PRESS RELEASE
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Final results confirm positive phase 1b results with ALZ-101 against Alzheimer's disease

Alzinova AB (publ) (ticker: ALZ) today announces that the final analysis of data from the Phase 1b clinical study with the vaccine candidate ALZ-101, which included patients with early Alzheimer's disease, is now complete. The primary and secondary objectives of the study – safety, tolerability and immunogenicity – have been achieved. In addition, the exploratory endpoints show a stable disease picture with no signs of deterioration. With this, Alzinova's Phase 1b clinical study is now completed.

Tord Labuda, CEO of Alzinova, comments: *"The results exceeded our expectations for a Phase 1b clinical trial. Although the study was designed to evaluate the safety, tolerability and immunogenicity of ALZ-101, we are already seeing clear trends suggesting a clinically meaningful treatment effect. These findings are further supported by positive effects on an important neurodegenerative biomarker. We look forward with confidence to confirming these promising results in a larger Phase 2 study."*

Anders Sandberg, CSO for Alzinova, comments: *"ALZ-101 has now been tested in humans for the first time with positive results. It is gratifying to see that more pieces of the puzzle are falling into place and indicating a mechanism of action in Alzheimer's disease that no other treatment has shown."*

Detailed information on the results of the study ALZ-C-001

Safety and tolerability

ALZ-101 has been shown to be safe and tolerable in the Phase 1b clinical trial. The most common adverse reactions were injection-related events, such as pain, redness, tenderness and heat at the injection site, with the majority of cases being mild in nature.

The incidence of Amyloid-Related Imaging Abnormalities - Hemorrhagic (ARIA-H) was comparable between the active groups and the placebo group. In the blinded part of the study, seven patients who received ALZ-101 and two patients who received placebo developed ARIA-H without symptoms. In the open-label part of the study, asymptomatic ARIA-H was observed in two patients, one of whom also developed asymptomatic ARIA-E (Edema).

Overall, the results indicate that ALZ-101 has a favorable safety profile with few and mild side effects, supporting its potential as a safe treatment alternative for patients with early Alzheimer's.

Immune response

Patients who received ALZ-101 in the blinded part of the study developed comparable levels of anti-oligomeric IgG antibodies regardless of dose. Four intramuscular injections were given at 0, 4, 8, and 16 weeks, triggering an adequate immune response with high and persistent antibody levels.

During the extension period, booster doses of 250 µg ALZ-101 were given, which led to a rapid and powerful production of IgG antibodies. These antibodies were still measurable 52 weeks after the last booster dose, suggesting a long-lasting immune response. T-cell analyses supported these results and showed a strong contribution from the humoral immune system, which is of the Th2 type. This indicates that ALZ-101 may provide a lasting and effective immunity against toxic amyloid-beta oligomers.

Altogether, these results show that ALZ-101 has the potential to induce a strong, long-lasting and recurrent immune response, which is an important step in the development of an effective treatment for Alzheimer's.

Exploratory endpoints

In the Phase 1b clinical study with ALZ-101, it was observed that most patients who received the active treatment did not experience any clinical deterioration during the course of the study, which lasted on average between 100 and 140 weeks. This suggests a potential benefit in slowing disease progression compared to other Aβ-targeted treatments. To confirm this hypothesis, however, a larger patient group is needed.

The vaccination with ALZ-101 did not cause neuroinflammation and did not alter plaque pathology, demonstrating that the vaccine is safe and specifically targeted against toxic amyloid-beta oligomers. In addition, measurements of neurofilament light (NFL), a biomarker of neuronal damage, showed a trend toward lower values in patients who received ALZ-101 compared to those who initially received placebo. This is consistent with a possible slowing down of the neurodegenerative process.

Other biomarkers such as P-Tau181, T-Tau, and Neurogranin responded to treatment with ALZ-101, but the changes were small and did not persist after further administration. These findings suggest that ALZ-101 works in a different way than treatments that directly affect plaques. The biomarkers are used to assess disease stage and distinguish Alzheimer's from other forms of dementia, but their dynamic changes associated with treatments are currently not fully understood.

Altogether, these results indicate that ALZ-101 has the potential to slow disease progression and provide a safe and specific treatment against toxic amyloid-beta oligomers. However, to fully confirm these findings, further studies with larger patient groups are required.

Henrik Zetterberg, Professor of Neurochemistry at the University of Gothenburg, who was involved in the biomarker analysis of the study, comments: *"The strong safety and immunogenicity profile of ALZ-101, together with early signs of a clinically meaningful effect, highlights its potential as a distinct and promising therapy for Alzheimer's disease."*

Summary of the study design

The Phase 1 clinical trial ALZ-C-001 was a randomized, double-blind, and placebo-controlled study that evaluated safety, tolerability, and immunogenicity in patients with early Alzheimer's disease. In the initial blinded part of the study, 26 patients were randomized to either ALZ-101 at doses of 125 µg (n=10) or 250 µg (n=10), or to placebo (n=6). Patients were followed for at least 30 weeks.

After the blinded phase, 23 of the 26 patients progressed to open-label treatment, where they received active treatment with 250 µg ALZ-101. This part of the study lasted for an additional 68 weeks. In addition, a dose group of six patients were treated with 400 µg ALZ-101 and followed for 20 weeks.

During the blinded phase, patients received four treatments with either ALZ-101 or placebo. In the open-label phase, patients who had received placebo in the blinded phase of the study were treated with 250 ug ALZ-101 on four occasions, while all other patients received active treatment on two occasions.

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About Alzinova AB
Alzinova AB is a Swedish biopharmaceutical company in clinical development specializing in the treatment of Alzheimer's disease, where the starting point is to attack toxic amyloid-beta oligomers. The lead candidate ALZ-101 is a therapeutic vaccine against Alzheimer's disease. Alzinova's patented AβCC peptide technology makes it possible to develop disease-modifying treatments that target the toxic amyloid-beta oligomers that are central to the onset and development of the disease with great accuracy. From a global perspective, Alzheimer's disease is one of the most common and devastating neurological diseases, with around 40 million affected today. Based on the same technology, the company is also developing the antibody ALZ-201, which is currently in preclinical development, and the goal is to further expand the pipeline. 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 2025-03-27 09:40 CET.

Attachments
Final results confirm positive phase 1b results with ALZ-101 against Alzheimer's disease