

# Alzinova's ALZ-101 vaccine shows new promising results in normalizing protective antibody levels in Alzheimer's disease patients

Alzinova AB (ALZ) announces new clinical results showing that healthy elderly people naturally have high levels of protective antibodies against toxic amyloid- $\beta$  oligomers, which are reduced in Alzheimer's patients. The vaccine, ALZ-101, raises these antibody levels in Alzheimer's patients to match those of healthy controls, offering a promising new approach to address immune deficits in Alzheimer's disease.

Advances in Alzheimer's disease research have identified naturally occurring antibodies (NAbs) as promising biomarkers and potential therapeutic agents due to their ability to neutralize amyloid- $\beta$  (A $\beta$ ) aggregates. However, progress in this field has been limited by inconsistent study results, largely stemming from the lack of reliable tools for specifically measuring NAbs against neurotoxic oligomeric forms of A $\beta$ .

In the clinical trial ALZ-C-001, Alzinova applied its proprietary oligomer-stabilizing A $\beta$ 42CC technology to accurately measure antibodies targeting neurotoxic A $\beta$  oligomers. Interestingly, the data revealed that healthy elderly individuals possess higher levels of anti-A $\beta$ 42CC IgG NAbs than both AD patients and younger adults. One compelling hypothesis that emerges from these results is that aging may naturally stimulate a protective immune response against toxic A $\beta$ . In contrast, AD patients appear to lack this important defense mechanism.

Treatment with Alzinova's vaccine, ALZ-101, elevated oligomer specific antibody levels in AD patients to match those observed in healthy elderly controls. This finding underscores ALZ-101's potential to correct the immune systems deficiency to neutralize the neurotoxic aggregates observed in Alzheimer's disease and offers new hope for slowing disease progression.

"These results highlight the importance of targeting neurotoxic Aβ oligomers with precision and offer a compelling rationale for advancing ALZ-101 as a novel therapy for Alzheimer's disease. By stimulating production of protective antibodies, we may be able to address a key vulnerability in the disease and improve outcomes for patients," comments Tord Labuda, CEO of Alzinova.

Collectively, these findings strengthens the hypothesis that enhancing the body's antibody response against neurotoxic A $\beta$  could play a central role in combating Alzheimer's disease progression. Alzinova remains committed to further developing ALZ-101 and exploring its potential as a next-generation treatment for AD.



## About Alzinova's Aβ42CC technology

AβCC Peptide<sup>™</sup> Technology stabilizes Aβ42 oligomers via conformational restriction by introducing a strategically placed disulfide bond. This covalent modification prevents the structural shift required for fibril formation, resulting in Aβ42CC accumulating as stable, homogeneous oligomers with an antiparallel β-sheet conformation. This structural signature distinguishes oligomers from fibrils, which adopt parallel β-sheet arrangements. Preclinical studies using brain-derived, physiologically relevant material confirm that ALZ-101 vaccination generates oligomer-specific antibodies capable of selectively neutralizing low-abundance toxic Aβ oligomers, highlighting its novel therapeutic mechanism for Alzheimer's disease.

## About ALZ-C-001

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  $\mu$ g (n=10) or 250  $\mu$ g (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  $\mu$ g 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  $\mu$ g 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.

#### For further information, please contact:

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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 2025-06-19 08:50 CEST.

## Attachments

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