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Intranasal Fully Human Anti-CD3 mAb (“FORALUMAB”) Therapy to Enable Breakthroughs in Neuroinflammatory and Neurodegenerative Diseases

Nasdaq: TLSA

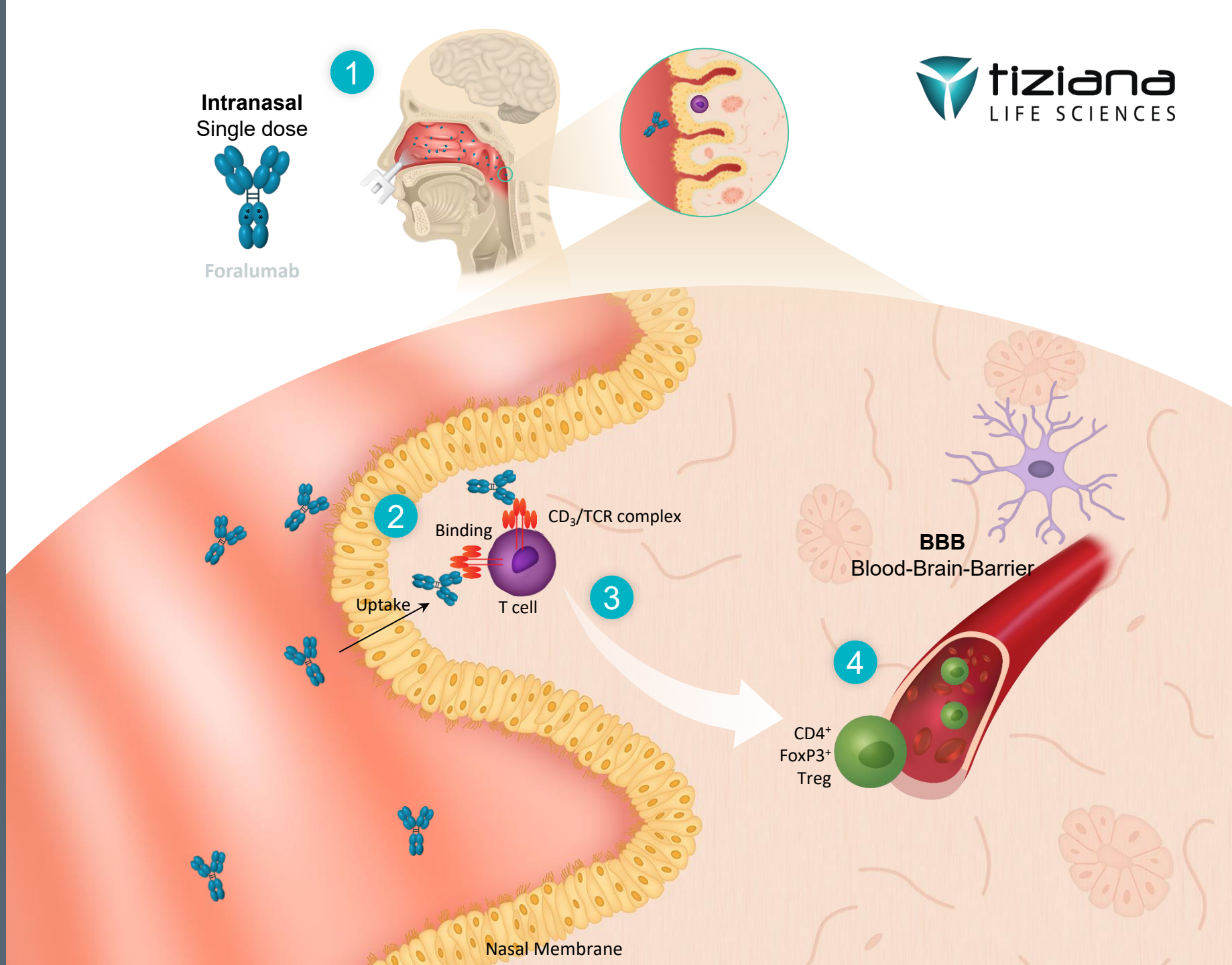
Foralumab: Mechanism of Action[1,2]

Patient inhales the antibody intranasally

Binding of foralumab to the T-cell receptor complex in cervical lymph node

Tregs are then created and activated

These created Tregs then cross the blood brain barrier and regulate the activated innate immune system (microglia).

