



Alzinova receives positive response from the European Medicines Agency EMA

Alzinova AB (publ) (FN STO: ALZ), announces today that the company has received a positive response from the European Medicines Agency (EMA) regarding the planned clinical development program for the vaccine candidate ALZ-101. This constitutes an important validation of the quality of the project and represents significant progress in the preparation for the inclusion of European study centers in future clinical studies as well as in potential partnering discussions.

"The response from EMA is of great help in the continued clinical development of ALZ-101 where the positive feedback from EMA is a clear confirmation that the documentation is of high quality. Through early interactions with the regulatory authorities, we can increase the possibility of a successful development process for the vaccine candidate ALZ-101. We are now looking towards the next milestone - topline data in the fourth quarter of this year.", comments Kristina Torfgård CEO, Alzinova AB.

During 2023, Alzinova has worked with regulatory interactions where advice from the EMA is an important part of the preparation for the next development phase. Alzinova's request for scientific advice includes questions about the planned clinical development program, study design, preclinical development as well as chemistry, manufacturing and quality control. EMA has now provided a positive response to the dossier submitted by Alzinova. Alzinova has previously announced that the company has also received positive feedback from a pre-IND meeting with the US Food and Drug Administration (FDA).

More about the interactions with FDA and EMA

The regulatory interactions 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 both in the US and in the EU. By interacting early with the authorities, Alzinova can prepare for the upcoming applications for 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 also important steps for the commercial development and future partnerships for ALZ-101.

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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 β 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

Attachments

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