



A higher dose of ALZ-101 also shows good safety and tolerability

Alzinova AB (publ) (ticker: ALZ) announces that the Company has received data for the treatment arm where the patients were treated with 400 µg in the Company's Phase 1b study. This treatment arm also shows good safety and tolerance. In this part of the study, a total of six patients were treated, open label, with 400 µg ALZ-101 at four occasions over 16 weeks.

As previously announced, all data points for the Company's entire Phase 1b study are now being processed, analyzed and compiled and the final results for the entire study period are planned to be communicated by the end of March 2025. The Phase 1b study was expanded with a treatment arm to investigate whether a higher dose, 400 µg ALZ-101, have the same safety and tolerability as lower doses, and whether secondary endpoints are met to a greater extent.

Six patients were enrolled in this arm and treated on four occasions at the same intervals as in the other groups. These patients were followed for a total of 20 weeks. The company has now analyzed data from this part, and the results show the same good safety and tolerability as for the lower doses and generate immune responses on par with other dose levels. No cases of ARIA-H or ARIA-E (Amyloid Related Imaging Abnormalities) were noted in this part of the study. These results strengthen confidence in the safety and efficacy of ALZ-101, which is crucial ahead of the planned Phase 2 study.

"The results from this particular part of the study are in line with our expectations, and we are of course very happy to have this confirmed", says Alzinova's CEO Tord Labuda.

About the Phase 1b study

The Phase 1b study has been completed. All data points are being processed, analyzed, and compiled. The primary objective of the study is to evaluate the safety and tolerability of repeated dosing of the ALZ-101 vaccine candidate in patients with early Alzheimer's disease. The study also includes secondary and exploratory endpoints related to immune response and biomarkers.

The Phase 1b study includes a total of 32 patients with early Alzheimer's disease. The study has examined three different dose strengths of ALZ-101, 125, 250 and 400 µg as well as placebo. In one part of the study, 20 of the patients were treated double-blind and randomized with the ALZ-101 vaccine in doses of 125 µg or 250 µg and six patients with placebo.

The study was expanded with an extension part (part B), which meant that all patients were offered active treatment with 250 µg ALZ-101 over a 20-week period and with an additional 48 weeks follow-up. The primary purpose of the B part is to provide information on long-term safety and tolerability, the long-term immune response, and information on the effect on biomarkers and cognitive functions.



The study was further expanded to investigate whether higher dose, 400 µg ALZ-101, has the same safety and tolerability as lower doses, and whether secondary endpoints are met to a greater extent. Six patients were enrolled in this treatment arm and were treated on four occasions at the same intervals as in the other groups. These patients were followed for a total of 20 weeks.

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

Attachments

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