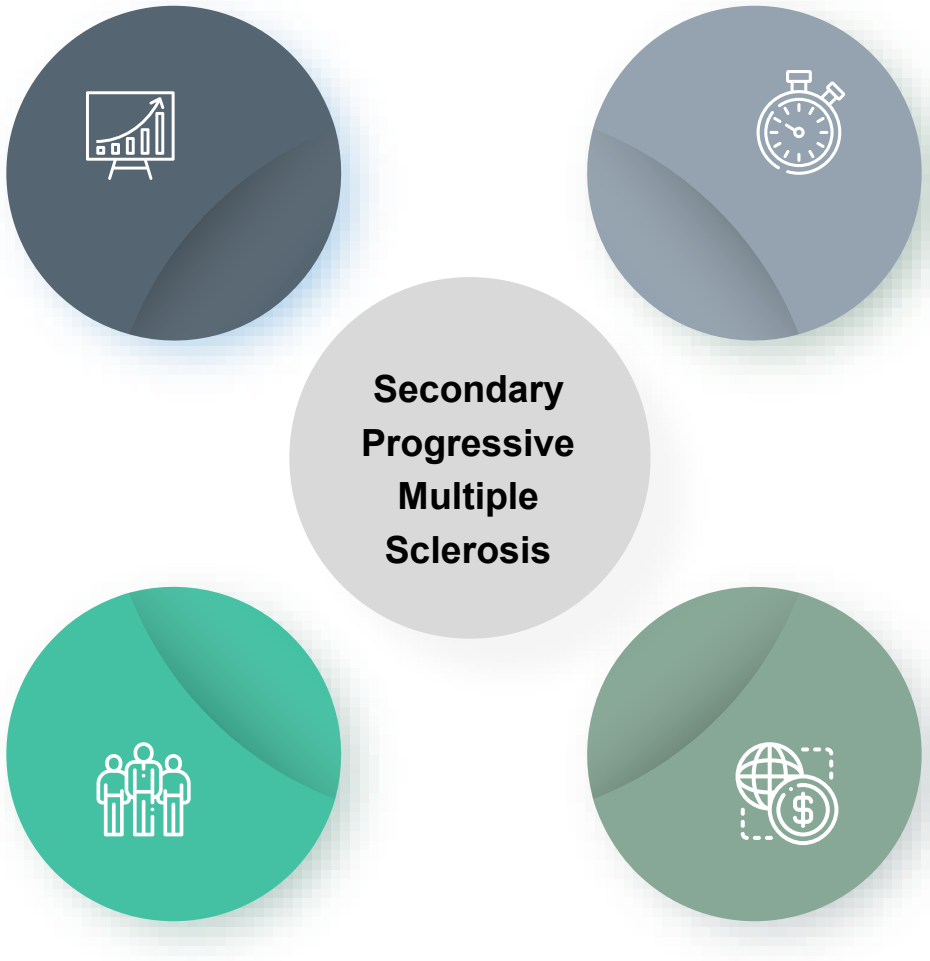


[1] https://www.pnas.org/doi/10.1073/pnas.2220272120
[2] https://www.pnas.org/doi/10.1073/pnas.2309221120

Non-active Secondary Progressive Multiple Sclerosis (na-SPMS)

Non-Active Secondary Progressive Multiple Sclerosis is an Attractive Market

Approximately 25% of Relapsing Remitting MS (RRMS) patients are estimated to progress to SPMS*



There are currently no effective treatments for Non-Active (non-relapsing) SPMS

Patients who have progression independent of relapses (PIRA) are underserved

Global Multiple Sclerosis therapeutic market size $25.9 billion (2023) CAGR of 5.9% from 2024 - 2030

