PRESS RELEASE
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Alzinova reports positive results from the phase 1b extension part of the ALZ-101 study in Alzheimer's disease

- ALZ-101 continues to demonstrate a favorable safety and tolerability profile after at least 84 weeks of study inclusion.
- The immune response from vaccination with ALZ-101 is robust and long-lasting in more than 95% of patients.
- Exploratory endpoints regarding the impact of treatment on cognitive and functional parameters have been analyzed with results showing a positive dose-dependent trend.
- Asymptomatic Amyloid Related Imaging Abnormalities (ARIA) were noted in both treated and placebo groups.

Alzinova AB (publ) (ticker: ALZ), reports continued promising results from its phase 1b clinical study with the vaccine candidate ALZ-101 in Alzheimer's disease. Analysis of data from patients who participated at least 84 weeks in the study shows that ALZ-101 continues to have a good tolerability and safety profile. Patients who responded to treatment (95%) developed antibodies in line with expectations. A clear immune response was observed even after longer time intervals between doses. The positive results provide strong support for further clinical development of ALZ-101, and preparations for a phase 2 study continues. In light of these encouraging results, the company invites for a live Q&A today at 13.00.

"We are extremely pleased with the promising results from our phase 1b study with ALZ-101. These data show not only a good tolerability and safety profile, but also a strong immune response in patients with Alzheimer's disease. This reinforces our belief in the potential of ALZ-101 and we look forward to taking the next step in our clinical program", says Alzinova's CSO Anders Sandberg.

Analysis of data from patients who participated for at least 84 weeks in parts A1 and B (the extension part up to week 42, where all patients received the higher dose of 250 µg) of the phase 1b study confirms the favorable safety and tolerability profile observed in both dose groups as well as a high rate of immune response. A clear response was also observed after longer time intervals between doses.

Observed side effects include local injection site reactions such as irritation, swelling, pain and redness. MRI scans showed ARIA-E (localized brain swelling) in one patient and ARIA-H (microhemorrhage) in 9 patients during the study period. These ARIAs were all asymptomatic. Clinical studies with targeted anti-Aβ antibody therapies have shown an increased risk of both ARIA-E and ARIA-H as a result of the treatments, but both can also occur spontaneously in individuals with mild cognitive impairment or Alzheimer's disease.

Exploratory endpoints regarding the impact of treatment on cognitive and functional parameters have also been analyzed, with results showing an apparent dose-dependent positive trend. Given the limited number of patients in the study, these preliminary observations should be interpreted with caution, but the results are encouraging and warrant further investigation in future studies. Additional biomarker data are expected to be available from the extension part of the study, which will continue in 2024, with results expected in the first quarter of 2025.

"These results are very promising and show a strong and long-lasting immune response, even after longer intervals between dosing. This significantly strengthens the potential of ALZ-101 as a breakthrough treatment for Alzheimer's disease. We are excited to continue to evaluate the effect of ALZ-101 on cognition and biomarkers in our upcoming studies. With these data in hand, we are determined to accelerate discussions with potential partners to maximize ALZ-101's development opportunities and bring this important treatment to those who need it most", says Alzinova CEO Tord Labuda.

Invitation to Q&A today at 13.00
The company will hold a live Q&A today, December 9 at 13.00. No pre-registration is required to participate. The call will be conducted in Swedish. To participate, please visit: **https://www.finwire.tv/webcast/alzinova/live/**

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 randomized phase 1b study includes 26 patients with early Alzheimer's disease. The study, which is divided into three parts, has examined several different dose strengths of ALZ-101, 125, 250 and 400 µg and placebo. In part A of the study, 20 of the patients were treated with the ALZ-101 vaccine and six patients with placebo.

Alzinova has continued with an extension part (part B) of the phase 1b study, which involved offering all patients active treatment with 250 µg of ALZ-101 for a 20-week period. Patients were then followed for 48 weeks. Part B of the study aims to 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.

Another part, part A2, is still ongoing where 400 µg ALZ-101 is administered to 6 patients four times following the same procedure as in the other groups but with a shorter follow-up. Data from this part of the study as well as a full analysis of all data from the study will be conducted after the last patient visit has been completed for all parts of the study, which is expected to take place in the first quarter of 2025.

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 accumulations of toxic 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.

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.

For more information, please contact:
Tord Labuda, CEO
E-mail: **tord.labuda@alzinova.com**

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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 Mangold Fondkommission 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 2024-12-09 07:30 CET.

Attachments
Alzinova reports positive results from the phase 1b extension part of the ALZ-101 study in Alzheimer's disease