**PRESS RELEASE**
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# Alzinova takes further step toward Phase 2a ADVANCE study with submitted FDA amendment for ALZ-101

**Alzinova AB ("Alzinova" or the "Company") today announces that it has submitted an amendment to its existing FDA-cleared Investigational New Drug (IND) for the Phase 2a ADVANCE study with ALZ-101 in early Alzheimer's disease. The submission includes an updated clinical study protocol, information on additional US clinical trial sites and supplementary documentation relating to the investigational medicinal product, including manufacturing, quality and stability information.**

The amendment has been submitted under the IND for ALZ-101 that was cleared by the US Food and Drug Administration (FDA) in September 2025. ALZ-101 subsequently also received Fast Track designation from the FDA.

The submission forms part of the ongoing operational preparations for ADVANCE, Alzinova's global Phase 2a study designed to evaluate ALZ-101 in approximately 120 participants with early Alzheimer's disease. The study is planned to be conducted in the United States, the European Union and the United Kingdom.

Alzinova recently finalised the selection of seven clinical trial sites in the United States with experience in Alzheimer's disease studies and participant recruitment. Preparations are progressing toward enrolment of the first participant, currently targeted around the turn of 2026 /2027.

**Tord Labuda, CEO of Alzinova, comments:**
"*Each step brings us closer to evaluating ALZ-101 in a larger patient population. With our existing FDA clearance, Fast Track designation, selected US clinical sites and now the updated study documentation submitted, we continue to make tangible progress toward the start of ADVANCE. Building on the encouraging immune responses observed in Phase 1b, our focus is now on advancing the study designed to investigate whether our oligomer-specific vaccine approach can deliver meaningful clinical benefits for patients with early Alzheimer's disease.*"

In parallel with the ongoing clinical preparations, the ADVANCE study design is also set to be presented at the international Clinical Trials on Alzheimer's Disease (CTAD) conference in Boston in November 2026, providing an opportunity to introduce the study to the global Alzheimer' s research community.

**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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