Global Ocrevus (Roche) sales estimated to be over $9.1 billion#

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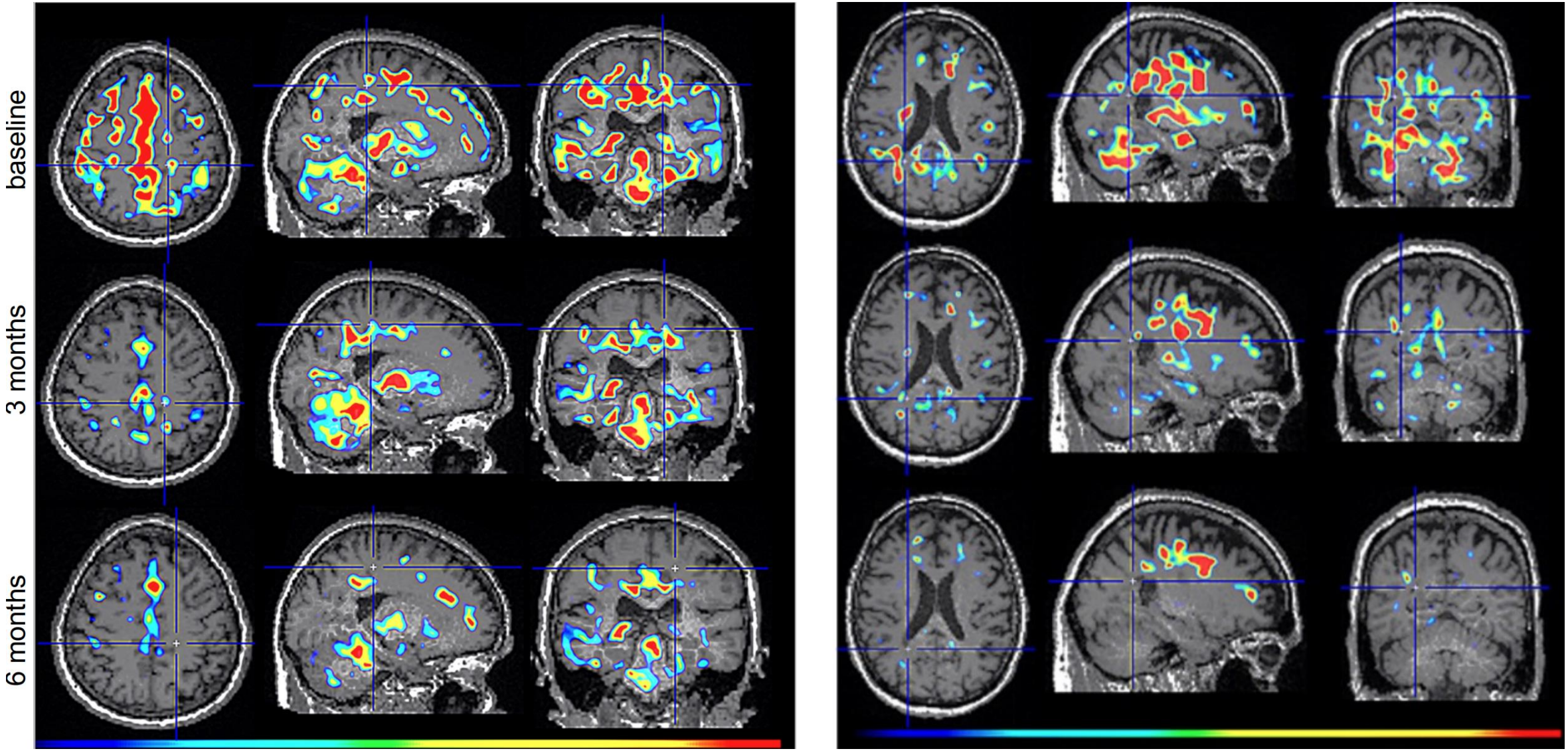
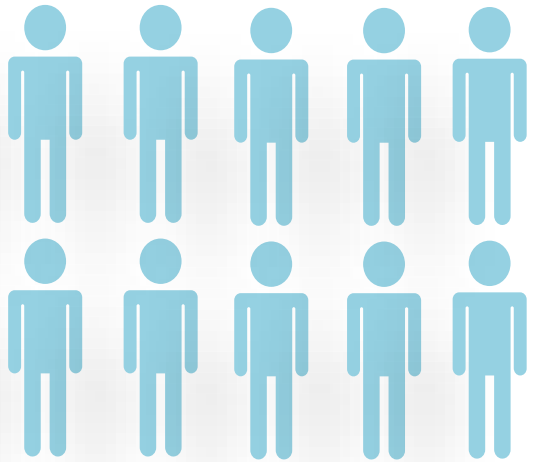
Sources: *Vasanthaprasad et al. BMC Neurology (2022) 22:301 **Tjalf Ziemssen, et. al Neurol Neuroimmunol Neuroinflamm. 2023 Jan; 10(1): e200064; #Ocrevus global sales reported by Roche as CHF 8.4 billion CHF in 2023

Intranasal Foralumab Reduces Neuroinflammation



Improvement or Stabilization in all na-SPMS Expanded Access Patients

- Clinical improvements or stabilization was reported across the entire group, as measured by Fatigue scores (MFIS), T25FW, EDSS, or Pyramidal Scores
- Fatigue scores improved in 7/10 patients
- TSPO-PET shows significant reduction in microglia activation after 6 months of treatment ($p<0.05$)
- 75% of patients treated continuously for 12 months showed improvement in EDSS scores



