PRESS RELEASE
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Alzinova Receives Fast Track Designation from US FDA for 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 granted Fast Track Designation (FTD) for the company's vaccine candidate ALZ-101 in Alzheimer's disease.

Tord Labuda, CEO of Alzinova comments:

"Fast Track designation for ALZ-101 is an important recognition of the unmet patient need in Alzheimer's disease. This designation follows encouraging safety and efficacy data from our completed Phase 1b clinical trial, demonstrating early indication of clinical benefit as well as mechanistic data supporting the activity of ALZ-101."

The US FDA Fast track process is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier.

For further information, please contact:
Tord Labuda, CEO
E-mail: **info@alzinova.com**

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**

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 2025-10-04 10:45 CEST.

Attachments

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