



Alzheon Promotes Glenn E. Pauly to Chief Commercial Officer and Strengthens Commercial Organization with New Executive Appointments to Lead Planned U.S. Commercial Launch of Oral ALZ-801/Valiltramiprosate in 2025

ALZ-801 Has Potential to Become the First Oral Agent to Slow and Prevent Alzheimer’s Pathology in Patients and Healthy Individuals at Risk for the Disease

Dina Lynch Appointed to Vice President of Market Access and Nate Greene Appointed to Vice President of Brand Marketing to Support US Commercial Launch

Fully Enrolled Pivotal APOLLOE4 Phase 3 Trial of ALZ-801/Valiltramiprosate Progressing Successfully, Enabling Topline Data Readout and NDA Filing in 2024

FRAMINGHAM, Mass., Dec. 5, 2023 — [Alzheon, Inc.](#), a clinical-stage biopharmaceutical company developing a broad portfolio of product candidates and diagnostic assays for patients suffering from Alzheimer’s disease (AD) and other neurodegenerative disorders, today announced that it has strengthened its commercial organization with the promotion of Glenn E. Pauly to Chief Commercial Officer and the appointments of Dina Lynch to Vice President of Market Access, and Nate Greene to Vice President of Brand Marketing. These appointments will support preparations for the commercial launch of investigational agent ALZ-801, which is currently being evaluated in the APOLLOE4 Phase 3 trial in Early Alzheimer’s disease patients with two copies of the APOE4 gene.

“Our well-differentiated efficacy results combined with a favorable safety profile, showing no increase in vasogenic brain edema in more than 2,800 patients, position ALZ-801 to potentially become the first oral agent that can slow or even stop and prevent Alzheimer’s pathology in patients and healthy individuals at risk for the disease,” said Martin Tolar, MD, PhD, Founder, President, and CEO of Alzheon. “Alzheon’s novel therapeutic approach has an opportunity to transform the standard of care and improve access to treatment for all Alzheimer’s patients. APOLLOE4 Phase 3 trial evaluating oral ALZ-801 in APOE4/4 patients with Early Alzheimer’s disease is expected to read out in the third quarter of 2024, and we are now building the team to prepare the NDA filing and commercial launch of the product in the U.S. in 2025.”

Mr. Pauly joined Alzheon in July of 2022 as the Head of Commercial, where he began the process of internal planning and building of organizational infrastructure to support preparations for a commercial launch of ALZ-801. He has more than 20 years of commercial launch, sales, market access, and leadership experience in the biopharmaceutical industry. Prior to joining Alzheon, Mr. Pauly was the West Division General Manager and Vice President at Biogen with responsibility for the launch of the anti-amyloid antibody Aduhelm®. Previously, he held roles at Johnson & Johnson, Genentech, and AstraZeneca, where he supported launches and commercialization for multiple products including Remicade®, Actemra®, Xolair®, and Fasenra®.

Ms. Lynch brings over 25 years of biopharma industry experience to Alzheon, with extensive expertise in building and managing market access functions. Ms. Lynch joins Alzheon from Nabriva Therapeutics, where she held dual roles as Vice President, Sales and Managed Care. Previously, she served as Vice President, Market Access at both Otonomy and Optimer.

Mr. Greene brings 25 years of experience in the biopharma industry in central nervous system (CNS) diseases. He has broad experience in marketing, sales, and access leadership as well as commercial strategy, operations, business development and alliance management. Previously, Mr. Greene held commercial and executive roles at Janssen, Otsuka, and Biogen, with over a dozen launches in CNS disorders and Alzheimer's.

“We are committed to delivering a disruptive option to the Alzheimer's disease market as quickly as possible and I am excited to have Dina and Nate join the commercial team,” said Mr. Pauly. “Their depth of experience and understanding of access pathways and marketing strategies are what we need during this crucial period. Having these strong leaders further enhances our ability to establish critical partnerships and patient advocacy programs to support a successful commercial launch in 2025.”

About ALZ-801

[ALZ-801/valiltramiprosate](#) is an investigational oral agent in [Phase 3 development](#) as a potentially disease modifying treatment for AD.^{1,3} ALZ-801 is designed to block the formation of neurotoxic soluble beta amyloid oligomers causing cognitive decline in Alzheimer's patients. In mechanism of action studies, ALZ-801 has fully inhibited the formation of neurotoxic soluble beta amyloid oligomers at the Phase 3 clinical dose.^{5,6} ALZ-801 acts through a novel [enveloping molecular mechanism of action](#) to fully block formation of neurotoxic soluble amyloid oligomers in the human brain⁷ associated with the onset and progression of cognitive decline in AD patients.¹⁻⁴ ALZ-801 received Fast Track designation from the U.S. Food and Drug Administration in 2017 for Alzheimer's disease. In clinical trials, ALZ-801 has shown favorable safety results.^{5-7,9} The initial [Phase 3 program for ALZ-801](#) is focusing on Early AD patients with the APOE4/4 genotype, with potential future program expansion to AD treatment and prevention in patients carrying one copy of the APOE4 gene and noncarriers.¹⁻⁴