Preprint Paper Online on MedRxiv and submitted for peer review May 2025

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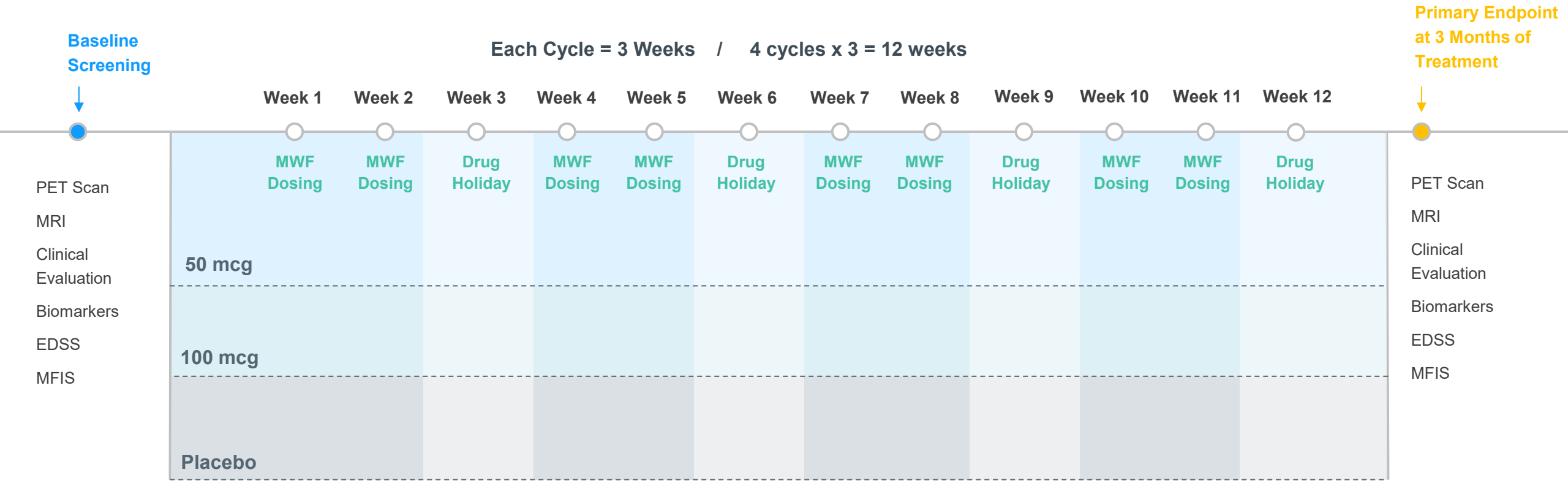
https://www.medrxiv.org/content/10.1101/2025.04.30.25326602v1

Non-Active Secondary Progressive MS: Phase 2a Study Design:

Intranasal Foralumab Dosing (n=48); Double-Blind, Placebo-Controlled



Sites Enrolled:

HARVARD MEDICAL SCHOOL
BRIGHAM AND WOMEN'S HOSPITAL
Jefferson Thomas Jefferson University
Yale UNIVERSITY
UNIVERSITY OF MASSACHUSETTS AMHERST 1863
JOHNS HOPKINS UNIVERSITY
University at Buffalo
Cornell University

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Multiple System Atrophy (MSA)

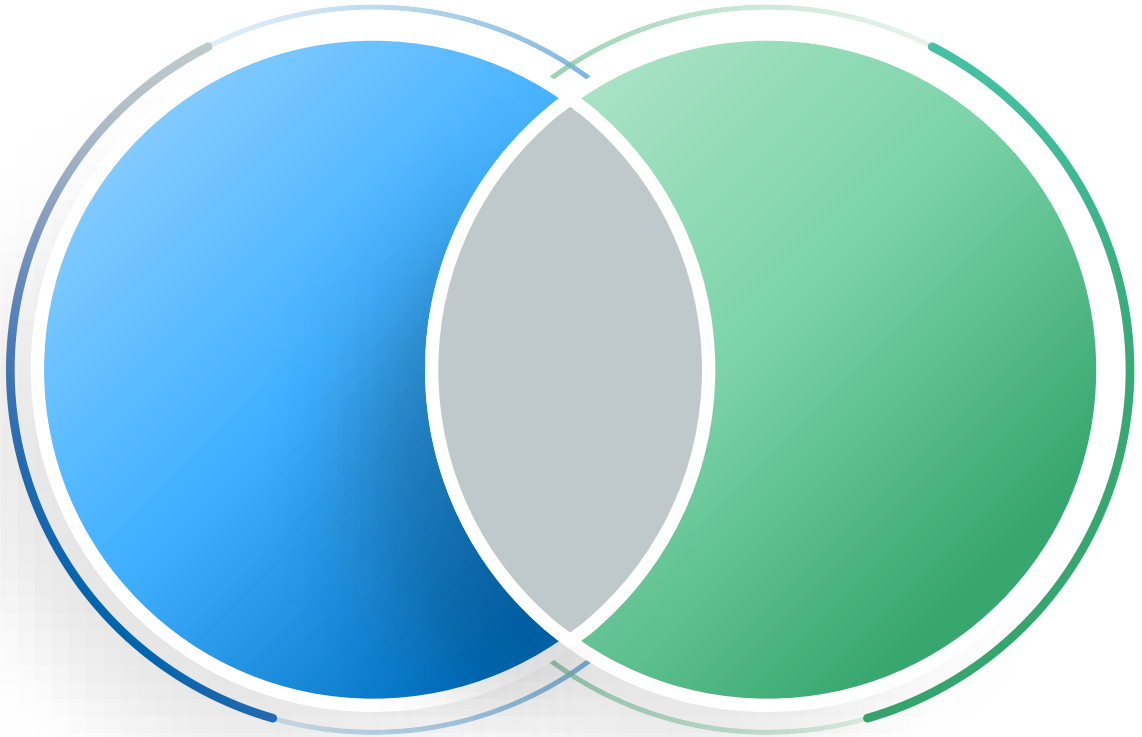
Multiple System Atrophy (MSA) Phase 2a Clinical Trial

