



Alzinova: New positive safety review of the Phase 1b study for the ALZ-101 vaccine

Alzinova AB (publ) ("Alzinova" or "the Company"), announces today that a planned external safety review has been conducted of the Company's clinical phase 1b study - with a positive assessment to continue the study as planned. The expert group Data Safety Monitoring Board ("DSMB") has also evaluated the safety data in relation to a possible extension of the study that the Company has announced plans to conduct. Based on the study's included patients, the DSMB recommends continuing the study as planned and that the study can also be extended if the Company so decides.

The DSMB consists of an independent expert group that continuously reviews the safety data accumulated during the progress of the study, which is standard for all drug development. The company has previously communicated several positive reviews from the DSMB, including one in December where even interim data from the study indicated an immunological response.

The DSMB has now conducted another review which also included an assessment of whether an extension of the phase 1b study can be carried out. The DSMB has concluded that no obstacles exist and that it is up to the Company to decide on such an extension. Alzinova continues the study as planned and also plans for a second blinded interim analysis of antibody levels when an additional 13 patients and thus all 26 patients have been treated with at least 3 doses or placebo. The Company plans to conduct this interim analysis in the spring of 2023 to generate additional data to support the decision to extend the study.

Kristina Torfgård, CEO at Alzinova, comments:

"We are pleased with the continued positive response from the independent expert group and that there are no obstacles to conducting an extension of the study from a safety perspective. I am very pleased that in the study we see continued good safety and tolerability as well as interesting data suggesting an immune response. The study will continue according to plan and we look forward to the second interim analysis, which will be conducted in the spring and will form the basis for a decision to extend the study. We also look forward to topline 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 of ALZ-101 in patients with early Alzheimer's disease is a placebo-controlled, randomized, double-blind First In Human (FIH) study. The study includes 26 patients where participants will receive four doses of either ALZ-101 or placebo. The study examines two different dose strengths of ALZ-101 over a 20-week treatment period. Alzinova is the first



company with an oligomer-specific vaccine in the clinical phase and has received positive interim data indicating an immunological response as well as good safety and tolerability. The study was fully recruited in December 2022 and topline data for the study is expected 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

Attachments

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