ALZ-801 Phase 2 Biomarker Trial

Biomarker Effects of ALZ-801 in APOE4 Carriers With Early Alzheimer's Disease ([NCT04693520](#)): This ongoing trial was designed to evaluate the effects of 265 mg twice daily oral dose of ALZ-801

on biomarkers of AD pathology in subjects with Early AD, who have either the APOE4/4 or APOE3/4 genotype and constitute 65-70% of Alzheimer's patients. The trial also included evaluation of clinical efficacy, safety, tolerability, and pharmacokinetic profile of ALZ-801 over 104 weeks of treatment. An ongoing long-term extension of the trial evaluates ALZ-801 for an additional 52 weeks of treatment for a total of 156 weeks.

ALZ-801 APOLLOE4 Phase 3 Trial

An Efficacy and Safety Study of ALZ-801 in APOE4/4 Early Alzheimer's Disease Subjects ([NCT04770220](#)): This ongoing trial is designed to evaluate the efficacy, safety, biomarker and imaging effects of 265 mg twice daily oral dose of ALZ-801 in Early AD subjects with two copies of the apolipoprotein ε4 allele (APOE4/4 homozygotes), who constitute approximately 15% of Alzheimer's patients. This is a double-blind, randomized trial comparing oral ALZ-801 to placebo treatment over 78 weeks. The APOLLOE4 trial is supported by a \$51 million [grant from the National Institute on Aging](#).

About Alzheon

[Alzheon, Inc.](#) is a clinical-stage biopharmaceutical company developing a broad portfolio of product candidates and diagnostic assays for patients suffering from Alzheimer's disease and other neurodegenerative disorders. We are committed to developing innovative medicines by directly addressing the underlying pathology of neurodegeneration. Our lead Alzheimer's clinical candidate, [ALZ-801/valiltramiprosate](#), is an oral agent in [Phase 3 development](#) as a potentially disease modifying treatment for AD. ALZ-801 is an oral small molecule that has been observed to fully block the formation of neurotoxic soluble amyloid oligomers in preclinical tests. Our clinical expertise and technology platform are focused on developing drug candidates and diagnostic assays using a [precision medicine approach](#) based on individual genetic and biomarker information to advance therapies with the greatest impact for patients.

Alzheon Scientific Publications

- ¹Tolar M, et al: *Neurotoxic Soluble Amyloid Oligomers Drive Alzheimer's Pathogenesis and Represent a Clinically Validated Target for Slowing Disease Progression*, **International Journal of Molecular Sciences**, 2021; 22, 6355.
- ²Abushakra S, et al: *APOE ε4/ε4 Homozygotes with Early Alzheimer's Disease Show Accelerated Hippocampal Atrophy and Cortical Thinning that Correlates with Cognitive Decline*, **Alzheimer's & Dementia**, 2020; 6: e12117.
- ³Tolar M, et al: *Aducanumab, Gantenerumab, BAN2401, and ALZ-801—the First Wave of Amyloid-Targeting Drugs for Alzheimer's Disease with Potential for Near Term Approval*, **Alzheimer's Research & Therapy**, 2020; 12: 95.
- ⁴Tolar M, et al: *The Path Forward in Alzheimer's Disease Therapeutics: Reevaluating the Amyloid Cascade Hypothesis*, **Alzheimer's & Dementia**, 2019; 1-8.
- ⁵Hey JA, et al: *Discovery and Identification of an Endogenous Metabolite of Tramiprosate and Its Prodrug ALZ-801 that Inhibits Beta Amyloid Oligomer Formation in the Human Brain*, **CNS Drugs**, 2018; 32(9): 849-861.

- ⁶ Hey JA, et al: *Clinical Pharmacokinetics and Safety of ALZ-801, a Novel Prodrug of Tramiprosate in Development for the Treatment of Alzheimer's Disease*, **Clinical Pharmacokinetics**, 2018; 57(3): 315–333.
- ⁷ Abushakra S, et al: *Clinical Effects of Tramiprosate in APOE4/4 Homozygous Patients with Mild Alzheimer's Disease Suggest Disease Modification Potential*, **Journal of Prevention of Alzheimer's Disease**, 2017; 4(3): 149-156.
- ⁸ Kocis P, et al: *Elucidating the Aβ42 Anti-Aggregation Mechanism of Action of Tramiprosate in Alzheimer's Disease: Integrating Molecular Analytical Methods, Pharmacokinetic and Clinical Data*, **CNS Drugs**, 2017; 31(6): 495-509.
- ⁹ Abushakra S, et al: *Clinical Benefits of Tramiprosate in Alzheimer's Disease Are Associated with Higher Number of APOE4 Alleles: The "APOE4 Gene-Dose Effect,"* **Journal of Prevention of Alzheimer's Disease**, 2016; 3(4): 219-228.

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