



Alzinova: First participant has successfully completed the entire phase 1b study with ALZ-101

Alzinova AB (publ) (FNSE: ALZ), a Swedish biopharma company specialising in the treatment of Alzheimer's disease, announces that the first participant in the company's ongoing phase 1b study for the vaccine candidate ALZ-101 has now completed the study and made their last visit. This is an important milestone in the development of the company's innovative treatment for Alzheimer's disease.

The first participant has now completed their last visit, thus ending their participation in the phase 1b study. The completion of the first participant represents a significant step forward in the development of a potentially ground-breaking treatment for one of the world's biggest challenges in neurodegenerative diseases. All study participants enrolled in the extension part of the phase 1b study are expected to complete their last visit in the first quarter of 2025.

"It is with great pleasure and pride that we can announce that the first participant has now completed participation in our phase 1b study. This achievement represents an important milestone for Alzinova and our endeavour to develop an effective and safe vaccine for patients affected by Alzheimer's disease. We now look forward to presenting data up to week 42 of part B in the fourth quarter of 2024", says Carol Routledge, acting CEO of Alzinova AB.

About the phase 1b study with ALZ-101

Alzinova's vaccine candidate, ALZ-101, is in a phase 1b clinical trial. The primary objective of the study is to evaluate the safety and tolerability of repeated doses of ALZ-101 in participants with early Alzheimer's disease. The study also includes secondary and exploratory endpoints related to immune response and Alzheimer's disease related biomarkers. The study is randomised, placebo-controlled and double-blind, meaning that neither participants nor researchers know which treatment each participant is receiving. This ensures objectivity in evaluating the safety and tolerability of the vaccine candidate.

The first part of the study (**part A1**) has evaluated two different dose strengths. In this part of the study, 20 participants were treated with the ALZ-101 vaccine and six participants with placebo. In November 2023, Alzinova announced strong topline results from part A1 when all participants had received four doses over a 20-week period. These results were then confirmed in a full analysis published in January 2024.

The second part of the study (**part B**), which is an extension of part A1 in the phase 1b study, is ongoing and involves all participants from part A1 being offered active treatment with ALZ-101 (250 ug) for a 20-week period. The participants are then followed for 48 weeks. Part B aims to provide information on long-term safety and tolerability, the long-term immune response, as well as information on the effect on biomarkers and signals on cognitive functions following



administration of ALZ-101. In April, all participants had received their final dose of ALZ-101 in part B where a 42-week follow-up period is now ongoing. Alzinova intends to analyse and present week 42 data in the fourth quarter of 2024 before the last follow-up visits of part B of the study are fully completed.

The third and final part of the phase 1b study, the high dose cohort (**part A2**), is being done with the purpose of investigating a higher dose (400 µg) of ALZ-101 following the earlier results indicating that a higher dose produces increased antibody levels. This part was initiated in spring 2024 and includes 6 new participants treated with ALZ-101 on four occasions over a 16-week period, followed by a four-week follow-up period that will end Q4 2024. Alzinova intends to present data from this high-dose cohort in the first quarter of 2025.

About ALZ-101 and Alzheimer's disease

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 accumulations of toxic 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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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 Mangold Fondkommission AB. For more information about Alzinova, please visit: www.alzinova.com

Attachments

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