PRESS RELEASE
16 November 2026 21:15:00 CET

Alzinova presents study design for Phase 2a ADVANCE trial with ALZ-101 at CTAD in Boston

Alzinova AB (“Alzinova” or the “Company”) today announces that it is presenting the study design for the planned Phase 2a ADVANCE trial (ALZ-C-002) with its Alzheimer’s vaccine ALZ-101 at the international Clinical Trials on Alzheimer’s Disease (CTAD) conference, taking place on November 16–19, 2026, in Boston, USA. The poster is being presented by Stefan Pierrou, Vice President R&D Projects at Alzinova, together with co-authors including Anders Sandberg, Chief Scientific Officer, and Professor Marwan Sabbagh of Barrow Neurological Institute.

ALZ-101 is an active immunotherapy comprising an oligomerised, conformationally constrained Aβ42 derivative (Aβ42CC) formulated with an aluminium hydroxide adjuvant. It is designed to induce a polyclonal antibody response that specifically targets a subset of soluble amyloid-β (Aβ) oligomers — believed to play a central role in synaptic dysfunction and neurodegeneration in Alzheimer's disease — while limiting recognition of monomeric and fibrillar Aβ.

In the completed Phase 1 study (ALZ-C-001), ALZ-101 showed a favourable safety and tolerability profile and induced antigen-specific immune responses, with approximately 90% of participants classified as responders (Lovró et al., Alzheimer's Research & Therapy, 2026).

About the ADVANCE study
ADVANCE is a randomised, double-blind, placebo-controlled Phase 2a study that will evaluate the clinical efficacy, safety, tolerability, immunogenicity and biomarker effects of ALZ-101 in approximately 120 participants aged 50–85 years with early Alzheimer's disease, defined as mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease according to NIA-AA criteria. The study is being conducted in the United States, the European Union and the United Kingdom, with seven US clinical trial sites already selected.

The primary endpoint is the effect of ALZ-101 versus placebo on clinical progression, measured as change from baseline in the Alzheimer's Disease Composite Score (ADCOMS) through Week 52 with a sample size that will provide 80% power. Participants will be randomised 2:1 to receive eight intramuscular injections of ALZ-101 (250 µg per dose) or placebo at Weeks 0, 4, 8, 16, 32, 48, 64 and 80, with follow-up through Week 92. Secondary endpoints include ADAS-Cog, CDR-Sum of Boxes, MMSE, ADCS-ADL for MCI, CSF neurofilament light chain, and ALZ-101-specific IgG antibody titres, as well as safety and tolerability. The study also includes exploratory biomarker endpoints, including plasma and CSF Aβ species and phosphorylated tau-217.

Enrolment of the first participant is planned for late December 2026. An interim analysis is planned for the third quarter of 2028, once approximately 50% of participants have completed the Week 52 assessment. The analysis will include a futility assessment and additional pre-specified evaluations, which will be described in a forthcoming company communication. Results from the study are anticipated in late 2029.

Comment from Tord Labuda:
"*With ADVANCE, we are taking the next important step in the clinical development of ALZ-101. Following the positive safety and immunological results from Phase 1, we will now investigate whether our oligomer-specific treatment strategy significantly can influence disease progression in patients with early Alzheimer's disease. Presenting the study design at CTAD provides an opportunity to showcase our clinical programme to the international research community. With patient enrolment planned around the turn of the year, we are approaching a significant milestone for the company*."

About ALZ-101
ALZ-101 is Alzinova's lead candidate, a therapeutic vaccine against Alzheimer's disease. Alzinova's patented AβCC peptide technology makes it possible to develop disease-modifying treatments that target the toxic amyloid-beta oligomers believed to be central to the onset and development of the disease with great accuracy. ALZ-101 has received Fast Track designation from the US FDA.

For further information, please contact:
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About Alzinova
Alzinova AB is a Swedish biopharmaceutical company in clinical development specializing in the treatment of Alzheimer's disease, with a focus on targeting toxic amyloid-beta oligomers. The lead candidate ALZ-101 is a therapeutic vaccine against Alzheimer's disease. Alzinova's patented AβCC peptide technology makes it possible to develop disease-modifying treatments that target the toxic amyloid-beta oligomers that are central to the onset and development of the disease with great accuracy. From a global perspective, Alzheimer's disease is one of the most common and devastating neurological diseases, with around 40 million people affected today. Based on the same technology, the company is also developing the antibody ALZ-201, which is currently in preclinical development, as well as the diagnostic project ALZ-401, which aims to develop a blood test to identify an increased risk of Alzheimer's disease before symptoms appear. The goal is to further expand the pipeline. The company's Certified Adviser on Nasdaq First North Growth Market is Mangold Fondkommission AB. For more information about Alzinova, please visit: **www.alzinova.com**

Attachments
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