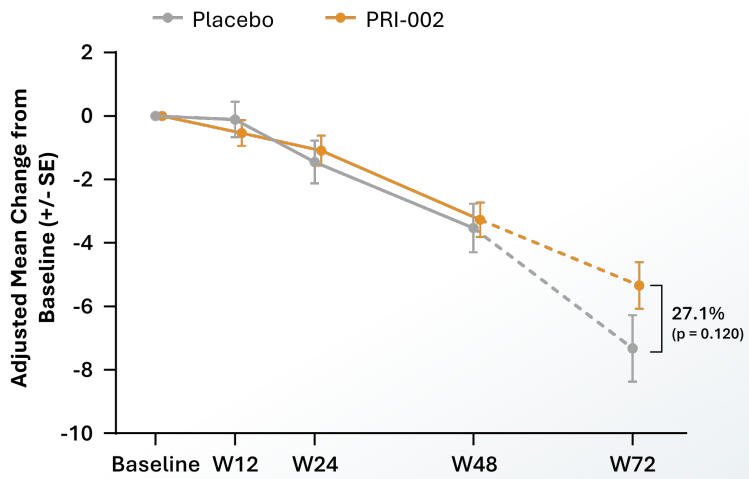


	Baseline	W12	W24	W48	W72
Placebo	86	81	83	82	51
PRI-002	158	151	151	152	93

Secondary Efficacy Outcome ADCS-ADL

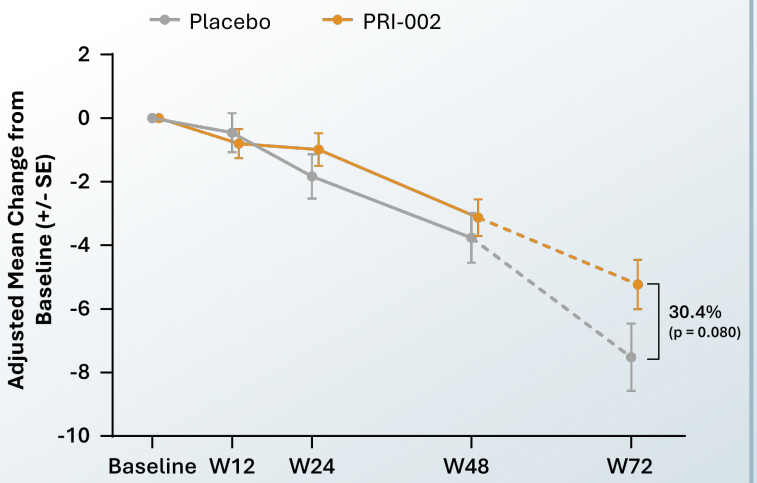
Pooled verum, 72 weeks, MMRM-based estimated mean