MSA is a rapidly progressive neurological disorder. It is caused by degeneration or atrophy (shrinking) of nerve cells in several (or multiple) areas of the brain.

Classified as Orphan disease by the FDA

No FDA approved treatments available

Similar symptoms to Parkinson's disease so often misdiagnosed



FDA Approved IND Q3 2025

First patient dosed in August 2025 and will assess microglial activation and MSA clinical outcome measures

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Early Symptomatic & Moderate Alzheimer's Disease (AD)

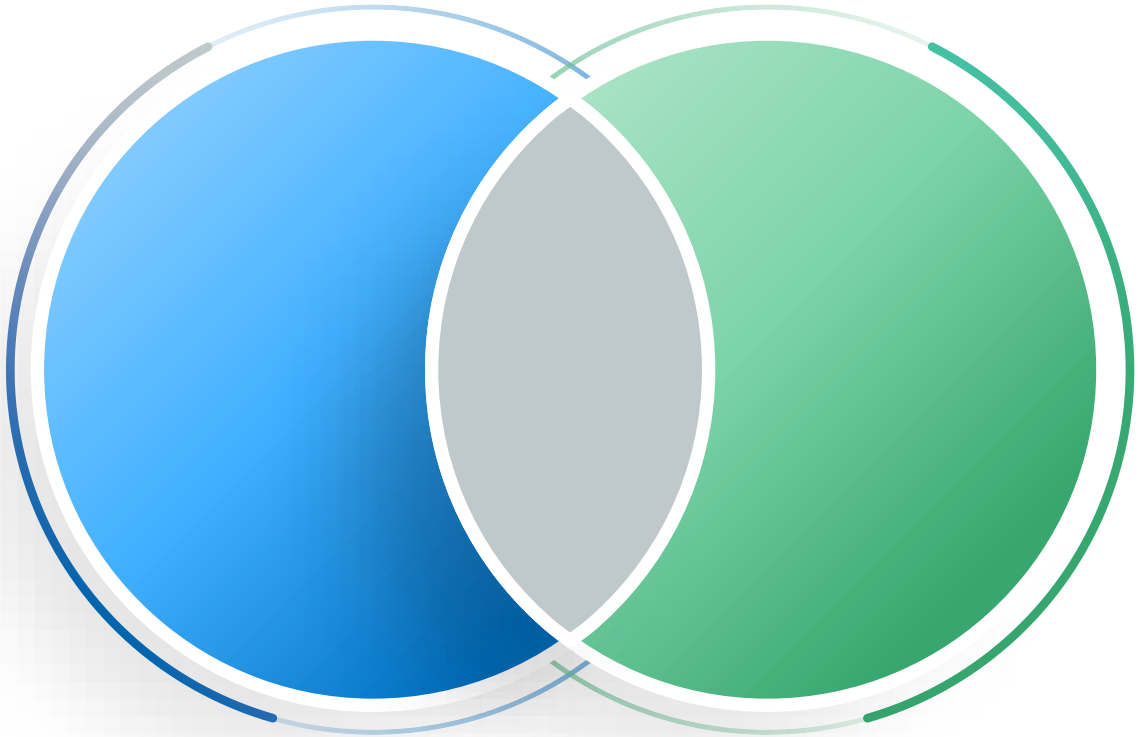
Alzheimer's Disease Program is Advancing and Equally Exciting

Awarded $4 Million Grant from National Institutes of Health (NIH), National Institute on Aging to Study Anti-CD3 in Alzheimer's Disease

