

First patient dosed in the extension part of the phase 1b study with ALZ-101

Alzinova AB (publ) (FN STO: ALZ), a Swedish biopharma company developing treatments of Alzheimer's disease, announces today that the extension part of the ongoing phase 1b study has been initiated by dosing the first patient with the vaccine candidate ALZ-101.

"We recently decided to initiate an extension part of the phase 1b study with the vaccine candidate ALZ-101 following the positive data we received from an interim analysis in May. The extension part will give us information on immune response, safety and tolerability, after a longer period of treatment. In addition, we have the opportunity to obtain information on the effect on biomarkers and cognitive functions. This is something that we see strengthens our position further and is valuable for future interactions with potential partners.," says Kristina Torfgård, CEO of Alzinova AB.

More about the extension part of the phase 1b study

Based on the positive interim data that the Company received earlier in May 2023, it was decided to conduct an extension part of the phase 1b study where everyone receives active treatment. The extension part means that all patients who have received their fourth vaccine dose are offered treatment with additional doses of ALZ-101 over a 16-week period. The extension part of the study aims to provide information on long-term safety and tolerability, immune response, as well as information on effect on biomarkers and cognitive functions.

Alzinova is developing a vaccine, ALZ-101, against Alzheimer's disease in a phase 1b clinical trial that accurately neutralizes the toxic accumulations of the peptide amyloid-beta, so-called oligomers, which are central to the onset and development of the disease. The Phase 1b clinical study with ALZ-101 in patients with early Alzheimer's disease is a placebo-controlled, randomized, double-blind FIH (First In Human) study. The study includes 26 patients where study participants have received four doses of either ALZ-101 or placebo. The study examines two different dose strengths of ALZ-101 over a 20-week treatment period. In the study, 20 of the patients are treated with the ALZ-101 vaccine and 6 patients with placebo. As previously communicated, topline data for the study is expected in the second half of 2023.

The study is conducted in Finland by Alzinova's partner, Clinical Research Services Turku (CRST Oy), which has extensive experience in Alzheimer's studies and research with centers in Turku and Helsinki. The work on biomarkers is part of a research collaboration with Sahlgrenska University Hospital in Gothenburg.

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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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