Alzheon To Present Pivotal Program of Oral ALZ-801/Valiltramiprosate at Singularity Conference, Goldman Sachs Alzheimer's Disease Day, and BIO Investor Forum

Fully Enrolled Pivotal APOLLOE4 Phase 3 Trial Progressing Successfully, Enabling Topline Data Readout and NDA Filing in 2024

ALZ-801 Tablet Inhibits Formation of Soluble Toxic Amyloid Aggregates in Brain and Acts Upstream from All Late-Stage Amyloid Targeting Treatments

Statistically Significant P-tau$_{181}$ Reduction in Plasma, Combined with Preservation of Brain Volume and Positive Correlations with Cognitive Benefits, Reinforces Potential of ALZ-801 to Halt Alzheimer's Disease Progression

Safety Profile of ALZ-801 Remains Favorable & Consistent with Prior Data in Over 2,800 AD Patients, with no Increased Risk of Vasogenic Brain Edema

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

FRAMINGHAM, Mass., September 26, 2023 — Alzheon, Inc., a clinical-stage biopharmaceutical company developing a portfolio of product candidates and diagnostic assays for patients suffering from Alzheimer's disease (AD) and related neurodegenerative disorders, today announced that the company will be presenting at upcoming industry and investor conferences.

The details of the upcoming presentations are as follows:
Event: SingularityU Czech Summit, meeting of world's leading business leaders and experts on exponentially accelerating technologies that impact the future and define global trends.

- **Keynote Presentation:** *A Quest for Pill to Defeat Alzheimer's: Insights into Healthy and Dying Human Brain*
- **Speaker:** Martin Tolar, MD, PhD, Founder, President, and CEO, Alzheon, Inc.
- **Date:** Tuesday, October 3, 2023, from 12 PM-12:45 PM (CEST)
- **Location:** Prague, Czech Republic

Event: Goldman Sachs Alzheimer's Disease Day, focused on key themes across the healthcare sector and featuring industry representatives, private, and public companies.

- **Panel Presentation:** *ALZ-801: Potentially First Oral Disease Modifying Drug for Alzheimer's*
- **Speaker:** Glenn Pauly, Chief Commercial Officer, Alzheon, Inc.
- **Date:** Tuesday, October 3, 2023
- **Location:** New York, NY

Event: BIO Investor Forum, independent biotech industry event dedicated to showcasing leading drug development programs for partnering and venture investments.

- **Panel Session:** *Fighting Neurodegeneration with New Tools*
- **Speaker:** Susan Abushakra, MD, Chief Medical Officer, Alzheon, Inc.
- **Date:** Wednesday, October 18, 2023, from 1:00 PM-1:50 PM (PST)
- **Location:** San Francisco, CA

"Alzheon has experienced tremendous progress in the past year and the recent announcement of industry-leading disease modifying effects in Alzheimer's patients provides validation of Alzheon's pioneering precision medicine approach evaluating ALZ-801 effects initially in high-risk APOE4 patients. These successes attracted enthusiastic investor support and provide us with a strong financial position to rapidly complete trials leading to NDA submission for oral ALZ-801 and a planned commercial launch in 2025," said Martin Tolar, MD, PhD, Alzheon Founder, President, and Chief Executive Officer. "Alzheon has developed a well-differentiated solution to both treatment and prevention of Alzheimer's disease with a broad platform of small molecules, which act on the same pathway as anti-amyloid antibodies but work upstream to prevent the formation of neurotoxic soluble amyloid oligomers, without disrupting the insoluble plaque deposits that may account for brain swelling and microbleeds. The treatment landscape for Alzheimer's disease is beginning to take shape and Alzheon's simplified approach has an opportunity to transform the standard of care and enhance access for patients with Alzheimer's disease. We look forward to these industry conferences where we can share our insights into Alzheimer's biology and progress with ALZ-801, which has the potential to become the first oral agent to slow, stop or even prevent Alzheimer's pathology in all patients and healthy individuals at risk for the disease."

ALZ-801/valiltramiprosate is an investigational oral disease-modifying therapy in Phase 3 development for the treatment of Early AD. In mechanism of action studies, ALZ-801 fully blocked the formation of neurotoxic soluble beta amyloid oligomers at the Phase 3 clinical dose. Oral ALZ-801 has shown potential for robust clinical efficacy in the highest-risk Alzheimer's population – patients with two copies of the apolipoprotein ε4 allele (APOE4), and favorable safety with no increased risk of vasogenic brain edema. This population is the focus of Alzheon's pivotal 78-week APOLLOE4 Phase 3 trial, which is now fully enrolled and topline data is expected in the third quarter of 2024.

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] It blocks the formation of neurotoxic soluble beta amyloid oligomers causing cognitive decline in Alzheimer's patients. 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 Phase 2 Biomarker Trial

Biomarker Effects of ALZ-801 in APOE4 Carriers With Early Alzheimer's Disease (NCT04693520): This ongoing trial is 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 includes 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 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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