



Alzinova announces new positive safety review and interim data from ongoing phase 1b study with vaccine candidate ALZ-101

Alzinova AB (publ) ("Alzinova" or the "Company") is currently conducting a phase 1b study with its vaccine candidate ALZ-101. The Company has analysed blinded data and the results indicate continued good safety and tolerability. The results indicate an immunological response i.e., antibody formation, and the study will proceed as planned. The Company also plans to conduct a second interim analysis during spring of 2023.

Alzinova's phase 1b study of ALZ-101 in patients with early Alzheimer's disease is being conducted as a placebo-controlled, randomized, double-blind, first-in-human (FIH) study. The Company has completed an interim analysis of blinded data from 13 patients who received three doses of the Company's ALZ-101 vaccine candidate or placebo. The interim analysis shows good safety and tolerability and evidence of an immunological response with increases in antibody levels. As the analysis of antibody levels is fully blinded, it also includes results from the group of patients who received placebo, which complicates the analysis. Alzinova is proceeding with the study as planned and plans to conduct a second blinded interim analysis of antibody levels once 13 additional patients, and thus all 26 patients, have been treated with at least 3 doses or placebo. The Company plans to conduct the second interim analysis in the spring of 2023 to generate additional data on which to base a decision on the extension of the study.

CEO Kristina Torfgård comments:

"It is very encouraging that we have come this far and have now analysed blinded safety data and antibody levels from half of the patients in our ongoing phase 1b study of the ALZ-101 vaccine candidate. I am very pleased that the study continues to show good safety and tolerability and interesting data suggesting an immune response. The study will continue as planned and we look forward to the second interim analysis that will be done this spring and top-line data in the second half of 2023 that will give us a more comprehensive picture of the vaccine candidate's immune response in all patients."

More about the study

The Phase 1b clinical study with ALZ-101 in patients with early Alzheimer's disease is a placebo-controlled, double blind, randomised First In Human (FIH) trial. In total, 26 patients will be included in the study. Study participants receive four doses of either ALZ-101 or placebo. The study is investigating two different dose strengths of ALZ-101 during a treatment period of 20 weeks. In October 2021, the first patient was recruited into the phase 1b clinical trial with the therapeutic vaccine ALZ-101. This was an important milestone and means that Alzinova is the first company with an oligomer-specific vaccine in the clinical phase. Enrolment in the study is ongoing and top-line data for the study is anticipated in the second half of 2023.



The clinical trial is being carried out in Finland by Alzinova's partner, Clinical Research Services Turku (CRST), who have extensive experience in Alzheimer's studies. The analysis of biomarkers will be made through a research collaboration with Sahlgrenska University Hospital in Gothenburg.

About ALZ-101

The market for treatment of Alzheimer's is large as there is currently no effective treatment to slow down the progress of or cure the disease. Alzinova's approach, to develop a therapeutic vaccine that specifically targets the toxic accumulations of amyloid-beta in the form of oligomers in the brain, has several advantages compared to other methods. Other players are developing treatments that target larger accumulations of amyloid-beta, so-called plaques in the brain, which are believed to contain both toxic and harmless protein. It has been shown that it is unlikely to be sufficiently effective and may result in serious side effects. Unlike these, Alzinova has succeeded in identifying a method that could specifically target the toxic accumulations in the brain (amyloid-beta oligomers) which is one of the causing factors behind Alzheimer's disease. Vaccination with ALZ-101 means that the body generates its own antibodies, specific against toxic accumulations of amyloid-beta oligomers in the brain. These toxic substances are expected to be neutralized thus, protecting the brain's synapses from damage which could prevent the development of Alzheimer's disease. The treatment method is also expected to have a lower risk of side effects such as bleeding and edema. Therefore, the Company believes that it is likely to be more successful, unlike other broader approaches for treating Alzheimer's disease.

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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



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 2022-12-12 18:24 CET.

Attachments

Alzinova announces new positive safety review and interim data from ongoing phase 1b study with vaccine candidate ALZ-101