



Alzinova initiates operational start-up of global Phase 2 study with ALZ-101

Alzinova AB ("Alzinova" or the "Company") today announces that the Company, together with contract research organization Worldwide Clinical Trials ("Worldwide"), has initiated the operational start-up phase of the Phase 2 study of the vaccine candidate ALZ-101 for the treatment of Alzheimer's disease. Alzinova and Worldwide have completed the study kick-off and are now working on preparations including regulatory and ethics submissions, as well as the allocation of clinical trial sites, with the aim of enrolling the first participants around the turn of the year 2026/2027. Approximately 120 participants are planned to be enrolled.

Tord Labuda, CEO of Alzinova, comments:

"With the study kick-off with Worldwide now completed, we have taken an important step from preparation to the start-up of our Phase 2 study with ALZ-101. Our focus now is to work together with Worldwide to establish the systems, processes and clinical trial sites required for high-quality and efficient participant recruitment. We are progressing according to plan towards enrolling the first participant around the turn of the year 2026/2027."

The operational start-up phase includes, among other activities, the establishment of study systems and databases, regulatory and ethics submissions, as well as the identification, evaluation and contracting of clinical trial sites. These activities are being conducted in parallel ahead of site activation and subsequent participant recruitment.

The Phase 2 study is a global, randomized, placebo-controlled study planned to include approximately 120 participants with early Alzheimer's disease. The primary endpoint is change in cognitive function, assessed using ADCOMS after 52 weeks of treatment. Secondary endpoints include safety and tolerability, as well as changes in disease-related biomarkers and other clinical outcomes. Participants will be followed for a total of 92 weeks.

Next steps towards participant recruitment

Worldwide was appointed as the CRO for the Phase 2 study in June 2025 following an evaluation of several CROs with experience in Alzheimer's disease clinical trials. Worldwide has extensive experience in neuroscience and dementia-related clinical trials.

Since the selection of the CRO, Alzinova and Worldwide have been working on the planning and preparations for the study. With the start-up phase now underway, the work is progressing towards the activation of clinical trial sites and subsequent participant recruitment. The first participant is expected to be enrolled around the turn of the year 2026/2027.



About the Phase 2 study with ALZ-101

The Phase 2 study builds on the results from Alzinova's completed Phase 1b study and represents the next step in the clinical development of ALZ-101. The study is designed to evaluate the efficacy of the vaccine candidate in a larger patient population and generate additional clinical data to support the continued development of ALZ-101.

ALZ-101 is an oligomer-specific vaccine candidate developed for the treatment of Alzheimer's disease. The vaccine stimulates the patient's own immune system to produce antibodies targeting the toxic amyloid-beta oligomers that play an important role in the development of the symptoms associated with Alzheimer's disease.

For further information, please contact:

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About Alzinova AB

Alzinova AB is a Swedish biopharmaceutical company in clinical development specializing in the treatment of Alzheimer's disease, where the starting point is to attack toxic amyloid-beta oligomers. The lead candidate ALZ-101 is a therapeutic vaccine against Alzheimer's disease. Alzinova's patented A β CC 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 affected today. Based on the same technology, the company is also developing the antibody ALZ-201, which is currently in preclinical development, and 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

This information is information that Alzinova is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-09-10 21:05 CEST.

Attachments

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