



Alzinova reaches important milestone - phase 1b study fully recruited

Alzinova AB (publ) ("Alzinova" or the "Company") announces today that the Company has reached an important milestone where the last patient in the Phase 1b study with the vaccine candidate ALZ-101 against Alzheimer's disease has been enrolled and received its first dose. After the fourth and final dose, patients will be followed for 48 weeks.

Alzinova is the first company with an oligomer-specific vaccine in clinical phase. The phase 1b clinical trial of ALZ-101 in patients with early Alzheimer's disease is a placebo-controlled, randomized, double-blind FIH (First In Human) study. A total of 26 Alzheimer's patients are enrolled in the study where participants will receive four doses of either the ALZ-101 vaccine or placebo. The study started in October 2021 when the first patient was enrolled. The study is looking at two different dose strengths of ALZ-101 over a 20-week treatment period. In December 2022, the Company announced positive interim data showing continued good safety and tolerability and data suggesting an immune response. Top-line data from the study is expected in the second half of 2023.

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

CEO Kristina Torfgård comments:

"Alzinova continues to successfully achieve its goals as we have now enrolled the last patient in this important Phase 1b study and have reached another significant milestone. Earlier in December, we were able to announce positive interim data which we will follow up with another interim analysis in spring 2023 before obtaining topline data in the second half of 2023. In addition to ensuring that the study progresses and is completed in the best possible way, the time until the results are presented will include interactions with regulatory authorities, among other things. First up will be the request for a pre-IND meeting with the FDA. We will also intensify our dialogues with current and new potential partners."

About ALZ-101

The market for treatments of Alzheimer's disease is large as there is currently no effective treatment to cure or slow down the progression of the disease. Alzinova's approach, to develop a therapeutic vaccine that specifically targets the toxic accumulation of amyloid-beta in the form of oligomers in the brain, has several advantages compared to other methods. Other companies are developing treatments that target larger accumulations of amyloid-beta, so-called plaques in the brain, which are believed to contain both toxic and harmless protein. It has been shown that it is unlikely to be sufficiently effective, and may also result in serious side effects. Unlike these, Alzinova has succeeded in identifying a method that could specifically target the most toxic accumulations in the brain (amyloid-beta oligomers), one of the causative factors behind



Alzheimer's disease. Vaccination with ALZ-101 means that the body generates its own antibodies that are specific against the toxic accumulations of amyloid-beta oligomers in the brain. The toxic substances are expected to be neutralized, thus protecting the brain's synapses from damage which could prevent the development of Alzheimer's disease. This treatment method is also expected to have a lower risk of side effects such as bleeding and edema. Therefore, the Company believes that it is likely to be more successful compared to other broader approaches for treating Alzheimer's disease.

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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 A β CC 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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