National Institutes of Health

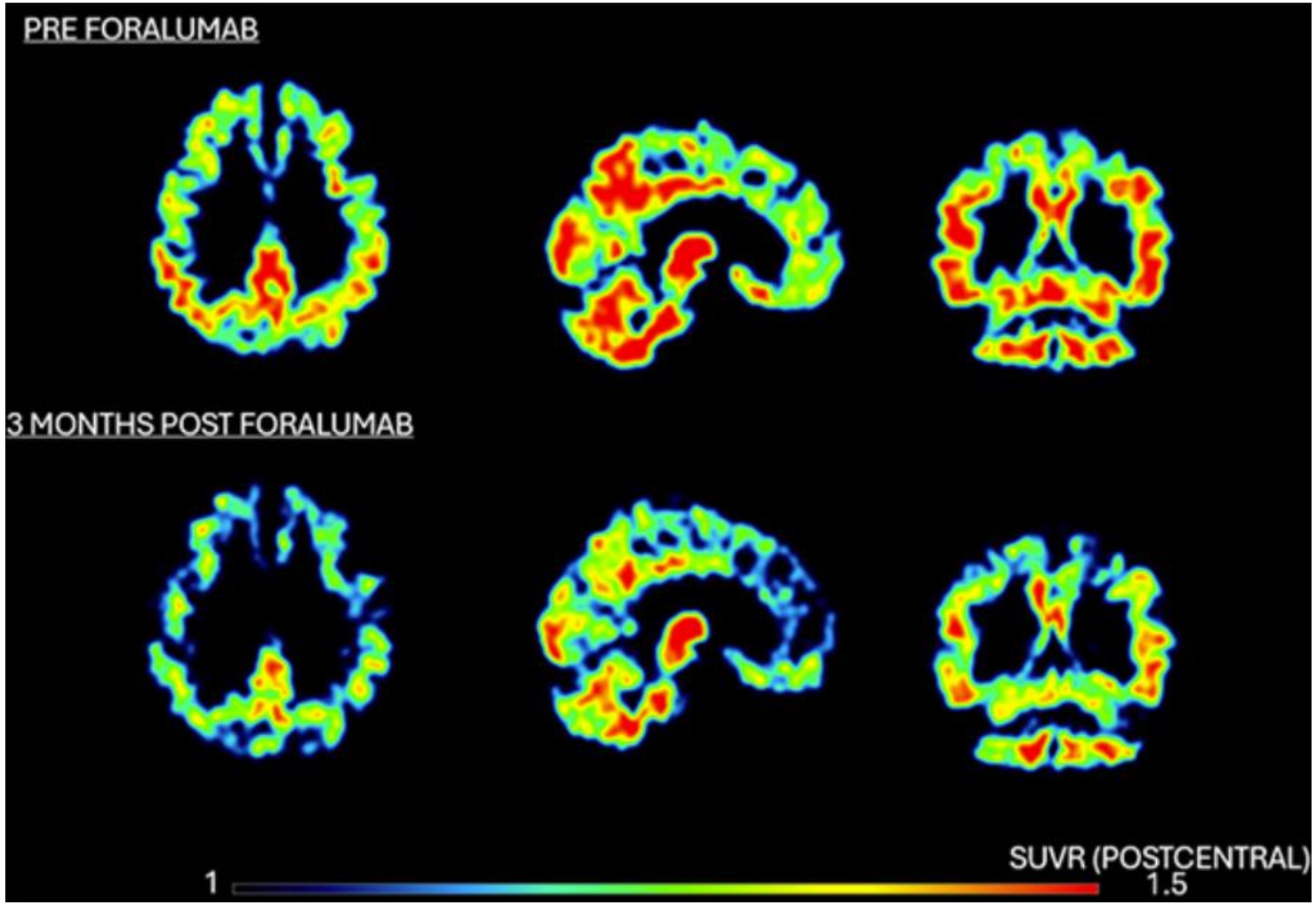
Letter to Proceed received for IND to conduct a Phase 2 study of intranasal foralumab in Alzheimer's disease patients

Phase 2 trial for Early Symptomatic Alzheimer's Disease started Dec 2025 and will assess microglial activation as part of combination therapy with recently approved drugs



Expanded Access program granted by FDA to treat Moderate Alzheimer's Disease began dosing in December 2024

