PRESS RELEASE
09 August 2023 08:00:00 CEST

Alzinova progresses following positive Pre-IND meeting with FDA

Alzinova AB (publ) (FN STO: ALZ), announced today that the company has successfully concluded a pre-IND meeting with the US Food and Drug Administration (FDA) receiving positive feedback on the planned clinical development program for the vaccine candidate ALZ-101. This marks an important validation of the project's quality and represents a step for potential partnering discussions, as well as for the pathway towards the submission of an application to include US study centers in future clinical studies (Investigational New Drug Application, IND).

"The FDA's positive response to our plans for continued clinical development of ALZ-101 represents an important quality stamp of the vaccine candidate's documentation. We are also looking forward to the response from the EMA in the autumn. This advice will not only help us adapt to the authorities' expectations of a proposed "best in class" drug like ALZ-101, but it will also hold value in our discussions with potential partners.", comments Kristina Torfgård CEO, Alzinova AB.

During the spring, Alzinova formally requested a meeting with the FDA and in June the company announced that the FDA had accepted Alzinova's pre-IND meeting request. The primary objective of the meeting was to discuss the overall clinical development plan for ALZ-101. Based on the background material and questions provided by Alzinova, the FDA answered questions about the study design, the clinical development program and preclinical development, as well as chemistry, manufacturing and quality control.

More about interactions with the FDA and EMA
A pre-IND meeting is the FDA's equivalent of what is known in the EU as the Scientific Advice Procedure, for which Alzinova has also submitted a request to the European Medicines Agency (EMA). These regulatory applications are intended to solicit advice and guidance from the authorities regarding the development plan for ALZ-101 and to ensure its alignment with regulatory requirements both in the US and in the EU. An EMA decision is expected to be received in the autumn. By interacting early with the authorities, Alzinova can prepare for the forthcoming applications for the phase 2 study. This strategy helps the company's progress towards significant milestones in the development process to offer a new treatment for patients suffering from Alzheimer's disease.
These steps are also pivotal for the commercial advancement and potential partnerships for ALZ-101.

For more information, please contact:
Kristina Torfgård, CEO
Tel. +46 708 46 79 75
E-mail: **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 AβCC 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**

Attachments
Alzinova progresses following positive Pre-IND meeting with FDA