



## Alzinova submits request for Pre-IND meeting with FDA and applies for EMA Scientific Advice

Alzinova AB (publ) (FN STO: ALZ), a leading biotechnology company focused on Alzheimer's disease. Following promising clinical phase 1b interim results, the company today announces that a request for a Pre-IND meeting with the US Food and Drug Administration (FDA) has been submitted and an application for EMA Scientific Advice from the European Medicines Agency (EMA). The purpose of these regulatory interactions is to prepare for the company's Phase 2 study with the ALZ-101 vaccine candidate being developed for the treatment of Alzheimer's disease.

*"The communication with the FDA and EMA is important in the planning of the phase 2 study for our vaccine candidate ALZ-101. It is important to understand the authorities' requirements early on and to receive their guidance when planning and conducting our phase 2 study. We look forward to working with the FDA and EMA to develop ALZ-101 into a new effective and safe treatment for all those suffering from Alzheimer's disease."*, comments Kristina Torfgård VD, Alzinova AB.

Alzinova announces today that the company has taken important steps in the development of its vaccine candidate, ALZ-101, for the treatment of Alzheimer's disease. The company has submitted a request for a Pre-Investigational New Drug (Pre-IND) meeting with the U.S. Food and Drug Administration (FDA), while Alzinova has also applied for Scientific Advice from the European Medicines Agency (EMA).

These regulatory applications aim to obtain advice and guidance from the authorities regarding the development plan for ALZ-101 and to ensure that it meets the regulatory requirements in both the US and the EU. By interacting early with the authorities, Alzinova can prepare for the upcoming applications and thereby shorten the time it takes to start the next clinical study - the phase 2 study. This strategy helps the company to more quickly reach important milestones in the development process to offer a new treatment for patients suffering from Alzheimer's disease. These are important steps for the commercial development as well as future partnerships for ALZ-101.

**For more information, please contact:**

Kristina Torfgård, CEO

Tel. +46 708 46 79 75

E-mail: [kristina.torfgard@alzinova.com](mailto:kristina.torfgard@alzinova.com)

*Please note that this is an English translation of a press release written in Swedish by Alzinova AB (publ), in the event of any inaccuracies, the Swedish version applies.*



**About Alzinova**

Alzinova AB is a Swedish clinical-stage biopharma company specializing in the treatment of Alzheimer's disease targeting toxic amyloid beta oligomers. The lead candidate, ALZ-101, is being developed as a therapeutic vaccine for the treatment of Alzheimer's. Alzinova's proprietary A $\beta$ CC peptide™ technology enables the development of disease-modifying treatments that target the toxic amyloid beta oligomers involved in the onset and progression of the disease with high precision. Alzheimer's is one of the most common and devastating neurological diseases globally, with of the order of 40 million people afflicted today. In addition, the antibody ALZ-201 is in preclinical development, and the ambition is to expand the pipeline further. The company's Certified Adviser on Nasdaq First North Growth Market is Redeye AB. For more information about Alzinova, please visit: [www.alzinova.com](http://www.alzinova.com)

**Attachments**

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