Moderate Alzheimer's Disease Expanded Access Study



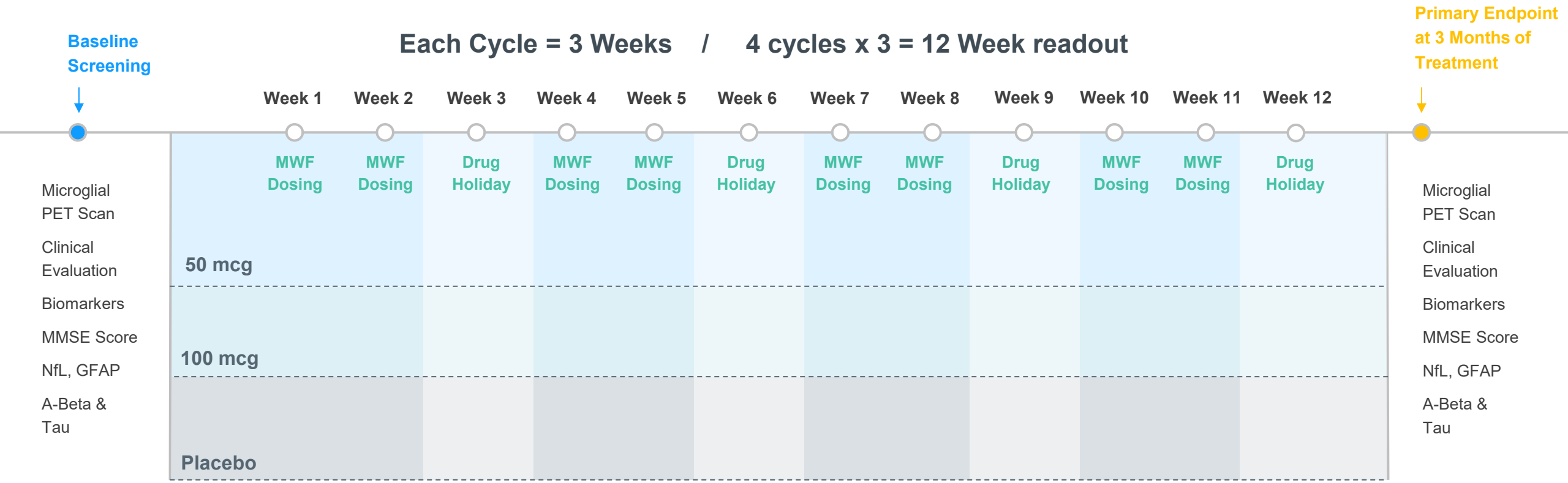
- 78-Year-Old Moderate Alzheimer's patient treated for 3 months with intranasal foralumab
- PET Scan shows significant reduction of microglia activity following 3 months of treatment

- Data presented at AD/PD in April 2025
- Data Published in the Journal of Clinical Nuclear Medicine in May 2025

https://journals.lww.com/nuclearmed/Fulltext/9900/dampening_of_microglial_activation_with_nasal.1721.aspx

Early Symptomatic Alzheimer's Disease: Phase 2a Study Design:

Intranasal Foralumab Dosing (n=32); Double-Blind, Placebo-Controlled, 2 Treatment Arms: 12 x 50mcg, 12 x 100mcg, 8 x Placebo.



Amyotrophic Lateral Sclerosis (ALS)

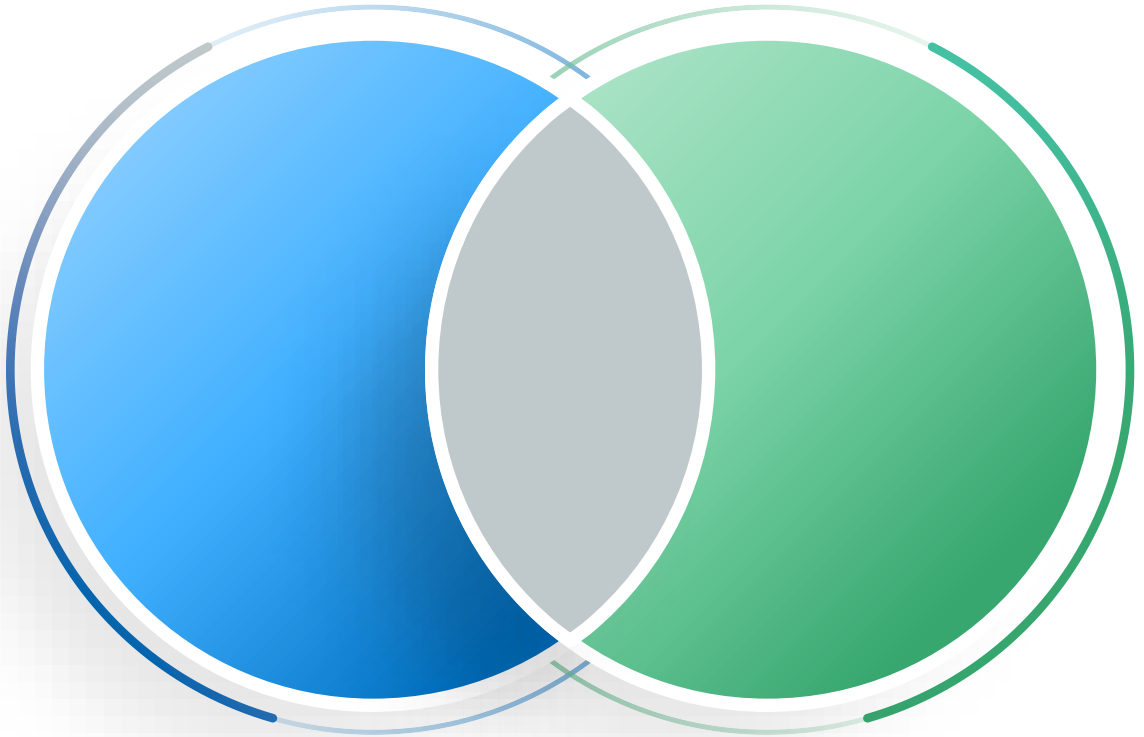
ALS Phase 2 Study Supported by The ALS Association