mITT



	Baseline	W12	W24	W48	W72
Placebo	97	94	91	87	53
PRI-002	198	191	186	179	109

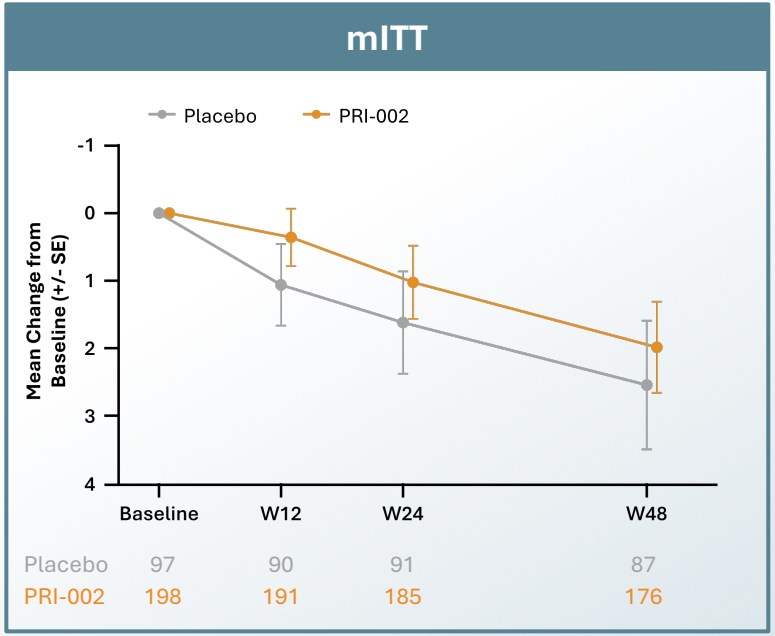
PP



	Baseline	W12	W24	W48	W72
Placebo	86	81	83	82	51
PRI-002	158	151	151	152	93

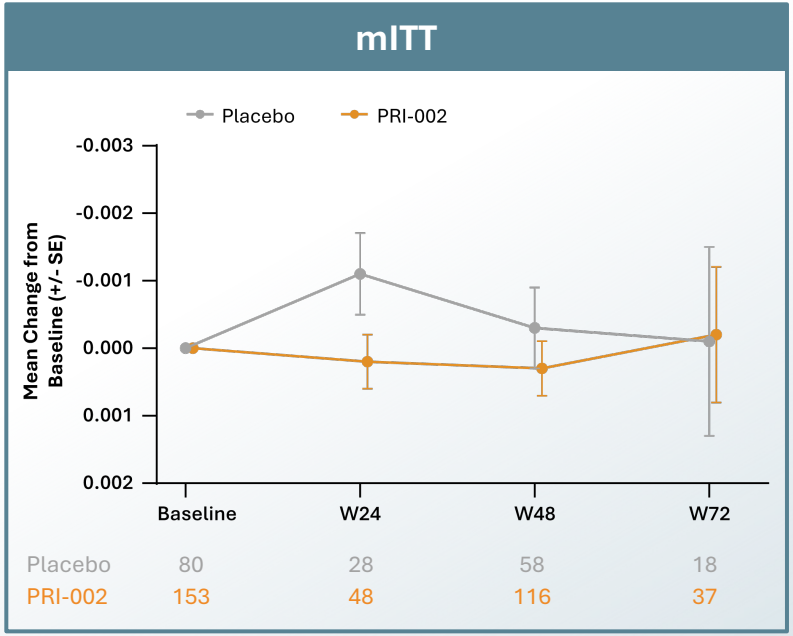
Preliminary Biomarker Observations: NFL (plasma)

Pooled verum, 48 weeks, MMRM-based estimated mean



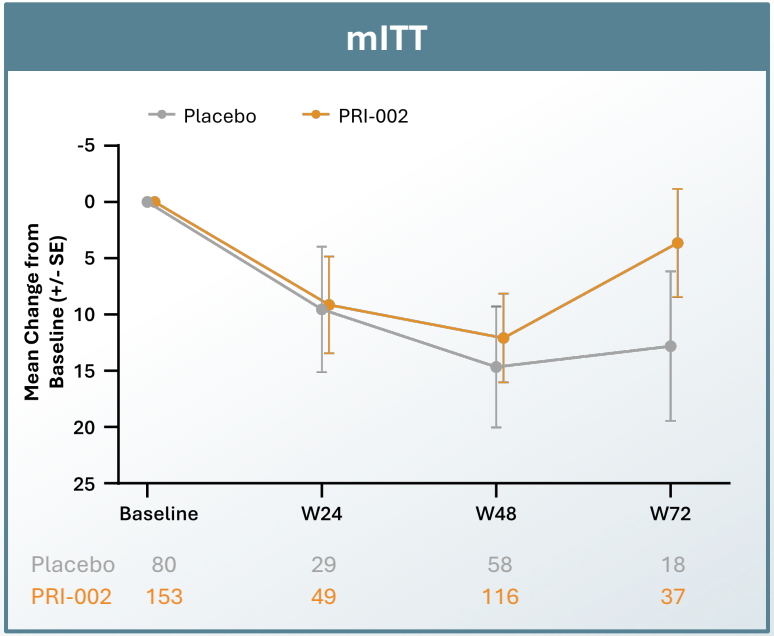
Preliminary Biomarker Observations: Aß42/40 ratio (CSF)

Pooled verum, 72 weeks, MMRM-based estimated mean



Preliminary Biomarker Observations: pTau181 (CSF)

Pooled verum, 72 weeks, MMRM-based estimated mean



Summary and Outlook

- The Phase 2 PRImus-AD trial met its primary safety endpoint with PRI-002 demonstrating a favorable safety and tolerability profile
- The trial did not meet its primary efficacy endpoint but showed encouraging clinical signals across key measures of cognition and daily functioning, with differences favoring PRI-002 becoming more pronounced at Week 72 and reaching statistical significance on ADAS-Cog in the per-protocol population
- Preliminary biomarker observations are consistent with PRI-002's proposed biological activity

- Comprehensive analyses of Alzheimer's disease-related biomarkers and brain volumetric measurements are ongoing to further characterize PRI-002's biological activity and its relationship with the observed clinical findings
- The full dataset is expected to be presented at scientific conferences in 2027

- The encouraging clinical signals, favorable safety profile and preliminary biomarker observations provide a rationale for further clinical development of PRI-002 as a potentially disease-modifying oral treatment for Alzheimer's disease

Thank You!



We sincerely thank all patients, care givers, investigators, clinical teams, collaborators and team members who made this study possible and support us on our mission to unlock new ways to address neurodegenerative disorders.

Abbreviations

AD	Alzheimer's Disease
ADAS-Cog13	Alzheimer's Disease Assessment Scale – Cognitive Subscale (13-item version)
ADCS-ADL	Alzheimer's Disease Cooperative Study – Activities of Daily Living
AE/ SAE/ TEAE	Adverse Events/ Serious Adverse Events/ Treatment-Emergent Adverse Event
ARIA-E	Amyloid-Related Imaging Abnormalities – Edema
ARIA-H	Amyloid-Related Imaging Abnormalities – Hemosiderin deposits, cerebral microhemorrhage
Aß	Amyloid-beta
CDR-G/SB	Clinical Dementia Rating-Global Score/ Sum of Boxes
CSF	Cerebral Spinal Fluid
ECG	Echocardiogram
EoS/ EoT	End of Study/ End of Treatment
IC	Informed Consent
IMP	Investigational Medicinal Product
MCI	Mild Cognitive Impairment
mITT	Modified Intention-to-Treat
MMRM	Mixed Model for Repeated Measures
MMSE	Mini-Mental State Examination
MoA	Mode of Action
NFL	Neurofilament Light Chain
PP	Per Protocol
P-Tau	Phospho-Tau