

Alzinova: First patient dosed with a higher dose of ALZ-101 in the phase 1b study

Alzinova AB (publ) (ticker: ALZ), today announces that the first patient has been dosed with a higher dose in the company's phase 1b study (part A2) with the vaccine candidate ALZ-101. The treatment is given to six patients who are treated with 400 µg ALZ-101 over a 16-week period.

"We are pleased that the first patient has been dosed with our vaccine candidate ALZ-101 in the high dose part of our phase 1b study. The results from the first part of the study showed a promising safety profile and an immune response in the patients. With this strategic addition to the study, we will evaluate the safety and tolerability of a higher dose of ALZ-101 which is important for the upcoming phase 2 study. Our goal is to continue to advance the development of treatments for Alzheimer's disease and improve the quality of life for those affected." says Kristina Torfgård CEO of Alzinova AB.

The full analysis from the first part of the phase 1b study (part A), reported in early 2024, confirmed the favourable safety and tolerability profile of the ALZ-101 vaccine candidate. In addition, a high frequency of immune response was demonstrated, showing that patients treated with ALZ-101 responded with antibody levels that increased with the number of doses given. The analysis also showed that patients dosed with the highest dose of the vaccine had a higher response rate. Based on the favourable results, Alzinova applied for an extension of the study (part A2) to evaluate an additional higher dose. This strengthens Alzinova's knowledge of, among other things, dosing of ALZ-101, which optimises the conditions for a future clinical phase 2 study.

The first patient in part A2 has now been dosed with 400 μ g of the vaccine candidate ALZ-101. The high-dose part is done as an open-label part of the study and includes a total of six patients who will be treated on four occasions over a 16-week period. The patients will then be followed up for another four weeks.

About Alzheimer's disease and the vaccine candidate ALZ-101

Alzheimer's is a fatal disease that initially affects the brain and leads to problems with memory, thinking and behaviour. It is the most common form of dementia, and it mostly affects older people. Symptoms develop gradually and include memory loss, confusion and difficulty doing everyday things. The cause of the disease is not entirely clear, but the accumulation of toxic substances in the brain plays a role. There is currently no cure and although the first disease-modifying drugs have recently been approved in the US, there is still a very long way to go to truly treat and prevent the development of Alzheimer's disease.

Alzinova's approach of developing vaccine and antibody treatments that specifically target the toxic accumulations of amyloid-beta in the form of oligomers in the brain, has several advantages over other approaches. Other treatments target larger accumulations of amyloid-beta, known as plaques in the brain, which are believed to contain both toxic and harmless proteins. Alzinova has



developed a method that could specifically target the brain's toxic amyloid-beta oligomers, one of the underlying causes of Alzheimer's disease. Vaccination with ALZ-101 involves the body generating its own antibodies, specific to toxic accumulations of amyloid-beta oligomers in the brain. These toxic substances are expected to be neutralised, thus protecting the brain's synapses from damage, which could slow or prevent the development of Alzheimer's disease. The treatment method is also expected to have a lower risk of side effects such as brain oedema. The company therefore believes that it is likely to be more successful than other broader approaches to 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 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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