



Alzinova: New positive interim data from ongoing phase 1b study with vaccine candidate ALZ-101 – Initiates extension of the study

Alzinova AB (publ) ("Alzinova" or the "Company") announces today that a second planned interim analysis has been conducted of the ongoing clinical phase 1b study with the vaccine candidate ALZ-101 against Alzheimer's disease. The analysis shows positive data with continued good safety and tolerability as well as a clear immunological response, that is, that specific antibodies have been formed. Based on this positive second interim analysis, the Company has decided to conduct an extension of the study.

Analysis of 26 patients administered with ALZ-101 or placebo showed that those treated with ALZ-101 responded to treatment with antibody levels increasing with the number of doses given. The analysis also shows continued good safety and tolerability.

Based on the positive data received today, the Company has decided to initiate an extension of the ongoing study. The planned extension means that all patients who have received their fourth vaccine dose will be offered treatment with two doses of ALZ-101 during an additional 16-week period. The extension part of the study aims to provide information on long-term safety and tolerability, immune response, as well as information on effects on biomarkers and cognitive functions.

CEO Kristina Torfgård comments:

"The fact that we are now obtaining good results in the second interim analysis is very positive and shows that we are well on the way to developing a vaccine that can make a big difference in the fight against Alzheimer's. Based on these positive data, we now look forward to conducting the extension part of the study, which means that all patients are offered active treatment with ALZ-101. We of course look forward to top-line data in the second half of 2023 that will give us a more comprehensive picture of the immune response of the vaccine candidate in all patients."

More about the study

Alzinova is developing a vaccine, ALZ-101, against Alzheimer's disease in a phase 1b clinical trial that accurately neutralizes the toxic accumulations of the peptide amyloid-beta, known as oligomers, which are central to the onset and progression of the disease. 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 the study participants have received four doses of either ALZ-101 or placebo. The study examines two different dose strengths of ALZ-101 over a 20-week treatment period. In the study, 20 of the patients are treated with the ALZ-101 vaccine and 6 patients with placebo. As previously communicated, top-line data for the study is expected in the second half of 2023.



The study is conducted in Finland by Alzinova's partner, Clinical Research Services Turku-CRST Oy, which has extensive experience in Alzheimer's studies and research with centers in Turku and Helsinki. The work on the biomarkers is part of a research collaboration with Sahlgrenska University Hospital in Gothenburg.

About ALZ-101

There is currently no cure, and although the first disease-modifying drugs have recently been approved in the US, there is still a very long way to go to truly treat and prevent the development of Alzheimer's disease. Alzinova's approach of developing a therapeutic vaccine that specifically targets the toxic accumulations of amyloid-beta in the form of oligomers in the brain has several advantages over other approaches. Other players are developing treatments that target larger accumulations of amyloid-beta, known as plaques in the brain, which are thought to contain both toxic and harmless protein. It has been shown that this is unlikely to be sufficiently effective and can result in serious side effects. In contrast, Alzinova has managed to identify a method that could specifically target the toxic protein in the brain, amyloid-beta oligomers, one of the underlying causes of Alzheimer's disease. Vaccination with ALZ-101 involves the body generating its own antibodies, specific to toxic accumulations of amyloid-beta oligomers in the brain. These toxic substances are expected to be neutralized, protecting the brain's synapses from damage and potentially preventing 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. The company therefore believes that it is likely to be more successful than other broader approaches to 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 2023-05-04 17:37 CEST.

Attachments

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