



## **Alzheon Announces Appointment of Renowned Biopharma Executive Gino Santini to Board of Directors**

*Mr. Santini's Extensive Global Commercial and Business Development Experience Strengthens Alzheon's Board Leadership*

*ALZ-801/Valitramiprosate Has Potential to Become the First Oral Agent to Slow Alzheimer's Pathology in Patients*

*Fully Enrolled Pivotal APOLLOE4 Phase 3 Trial in Early Alzheimer's Disease Patients on Track for Topline Data Readout and Initiation of NDA Submission in 2024*

FRAMINGHAM, Mass., June 12, 2024 — [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 appointed Gino Santini to its Board of Directors.

"2024 is a transformational year at Alzheon and with the anticipated readout of our APOLLOE4 Phase 3 trial, we are preparing for potential approval and commercialization of our pathbreaking product. Gino's addition to our Board of Directors will help guide this broadening of our focus from running clinical trials to executing regulatory submissions and planning for commercial launch in number of territories," said Martin Tolar, MD, PhD, Founder, President, and CEO of Alzheon. "Alzheon's well differentiated and simplified approach to disease modification has the potential to address crucial roadblocks in a market struggling to activate, and I look forward to strategic and business guidance from someone as experienced and accomplished as Gino."

Mr. Santini retired from a long and distinguished career at Eli Lilly in 2010. During his tenure at Eli Lilly, Mr. Santini held various leadership positions of increasing responsibility, including manager of various international regions, President of the Women's Health Franchise and President of U.S. Operations. Mr. Santini capped his career at Eli Lilly as a member of the company's executive committee and as Senior Vice President of Corporate Strategy and Business Development. Mr. Santini currently serves on the Boards of Directors of Intercept Pharmaceuticals and Collegium Pharmaceuticals. He previously served on the boards of SORIN SpA, Vitae Pharmaceuticals, Horizon Therapeutics, and AMAG Pharmaceuticals, until their

acquisitions, and of Intarcia Therapeutics and Alleva Pharmaceuticals. Mr. Santini is fluent in four languages and holds an undergraduate degree in mechanical engineering from the University of Bologna and an MBA from the University of Rochester.

“Alzheon’s pioneering precision medicine and therapeutic approach has an opportunity to transform the standard of care and improve access to treatment for all Alzheimer’s patients, and it is an honor to be joining the Alzheon Board during this impactful period,” said Mr. Santini. “Bringing safe and effective therapies to the Alzheimer’s community is a noble mission and I could not be more excited about the prospects for Alzheon and the potential for ALZ-801 to fill a tremendous unmet medical need. APOLLOE4 Phase 3 trial evaluating oral ALZ-801 is expected to read out in the third quarter of 2024, and we are now preparing for a potential NDA submission this year followed by a commercial launch of the product in the U.S. in 2025.”

### **About ALZ-801**

ALZ-801/[valiltamiprosate](#) is a potential first-in-class, investigational oral agent in [Phase 3 development](#) as a potentially disease modifying treatment for AD.<sup>1,2,4,5</sup> ALZ-801 is designed to block the formation of neurotoxic soluble beta amyloid oligomers implicated in cognitive decline in Alzheimer’s patients.<sup>1,2,4</sup> In mechanism of action studies, ALZ-801 has fully inhibited the formation of neurotoxic soluble beta amyloid oligomers at the Phase 3 clinical dose.<sup>6,7</sup> ALZ-801 acts through a novel [enveloping molecular mechanism of action](#) to block formation of neurotoxic soluble amyloid oligomers in the human brain<sup>8</sup> associated with the onset and progression of cognitive decline in AD patients.<sup>1,2,4</sup> 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 potential for robust clinical efficacy and favorable safety results with no increased risk of brain vasogenic edema.<sup>6-8,10</sup> The initial [Phase 3 program for ALZ-801](#) is focusing on Early AD patients with two copies of the apolipoprotein ε4 allele (APOE4/4 homozygotes), with potential future program expansion to AD treatment and prevention in patients carrying one copy of the APOE4 gene and noncarriers.<sup>1-5</sup>

### **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 104 weeks of treatment for a total of 208 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](#). An ongoing long-term extension of the trial evaluates ALZ-801 for an additional 52 weeks of treatment for a total of 130 weeks.

### **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/valiltamiprosate](#), is a first-in-class 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**

<sup>1</sup>Tolar M, et al: *The Single Toxin Origin of Alzheimer's Disease and Other Neurodegenerative Disorders Enables Targeted Approach to Treatment and Prevention*, **International Journal of Molecular Sciences**, 2024; 25, 2727.

<sup>2</sup>Tolar 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.

<sup>3</sup>Abushakra 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.

<sup>4</sup>Tolar 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.

<sup>5</sup>Tolar M, et al: *The Path Forward in Alzheimer's Disease Therapeutics: Reevaluating the Amyloid Cascade Hypothesis*, **Alzheimer's & Dementia**, 2019; 1-8.

<sup>6</sup>Hey 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.

<sup>7</sup>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.

<sup>8</sup>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.

<sup>9</sup>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.

<sup>10</sup>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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