



Alzinova: Positive results from the phase 1b study are presented at AAIC 2024

Alzinova AB (publ) (ticker:ALZ), a Swedish biopharma company focused on the development of treatments for Alzheimer's disease, present in-depth data from the company's phase 1b clinical trial with the vaccine candidate ALZ-101 at the Alzheimer's Association International Conference, AAIC, in Philadelphia, USA on 28 July - 1 August 2024. The presentation is made by Henrik Zetterberg, Professor of Neurochemistry at the University of Gothenburg and University College London and Scientific Advisor to Alzinova. The presentation includes data from the phase 1b study on the safety, tolerability and immunogenicity of the vaccine candidate ALZ-101 in patients with mild cognitive impairment (MCI) or mild Alzheimer's disease (AD).

'The promising results from our phase 1b study show that ALZ-101 is not only safe and tolerable, but also effective in inducing an immune response in patients with mild Alzheimer's disease. This strengthens our conviction that ALZ-101 has the potential to be the next disease-modifying treatment for Alzheimer's disease with potential to be best-in-class', comments Anders Sandberg, Chief Scientific Officer at Alzinova.

ALZ-101 is a vaccine being developed to help the body's immune system fight Alzheimer's disease. It consists of a stabilised form of the protein amyloid-beta-42 (A β 42), which stimulates the body's own immune response specifically against harmful protein accumulations, also known as oligomers, in the brain that are linked to the disease. By targeting these toxic oligomers, the company hopes to offer a new disease-modifying treatment for Alzheimer's disease with the potential to slow or prevent its progression. Alzinova's treatment differs from other drugs in development in that the vaccine candidate ALZ-101 is significantly more specific in targeting toxic oligomers and, as a vaccine, is easy to administer. This makes ALZ-101 a very attractive drug candidate.

Summary of the poster:

- The study met its primary endpoint of safety and tolerability after 20 weeks in patients with MCI and mild Alzheimer's disease.
- No cases of meningoencephalitis or ARIA-E were detected.
- ALZ-101 generated an oligomer-specific immune response in all, i.e. 100%, treated subjects in both dose groups.
- Patients treated with a higher dose of ALZ-101 had a higher response to treatment.
- Despite a short exposure time to antibodies (from week 8), high antibody levels had a positive effect on biomarkers (neurogranin and tau) related to Alzheimer's disease already at week 20. Longer treatment duration may have further positive effects, including in patients with lower antibody responses (IgG titres), and this is currently being investigated in an open-label extension of the study (part B).



Poster Title: *Phase 1b trial on the safety, tolerability and immunogenicity of anti-amyloid vaccine ALZ-101 in subjects with MCI or mild AD (#95440)*

Session: Developing topics: Drug Development

About the phase 1b study, its results and further studies

The presented phase 1b study, referred to as ALZ-C-001 or part A, is a double-blind, placebo-controlled study with 26 patients randomised to receive either placebo, a 125 µg dose or a 250 µg dose of ALZ-101. The study also has an open-label extension phase (part B) with 23 of the original participants, as well as a new group of 6 patients receiving a 400 µg dose (part A2).

ALZ-101 was shown to be safe and tolerable in the phase 1b study, eliciting a strong immune response in patients with MCI and mild AD. The positive changes in CSF biomarkers are encouraging, and the open-label extension phase of the study currently in progress is investigating this further.

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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.

Attachments

Alzinova: Positive results from the phase 1b study are presented at AAIC 2024