

Alzheon to Present at H.C. Wainwright Global Life Sciences Conference on March 9, 2021

Alzheon CEO Dr. Martin Tolar Will Provide Overview of Company Business and Update on Oral Anti-Amyloid ALZ-801 Phase 3 Program

FRAMINGHAM, Mass., March 9, 2021 — [Alzheon, Inc.](#), a clinical-stage biopharmaceutical company focused on developing new medicines for patients suffering from Alzheimer's disease (AD) and other neurodegenerative disorders, today announced that Martin Tolar, MD, PhD, company's Founder, President and Chief Executive Officer will present at the [H.C. Wainwright Global Life Sciences Conference](#) on March 9th. Presentation will be available live on-demand from 7:00 AM EST until the end of the conference on March 10th.

The virtual conference will provide an opportunity for investors to engage in one-on-one meetings with Dr. Tolar, and to hear about recent developments in Alzheon's research including the Phase 3 program for oral anti-amyloid treatment ALZ-801 and the ongoing Phase 2 biomarker trial.

"ALZ-801 acts on the same pathway as the leading anti-amyloid antibodies, but it works to prevent formation of toxic amyloid fragments upstream and, therefore, it is in a class of its own as an oral, small-molecule drug that has shown greater efficacy and safety than any of the late-stage anti-amyloid antibodies. ALZ-801 has the potential to be used as an effective disease modifying monotherapy, and its favorable safety profile and ease of administration also make it an ideal candidate for use in combination with these drugs," said Dr. Tolar.

Dr. Tolar's presentation will provide an overview of Alzheon's Phase 3 program with an oral drug candidate, ALZ-801, which prevents formation of neurotoxic soluble amyloid oligomers that drive onset and progression of AD. ALZ-801 is an oral small molecule drug targeting amyloid toxicity, and has shown potential for robust efficacy and favorable safety in the high-risk population of patients with two copies of the apolipoprotein ε4 allele (APOE4/4).

With endorsement and Phase 3 support from the National Institute of Aging in the form of a \$47 million grant, Alzheon is advancing its oral drug ALZ-801 into [Phase 3 \(NCT04770220\)](#) and will begin enrolling patients in the 2nd quarter of 2021. Alzheon's precision medicine approach will enroll the highest-risk AD patient group of APOE4/4 subjects and will incorporate the latest biomarkers to track patient benefits — phosphorylated tau in cerebrospinal fluid and blood, synaptic and inflammatory biomarkers, hippocampal volume and cortical thickness measures, and positron emission tomography of tau and neurofibrillary tangle pathology in a subset of enrolled subjects.

"By incorporating the latest fluid and imaging biomarkers in our development program, we will generate robust data regarding efficacy and patient benefits throughout our studies," said Dr. Tolar. "Combined with our genetics-based precision medicine approach to target those

individuals most likely to develop Alzheimer's, these biomarkers will maximize the likelihood of a successful Phase 3 trial, which could support a New Drug Application submission in 2024."

About ALZ-801

An oral anti-amyloid drug, [ALZ-801](#) is an optimized prodrug of tramiprosate that has shown promising results in analyses of Phase 3 clinical data,^{6,8} and has a novel anti-amyloid oligomer mechanism of action.^{4,7} 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.^{4,6,8} ALZ-801 acts through a unique [enveloping molecular mechanism of action](#) to fully block formation of neurotoxic soluble amyloid oligomers⁶ associated with the onset of cognitive symptoms and progression of AD.^{2,3} 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 in the human brain discovered by Alzheon scientists](#) that, like tramiprosate, inhibits formation of toxic amyloid oligomers.⁴ 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. 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.^{4,5} The initial [Phase 3 program for ALZ-801](#) will focus on Early AD patients with the APOE4/4 genotype, with future expansion to investigate ALZ-801 for prevention of Alzheimer's onset and in patients carrying only one copy of the APOE4 gene.^{1,2,3}

About Alzheon

[Alzheon, Inc.](#) is 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 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 using a [precision medicine approach](#) based on individual genetic and biological information to advance therapies with the greatest impact for patients.

Alzheon Scientific Publications

¹ 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.

² 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.

³ Tolar M, et al: [The Path Forward in Alzheimer's Disease Therapeutics: Reevaluating the Amyloid Cascade Hypothesis, Alzheimer's & Dementia](#), 2019; 1-8.

⁴ 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.

⁵ 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.

⁶ 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.

⁷ 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.

⁸ 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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