PRESS RELEASE
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Alzinova receives regulatory approval to evaluate a higher dose

Alzinova AB (publ) (ticker: ALZ) announces today that based on strong clinical data, the company has received approval from regulatory authorities to evaluate a higher dose of the vaccine candidate ALZ-101 in the ongoing phase 1b study. The company considers this to be strategically important for the upcoming phase 2 study.

"The strong data read out in January confirmed that ALZ-101 is a very promising vaccine candidate against Alzheimer's disease. It feels great to have come this far and to be able to contribute to the development of a vaccine that really has the potential to treat patients with this devastating disease", says Alzinova's CEO Kristina Torfgård.

The full analysis from the first part of the phase 1b study (part A) confirmed the favourable safety and tolerability profile observed in both dose groups. In addition, a high frequency of immune response was demonstrated and furthermore that patients treated with ALZ-101 responded with antibody levels that increased with the number of doses given. The analysis also shows that patients dosed with the highest dose of the vaccine had a higher response rate compared with the lower dose.

Based on the favourable results, Alzinova applied for an extension of the study to evaluate an additional higher dose, which has now been approved by the regulatory authorities. The extension is made as an open-label part of the study and includes six patients who are treated with 400 µg over a 16-week period with four treatment sessions. The patients will then be followed up after another 4 weeks. Alzinova expects to be able to start recruitment for the extension in the spring of 2024 and this is not expected to affect the timetable for the planned phase 2 study.

More about the phase 1b study
Alzinova's phase 1b study is the first of its kind with a vaccine against the toxic oligomers believed to cause Alzheimer's disease. 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 randomised phase 1b study included 26 patients with early Alzheimer's disease. The study, which is divided into two parts, is evaluating two different dose levels of ALZ-101, 125 and 250 µg, as well as placebo. In part A of the study, 20 patients were treated with ALZ-101 vaccine and six patients with placebo. The full analysis presented in January 2024 confirmed previously communicated topline results. The positive results show that the company has reached the primary endpoint regarding safety and tolerability but also secondary endpoint regarding immune response.

Alzinova has since earlier also an extension part (part B) ongoing as part of the study. The purpose is to learn more about the vaccine candidate during a longer period of treatment with a focus on safety and tolerability as well as immune response before the next part of the clinical development. Part B involves all patients being offered active treatment with ALZ-101 for a 20-week period and then followed for 48 weeks. It is done as an open-label study where Alzinova can obtain information on safety and tolerability at the same time as applying to start the phase 2 study. Thus, the B part does not need to be fully reported before starting the next study.

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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.

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 Redeye AB. For more information about Alzinova, please visit: **www.alzinova.com**

Attachments
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