Alzinova announces positive safety review and continuation of its Phase 1b study in Alzheimer's disease

Alzinova AB (publ) (FN STO: ALZ), a Swedish biopharma company developing treatments for Alzheimer's disease by specifically targeting neurotoxic amyloid beta oligomers, today announces that the Data and Safety Monitoring Board (DSMB) completed a planned assessment of the ongoing ALZ-101 Phase 1b clinical study and recommended continuation of the study.

The DSMB consists of independent group of experts who review data during the study, with particular attention to safety. The data are kept within the DSMB group and may not be revealed to the company, unless action is necessary regarding the execution of the study. As specified in the ALZ-101 study protocol, the DMSB meets periodically to examine the safety data accumulated during progress of the study.

Kristina Torfgård, CEO at Alzinova, commented: "Even though we expected this favourable opinion from the DSMB, it is an important step in the development of ALZ-101. We are very proud to be advancing this potential "best in class" treatment for Alzheimer's disease, and to bring hope to millions of patients and their loved ones who are suffering from this terrible disease."

More about the study
The Phase 1b clinical study with ALZ-101 in patients with early Alzheimer's disease is a placebo-controlled, double blind, randomised First In Human (FIH) trial. It is evaluating the vaccine candidate's tolerability and safety. It is also studying the immunological response to the vaccine after multiple doses, as well as a number of biomarkers associated with Alzheimer's disease. In total, 26 patients will be included in the study. Study participants receive four doses of either ALZ-101 or placebo. The study is investigating two different dose strengths of ALZ-101 during a treatment period of 20 weeks. Enrolment in the study is ongoing and topline data for the study is anticipated in the second half of 2023.

The clinical trial is being carried out in Finland by Alzinova's partner, Clinical Research Services Turku (CRST), who have extensive experience in Alzheimer's studies. The analysis of biomarkers will be made through a research collaboration with Sahlgrenska University Hospital in Gothenburg.

About ALZ-101
ALZ-101 is an active, therapeutic oligomer-specific vaccine against Alzheimer's disease. Vaccination with ALZ-101 means that the body generates its own antibodies specifically targeted at neurotoxic amyloid beta oligomers in the brain. These toxic substances are thus neutralised and, in this way, nerve cells in the brain are protected from damage.

In October 2021, the first patient was recruited into the Phase 1b clinical study with the therapeutic vaccine, ALZ-101. This was an important milestone and means that Alzinova is the first company with an oligomer-specific vaccine in the clinical phase.

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

The information was submitted for publication, through the agency of the contact person set out above, at 08:01 a.m. CEST 28 April, 2022.

About Alzinova AB
Alzinova AB is a Swedish clinical-stage biopharma company developing treatments for Alzheimer's disease by specifically targeting neurotoxic 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 therapies 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 early preclinical development, and the ambition is to expand the pipeline further. The company's Certified Advisor on Nasdaq First North Growth Market is Corpura info@corpura.se +46 768-532 822. For more information about Alzinova, please visit: www.alzinova.com