PRESS RELEASE
29 November 2023 07:00:00 CET

Alzinova announces positive phase 1b results with the vaccine candidate ALZ-101 against Alzheimer's disease

- The study met the primary endpoint of safety and tolerability after 20 weeks.
- Patients treated with ALZ-101 responded to treatment with antibody levels increasing with the number of doses given.
- No cases of ARIA-E and one case of ARIA-H detected in the treatment groups.

Alzinova AB (publ) (ticker: ALZ) announces positive top-line results from its phase 1b clinical trial of the vaccine candidate ALZ-101 in Alzheimer's disease. A first analysis of the study data shows that ALZ-101 has continued good tolerability, an acceptable safety profile and a high immune responder rate. Furthermore, the results show that patients treated with ALZ-101 responded with antibody levels that increased with the number of doses given. A full analysis of the study data is expected to be completed in the first quarter of 2024. The positive results support continued clinical development of ALZ-101, and preparations for a planned phase 2 study are ongoing.

The primary endpoint 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. Exploratory efficacy data of the treatment's effect on biomarkers and cognition will be included in the full analysis of the study results, which is expected to be completed in the first quarter of 2024.

“The positive top-line results further strengthen our confidence in that ALZ-101 can become a unique therapeutic vaccine and thus help patients suffering from Alzheimer's disease and their families to a better life. Alzinova has the potential to revolutionise the treatment of Alzheimer's, and we look forward to the final analysis, where we will see outcomes on several different endpoints. This result also strengthens our position in discussions with potential partners”, says Alzinova’s CEO Kristina Torfgård.

The double-blind randomised phase 1b study included 26 patients with early Alzheimer's disease. The study, which is divided into two parts, is examining 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 top-line results are based on analysis after the first part of treatment when all patients received four doses over 20 weeks of treatment.

Results from part A show good tolerability, an acceptable safety profile and a high immune responder rate. All 26 patients completed part A of the study. Antibody levels show that the patients administered with ALZ-101 responded favourably to treatment with antibody levels increasing with the number of doses given. One patient who entered the study with a history of ARIA-H (microbleeding) had a symptom-free increase in size. No patients developed ARIA-E (localised brain swelling).

”Alzinova has the potential to transform the treatment of Alzheimer's, which has now been confirmed by the strong results from the first part of the study, and we look forward to seeing the results from part B of the study. Our vaccine candidate has great potential to make a difference in reducing the burden for both patients and the healthcare system.”, says Alzinova’s CMO Kirsten Harting.

All patients underwent magnetic resonance imaging to detect ARIA-E and ARIA-H. These types of side effects can occur with antibody treatment against the peptide Aβ. ARIA-H may occur spontaneously in individuals with mild cognitive impairment or Alzheimer's disease. Clinical studies on Aβ antibodies have previously shown an increased risk of both ARIA-E and ARIA-H as a result of the treatments.

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 on biomarkers and cognitive functions.

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.

For more information, please contact:
Kristina Torfgård, CEO
Tel. +46 708 46 79 75
E-mail: **kristina.torfgard@alzinova.com**

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 AβCC 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 2023-11-29 07:00 CET.

Attachments
Alzinova announces positive phase 1b results with the vaccine candidate ALZ-101 against Alzheimer's disease