PRESS RELEASE
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Alzinova submits applications for clinical trial initiation (IND) and Fast Track status to the FDA

Alzinova AB (publ) (Nasdaq First North: ALZ) today announced that the company has submitted an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) for the planned Phase II study of ALZ-101. At the same time, Alzinova has also applied for Fast Track Designation (FTD) to the FDA.

To enable the start of the planned Phase II study with ALZ-101, which is expected to commence in the second half of 2025, Alzinova has now submitted an IND application to the FDA. The IND application is a regulatory requirement for conducting clinical trials in the US and includes for example study design, quality- and safety data.

Concurrently with the IND, the company has also applied for Fast Track Designation (FTD) to the FDA. Fast track is a regulatory program designed to accelerate the development and review of new drugs intended to treat serious or life-threatening conditions and where there is an unmet medical need.

The FDA's processing time for IND applications is normally up to 30 days. If no objections are raised within that period, the study can begin according to the submitted protocol. Notification of Fast Track Designation is usually provided within approximately 60 days of submission. Alzinova therefore estimates that notifications in both cases can be expected during the third and fourth quarters of 2025.

"The fact that we have now submitted both the IND and a Fast Track application to the FDA is an important step in the work of taking ALZ-101 further into the next clinical phase. Our focus is now on preparing for the start of the study and ensuring that all parts of the implementation are in place for the Phase II study," says Tord Labuda, CEO.

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**

Attachments

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