Alzheon Appoints Glenn Pauly as Head of Commercial

New Executive Joins Leadership Team to Build Commercial Infrastructure for Launch of Oral Tablet ALZ-801 (Valiltramiprosate) in Alzheimer's Disease

Initiation of Clinical Studies with ALZ-801 to Treat Additional Alzheimer's Populations as well as Healthy Individuals at Risk for the Disease

Strong Financial Position to Build World-Class Commercial and Business Organizations and Expand New Platform and Indication Opportunities

FRAMINGHAM, Mass., September 20, 2022 — 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 the appointment of Glenn E. Pauly as Head of Commercial.

ALZ-801 (valiltramiprosate) is an oral agent in Phase 3 development as a potentially disease modifying treatment for AD that blocks formation of neurotoxic soluble beta amyloid (Aβ) oligomers causing cognitive decline in Alzheimer's patients. In mechanism of action studies, ALZ-801 fully inhibited the formation of amyloid oligomers at the Phase 3 clinical dose. ALZ-801 has shown potential for robust efficacy in the highest-risk Alzheimer's population – patients with two copies of the apolipoprotein ε4 allele (APOE4/4 homozygotes), and favorable safety with no events of brain vasogenic edema, as seen in trials with plaque-clearing antibodies. This population is the focus of Alzheon's pivotal Phase 3 APOLLOE4 trial and has the highest likelihood of demonstrating successful efficacy outcomes.

"Alzheon has experienced tremendous growth and progress in the past year, and today's announcement of industry-leading disease modifying effects from our Phase 2 trial provides further validation of Alzheon's pioneering precision medicine approach in blocking formation of amyloid oligomers, as well as the advantages of our path over infusions of plaque-clearing antibodies," said Martin Tolar, MD, PhD, Alzheon Founder, President, and Chief Executive Officer. "These advances and our strong financial position, following the recent completion of the oversubscribed $50M Series D round, combined with the prestigious grants awarded by the National Institute on Aging totaling $51M, attracted top talent to Alzheon, to build a world-class

development and business organizations. These funds will allow us to accelerate clinical trials leading to NDA submission and commercialization of ALZ-801, to potentially become the first oral agent that can slow or even stop and prevent Alzheimer's pathology in all patients and healthy individuals at risk for the disease."

Mr. Pauly brings to Alzheon more than 20 years of commercial launch experience in the biopharmaceutical industry. He has extensive experience with launching disease-modifying agents in multiple therapeutic areas working across multiple commercial functions including sales, account management and market access. Most recently, Mr. Pauly was the U.S. Western Division General Manager and Vice President for Alzheimer's Disease at Biogen with responsibility for commercialization of Aduhelm®. Previously, Mr. Pauly has held commercial and executive roles at Johnson & Johnson, Genentech, and AstraZeneca, where he supported successful launches and commercialization for multiple products including Remicade®, Actemra®, Xolair® and Fasenra®.

"It is an incredibly exciting time to be joining Alzheon," said Mr. Pauly. "Our lead molecule, ALZ-801, has an opportunity to be decisively disruptive in a market searching for viable therapeutic options. The ability of ALZ-801 to prevent the formation of neurotoxic amyloid-beta oligomers is unique and provides an attractive alternative to current plaque-removal strategies applied by amyloid-targeting antibodies. A precision medicine approach with an initial focus on patients carrying two copies of the APOE4 gene allows for a simplified diagnostic journey. Importantly, the oral mode of administration minimizes the potential burden patients and caregivers may endure in order to receive disease-modifying therapies and may also reduce the organizational infrastructure needs and healthcare resources required to manage patient care. I am looking forward to building a competitive commercial organization to support the potential launch of this breakthrough therapy."

Alzheon has developed a well-differentiated solution to both treatment and prevention of Alzheimer's disease and other neurodegenerative disorders with a broad platform of small molecules, which act upstream on the same pathway as anti-amyloid antibodies, preventing the formation of neurotoxic soluble amyloid oligomers without disrupting the insoluble plaque deposits in brain tissue and small vessels. ALZ-801 is, therefore, in a class of its own as an easy to administer oral tablet that has shown the potential for robust efficacy with a favorable safety profile, avoiding the vascular complications of brain edema and microbleeds seen with infusions of plaque-clearing antibodies.

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] In mechanism of action studies, ALZ-801 has been shown to fully inhibit 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 brain[7] associated with the onset of cognitive symptoms and progression of AD.[1–4] ALZ-801 received Fast Track designation from the U.S. Food and Drug Administration in 2017. The clinical data for ALZ-801 and Alzheon's safety database indicate a favorable safety profile.[5–7,9] The initial Phase 3 program for ALZ-801 is focusing on Early AD patients with the APOE4/4 genotype, with future expansion to AD treatment and prevention in patients carrying one copy of the APOE4 gene and noncarriers.[1–4]

ALZ-801 APOLLOE4 Phase 3 Study

An Efficacy and Safety Study of ALZ-801 in APOE4/4 Early Alzheimer's Disease Subjects (NCT04770220): This ongoing study 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 the APOE4/4 genotype, 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 $47 million grant from the National Institute on Aging.

ALZ-801 Phase 2 Biomarker Study

Biomarker Effects of ALZ-801 in APOE4 Carriers With Early Alzheimer's Disease (NCT04693520): This ongoing study is designed to evaluate the effects of 265 mg twice daily oral dose of ALZ-801 on biomarkers of Alzheimer's pathology in subjects with Early AD, who have either the APOE4/4 or APOE3/4 genotypes, who together constitute 65-70% of Alzheimer's patients. The study also includes evaluation of clinical efficacy, safety, tolerability, and pharmacokinetic profile of ALZ-801 over 104 weeks of treatment.

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 fully blocks formation of neurotoxic soluble amyloid oligomers in the brain. 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

[1] 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.

[2] 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.

[3] 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.

[4] Tolar M, et al: *The Path Forward in Alzheimer's Disease Therapeutics: Reevaluating the Amyloid Cascade Hypothesis,* **Alzheimer's & Dementia**, 2019; 1-8.

[5] 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.

[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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