



Alzinova: Primary analysis confirms positive phase 1b results with ALZ-101 against Alzheimer's

Alzinova AB (publ) (ticker: ALZ) announces today the primary analysis of study data from Alzinova's phase 1b clinical trial in Alzheimer's disease with the vaccine candidate ALZ-101. The analysis confirms the positive top-line results and that ALZ-101 was well tolerated and safe. Furthermore, the analysis confirms a high frequency of immune response and that patients treated with ALZ-101 responded with antibody levels that increased with the number of doses given.

"The results from the full analysis confirm that ALZ-101 is a promising vaccine candidate against Alzheimer's disease. The analysis confirms that the primary objective of safety and tolerability was met and also indicates positive results for the antibody response. We look forward to sharing our results with potential partners", says Alzinova's CEO Kristina Torfgård.

Full analysis of the dataset from the first part of this Phase 1b study (part A) confirms the favourable safety and tolerability profile observed in all dose groups and a high frequency of immune response, and that patients treated with ALZ-101 responded with antibody levels that increased with the number of doses given. The analysis also shows that patients dosed with the highest dose of vaccine, 250 µg, had a higher response rate compared to 125 µg,

Exploratory endpoints regarding the effect of treatment on biomarkers and cognition were also analysed. The results show no clear change in biomarkers and exploratory endpoints for cognition, possibly due to the short duration of treatment. This is expected to be observed in the extension part of the study, which continues in 2024 with expected results in the first half of 2025.

Given the favourable safety and tolerability profile, Alzinova has applied for an addition to the study where a higher dose will be evaluated. The extension will be done as an open-label part of the study and includes six patients who will be treated with 400 µg over a 16-week period with four treatment sessions. The patients will then be followed up for an additional 4 weeks. This is not expected to affect the timetable for the planned phase 2 study.

"The excellent safety profile opens up the possibility of optimising the treatment effect by maximising dose strengths", she continues.

A scientific article describing the study results will be compiled for submission to a medical journal for publication. The results are also planned to be presented at upcoming international medical conferences.

About ALZ-101 and Alzheimer's disease

Alzheimer's is a fatal disease that initially affects the brain and leads to problems with memory, thinking and behaviour. It is the most common form of dementia, and it mostly affects older people. Symptoms develop gradually and include memory loss, confusion and difficulty doing everyday things. The cause of the disease is not entirely clear, but the accumulation of toxic



substances in the brain plays a role. 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 vaccine and antibody treatments that specifically target the toxic accumulations of amyloid-beta in the form of oligomers in the brain has several advantages over other approaches. Other treatments target larger accumulations of amyloid-beta, known as plaques in the brain, which are believed to contain both toxic and harmless proteins. Alzinova has developed a method that could specifically target the brain's toxic 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 neutralised, thus protecting the brain's synapses from damage, which could slow or prevent the development of Alzheimer's disease. The treatment method is also expected to have a lower risk of side effects such as brain oedema. The company therefore believes that it is likely to be more successful than other broader approaches to Alzheimer's disease.

More about the phase 1b study

The primary objective of the study is to evaluate the safety and tolerability of repeated doses of the vaccine candidate ALZ-101 in patients with early Alzheimer's disease. The study also includes secondary and exploratory endpoints related to immune response and biomarkers.

The double-blind randomised phase 1b study included 26 patients with early Alzheimer's disease. The study, which is divided into two parts, is evaluating two different dose levels of ALZ-101, 125 and 250 µg, as well as placebo. In part A of the study, 20 patients were treated with ALZ-101 vaccine and six patients with placebo. The full analysis is based on previously communicated topline results from the first treatment arm when all patients received four doses over a 20-week period.

Alzinova is proceeding with the extension part (part B) of the study, where all patients are offered active treatment with ALZ-101 for a 20-week period. Patients are then followed during 48 weeks. Part B of the study will provide information on long-term safety and tolerability, the long-term immune response, as well as information on the effect of ALZ-101 on biomarkers and cognitive functions.

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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 2024-01-30 08:20 CET.

Attachments

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