Grant Awarded from The ALS Association to Study Intranasal Foralumab in ALS patients in a 20 Patient, Dose Ranging, Phase 2 Clinical Trial

Global Market size of $790m

CARG of 5.8% from 2024-2030

$1.38bln by 2035

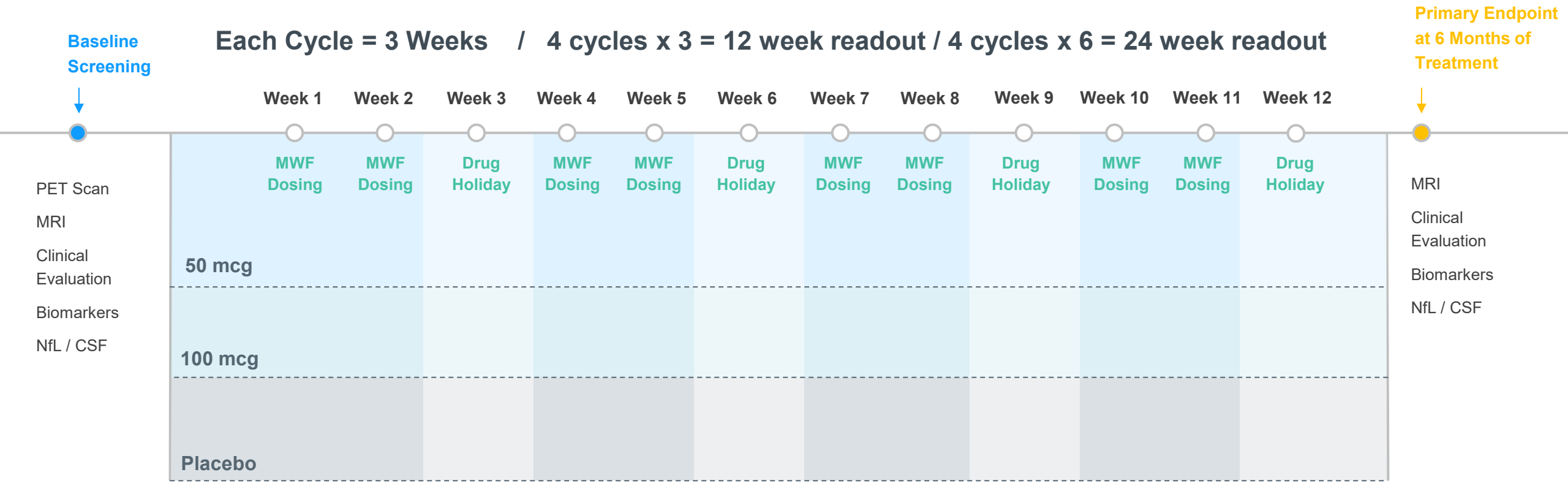


IND Filed March 2025

Phase 2 trial planned to start H1 2026 and will assess microglial activation

ALS: Phase 2a Study Design:

Intranasal Foralumab Dosing (n=24); Randomized, Placebo Controlled Trial



Intranasal Foralumab Pipeline

	Preclinical	IND	Phase 1	Expanded Access Program	Phase 2	Phase 3	
Non-Active Secondary Progressive Multiple Sclerosis Phase 2 Study							Expecting Topline Data 2H 2026
Multiple System Atrophy (MSA) Phase 2 Study							Began dosing Aug 2025
Alzheimer's Disease (Mild) Phase 2 Study							Began dosing Dec 2025
ALS Phase 2 Study							Expected 1H 2026 Start
Non-Active Secondary Progressive Multiple Sclerosis (EA Program)							Ongoing Expanded Access Program, Began 2021
Moderate Alzheimer's Disease (EA Program)							Expanded Access Program Began Dec 2024

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