PRESS RELEASE
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Alzinova Receives FDA (IND) Approval for Phase II Study of ALZ-101 in Alzheimer's Disease

Alzinova AB (publ) (Nasdaq First North: ALZ) today announces that the U.S. Food and Drug Administration (FDA) has approved the company's Investigational New Drug (IND) application for its planned Phase II clinical study with the vaccine candidate ALZ-101 in Alzheimer's disease.

Tord Labuda, CEO of Alzinova comments:
"The FDA's approval of our IND is a decisive confirmation of our readiness to advance ALZ-101 into the next stage of development. The approval gives us the green light to initiate the Phase II study in the U.S. and to build on the promising results from Phase Ib, while for the first time evaluating our vaccine candidate in a larger patient population. This marks an important step in realizing the therapeutic potential of ALZ-101 and bringing us closer to our goal of making our vaccine candidate available to patients."

The IND application submitted by Alzinova to the FDA on August 8, 2025, has now been approved, marking an important step in the process of initiating the planned Phase II study in the U.S. With this decision, the study design, safety data, and manufacturing processes have been confirmed to meet regulatory requirements, enabling Alzinova to proceed with preparations as planned. The approval also allows the company to take the next step in evaluating the promising results from the Phase Ib study in a larger patient population, a decisive step in confirming the therapeutic potential of ALZ-101.

About the Phase II Study
The planned Phase II study with ALZ-101 is designed as a multicenter trial, including sites in the U.S., with the objective of evaluating safety, tolerability, and efficacy in patients with early Alzheimer's disease. The study will enroll approximately 240 patients. Following dosing, a series of follow-up visits is planned during which both primary and secondary endpoints will be assessed. The primary endpoint is a cognitive test, ADCOMS, while the secondary endpoints include safety and tolerability.

The study will be conducted at several clinics, including sites the U.S., in collaboration with the contract research organization Worldwide Clinical Trials, which has extensive experience in Alzheimer's studies.

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 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 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**

Attachments

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