



Alzheon Appoints Adem Albayrak as Head of Operations and Earvin Liang, PhD, as Vice President of Clinical Development

New Hires Bring Extensive Precision Medicine and Clinical Development Expertise as Alzheon Advances Phase 2 & 3 Trials of ALZ-801 Tablet in Alzheimer's Disease

FRAMINGHAM, Mass., September 13, 2021 — [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 Adem Albayrak as Head of Operations, and Earvin Liang, PhD, as Vice President of Clinical Development.

"Alzheon's pioneering precision medicine approach to Alzheimer's disease that blocks formation of toxic forms of amyloid continues to be validated by new data," said Martin Tolar, MD, PhD, Alzheon Founder, President and Chief Executive Officer. "This new era of Alzheimer's drug development has been galvanized by our team of world-class scientists and industry leaders, and the addition of new executives will help accelerate the completion of our clinical programs, in particular the Phase 2 biomarker trial of our tablet ALZ-801 that runs concurrently with the confirmatory APOLLOE4 Phase 3 trial. These studies position ALZ-801 to potentially become the first oral disease-modifying agent for patients with Alzheimer's, as well as healthy people at risk for the disease."

Mr. Albayrak brings more than a decade of precision medicine experience in both biopharma and academic medical centers to drive execution of Alzheon's business and clinical programs. Most recently, Mr. Albayrak served as the Senior Vice President for Technology in Health Catalyst's emerging Life Sciences Business, where he led development of new products and analytical capabilities. Mr. Albayrak began his career at Knome, one of the first organizations to commercialize the analysis and interpretation of whole genome sequencing data, where he led development of software applications. Subsequently, he led product development of pharmacogenomics products at BIOBASE, before its acquisition by Qiagen. While at Dana-Farber Cancer Institute, Mr. Albayrak oversaw its precision medicine activities, enabling research, clinical interpretation, and clinical trial matching of the hospital's genomic sequencing program, *Profile*. Mr. Albayrak served as a Sergeant in the United States Marine Corps, where he received training in operational excellence and leadership in military communications. Mr. Albayrak earned his B.S. and M.S. in Computer Science with a bioinformatics focus from the University of

Massachusetts at Lowell, with graduate work in data visualization of genomics data, and executive management training from Harvard Business School.

“The application of precision medicine for diseases such as cancer has enabled breakthrough therapies, and we are at a similar inflection point in the treatment of neurodegenerative disorders,” said Mr. Albayrak. “Alzheon scientists and clinicians are leading the application of precision medicine in Alzheimer’s disease, so patients can now benefit from similar diagnostic and theragnostic advances. I am thrilled to join the team bringing revolutionary disease modifying treatments to patients with the genetic profile known to respond to the drug.”

Dr. Liang brings to Alzheon over 20 years of industry experience, ranging from non-clinical drug identification to late-stage global clinical trials, and will be responsible for effective conduct of ALZ-801 clinical programs. Dr. Liang’s clinical experience includes application of passive and active amyloid immunotherapies, as well as gamma secretase inhibitors for disease modification in Alzheimer’s disease, cognition in Down syndrome, and neuropsychiatric indications in dementia and Parkinson’s disease. During his career, Dr. Liang supported clinical development of bapineuzumab (anti-amyloid antibody), ACC101 (amyloid vaccine), ELND005 (amyloid anti-oligomer agent), and multiple sclerosis immune-modulation programs at Elan Pharmaceuticals, Janssen Alzheimer’s Immunotherapy, and Transition Therapeutics. Dr. Liang earned his Ph.D. in Pharmaceutical Sciences from the University of Florida, and B.S. in Pharmacy from Taipei Medical University. He is a licensed pharmacist, has authored over 50 peer-reviewed scientific papers, and given more than 130 presentations at international conferences and symposia.

“The Alzheimer’s space has seen tremendous advances this year, and Alzheon scientists are at the forefront of advancements in understanding the biology of Alzheimer’s and therapeutic opportunities,” said Dr. Liang. “Our lead product ALZ-801, which inhibits the oligomerization of beta amyloid protein, can potentially slow the downstream pathology and cognitive decline in Alzheimer’s disease. I am excited to join the world-class team of clinicians at Alzheon, and with Phase 2 and 3 trials of ALZ-801 well underway, support their work to bring relief to the millions of patients suffering from Alzheimer’s disease.”

About ALZ-801

[ALZ-801](#) is an 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 amyloid oligomers at the Phase 3 clinical dose.^{5,6} ALZ-801 is an optimized prodrug of tramiprosate that has shown promising results in analyses of Phase 3 clinical data,^{7,9} and has a novel anti-amyloid oligomer mechanism of action.^{5,8} ALZ-801 received Fast Track designation from the U.S. Food and Drug Administration in 2017. The clinical data for ALZ-801 and its active agent, tramiprosate indicate long-term clinical efficacy in AD patients with the APOE4 genotype and a favorable safety profile.^{5-7,9} 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 of cognitive symptoms and progression of AD.¹⁻⁴

The cognitive improvements observed in the tramiprosate Phase 3 studies may also be attributed in part to the therapeutic effects of 3-sulfopropanoic acid (3-SPA), [an endogenous](#)

[anti-oligomer substance found in the human brain discovered by Alzheon scientists](#) that, like tramiprosate, inhibits formation of toxic amyloid oligomers.⁵ 3-SPA is the primary metabolite of ALZ-801 and its discovery helps explain the beneficial pharmaceutical attributes of ALZ-801, including favorable safety profile, high selectivity for amyloid, and excellent brain penetration.^{3,5,6} ALZ-801 treatment increases levels of 3-SPA in the brain and augments the body's natural mechanism to inhibit formation of toxic amyloid oligomers.^{5,6} 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.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 one dose of 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 constitute 65-70% of Alzheimer's patients. The study also includes evaluation of clinical efficacy, safety, and tolerability of ALZ-801 over 104 weeks of treatment and will evaluate the extended pharmacokinetic profile of ALZ-801 over 8 hours in 24 subjects after 65 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 devastating neurodegenerative disorders. Our lead Alzheimer's clinical candidate, [ALZ-801](#), is an oral agent in [Phase 3 development](#) as a potentially disease modifying treatment for AD. ALZ-801 is an oral small molecule prodrug of tramiprosate that fully blocks formation of neurotoxic soluble amyloid oligomers in the brain. ALZ-801 is an easy-to-take tablet that builds on the safety and efficacy profile of its active compound tramiprosate, which has been evaluated in clinical trials involving over 2,000 Alzheimer's patients. 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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