PRESS RELEASE
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Alzinova receives regulatory approval for extension part of phase 1b study

Alzinova AB (publ) ("Alzinova" or the "Company") announces today, that the Company has received regulatory approval from the Finnish Medicines Agency, Fimea, and the Finnish National Ethics Committee to initiate an extension of the phase 1b study. The extension part aims to provide information on long-term safety and tolerability, immune response and also information on effects on biomarkers and cognitive functions. The approvals are an important part of the preparations for a decision on an extension of the study, which the Company intends to make in connection with a second interim analysis of the phase 1b study in the spring of 2023.

Alzinova announced in connection with the rights issue that the Company is planning an extension of the phase 1b study aimed at providing additional information on long-term safety and tolerability, immune response as well as information on effects on biomarkers and cognitive functions. To efficiently initiate the extension part, the Company has worked with preparatory activities such as the application for regulatory approval. The regulatory approval that Alzinova has now received from the Finnish Medicines Agency, Fimea, is part of the preparations for an extension decision that the Company intends to make in connection with a second interim analysis of the phase 1b study in the spring of 2023.

CEO Kristina Torfgård comments:
" We are very pleased to have received the regulatory approval from Fimea and the ethics committee for an extension part of our phase 1b study. This extension may provide important information on long-term safety and tolerability, immune response and effects on biomarkers and cognitive functions, which will help us to understand the potential long-term effect of our vaccine candidate in patients with Alzheimer's disease."

The phase 1b clinical study of ALZ-101 in patients with early Alzheimer's disease is a placebo-controlled, randomized, double-blind First In Human (FIH) study. The study includes 26 patients where the study participants have received four doses of either ALZ-101 or placebo. The study is investigating two different dose strengths of ALZ-101 over a 20-week treatment period. The planned extension component means that all patients participating in the study will be offered treatment with ALZ-101 for an additional 16-week period, which may provide valuable long-term data.

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 the biomarkers is part of a research collaboration with Sahlgrenska University Hospital in Gothenburg.

About ALZ-101

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 a therapeutic vaccine that specifically targets the toxic accumulations of amyloid-beta in the form of oligomers in the brain has several advantages over other approaches. Other players are developing treatments that target larger accumulations of amyloid-beta, known as plaques in the brain, which are thought to contain both toxic and harmless protein. It has been shown that this is unlikely to be sufficiently effective and can result in serious side effects. In contrast, Alzinova has managed to identify a method that could specifically target the toxic protein in the brain, 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 neutralized, protecting the brain's synapses from damage and potentially preventing the development of Alzheimer's disease. The treatment method is also expected to have a lower risk of side effects such as bleeding and edema. The company therefore believes that it is likely to be more successful than other broader approaches to Alzheimer's disease.

For more information, please contact:
Kristina Torfgård, CEO
Tel. +46 708 46 79 75
E-mail: **kristina.torfgard@alzinova.com**

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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