

Positive data from the clinical phase I MAD study with AlzeCure's Alzheimer's project NeuroRestore ACD856

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a pharmaceutical company that develops a broad portfolio of small molecule candidate drugs for diseases affecting the central nervous system, with projects in both Alzheimer's disease and pain, today announced that the company has completed the clinical phase I study (multiple ascending dose, MAD) with repeated dosing of the drug candidate ACD856, with a focus on Alzheimer's disease.

Data show that ACD856, the primary drug candidate within the company's NeuroRestore platform, has good tolerability and safety. Furthermore, the results demonstrate that the substance has suitable pharmacokinetic properties with rapid uptake into the body as well as relevant and dose-dependent exposure in the CNS.

The MAD Phase I study is AlzeCure's third clinical study with ACD856, the company's leading drug candidate in the NeuroRestore platform. The substance is being developed as a symptom-relieving treatment for disease states where cognitive ability is impaired, for example in Alzheimer's disease. The primary objective of the study was to evaluate the tolerability, safety and pharmacokinetics of the drug candidate after repeated dosing.

"We are very pleased that ACD856 has a very good profile for further clinical development," said Johan Sandin, CSO at AlzeCure Pharma. "With its potential to improve memory function in a variety of diseases, ACD856 may play a significant role in the treatment of indications where these key functions are impaired, such as Alzheimer's disease, sleep apnea, traumatic brain injury and Parkinson's disease."

The company started the study in September 2021 and is now presenting according to plan results from this clinical study with ACD856. Preparations are now being made to initiate further clinical trials. These upcoming studies are focused on evaluating early effect-signals in humans.

"The results for the NeuroRestore candidate ACD856 follow the previous positive clinical results with the substance, and we are now looking forward to the continued clinical studies," said Martin Jönsson, CEO of AlzeCure. "I also see that these data will stimulate potential partnership and out-licensing discussions and increase interest in the NeuroRestore platform."

For more information, please contact

Martin Jönsson, CEO
Tel: +46 707 86 94 43
martin.jonsson@alzecurepharma.com

About AlzeCure Pharma AB (publ)

AlzeCure® is a Swedish pharmaceutical company that develops new innovative small molecule drug therapies for the treatment of severe diseases and conditions that affect the central nervous system, such as Alzheimer's disease and pain – indications for which currently available treatment is very limited. The company is listed on Nasdaq First North Premier Growth Market and is developing several parallel drug candidates based on three research platforms: NeuroRestore®, Alzstatin® and Painless.

NeuroRestore consists of two symptomatic drug candidates where the unique mechanism of action allows for multiple indications, including Alzheimer's disease, as well as cognitive disorders associated with traumatic brain injury, sleep apnea and Parkinson's disease. The Alzstatin platform focuses on developing disease-modifying and preventive drug candidates for early treatment of Alzheimer's disease and comprises two drug candidates. Painless is the company's research platform in the field of pain and contains two projects: ACD440, which is a drug candidate in the clinical development phase for the treatment of neuropathic pain, and TrkA-NAM, which targets other types of severe pain in conditions such as osteoarthritis. AlzeCure aims to pursue its own projects through preclinical research and development through an early clinical phase and is continually working on business development to find suitable solutions for license agreements with other pharmaceutical companies.

FNCA Sweden AB, +46(0)8 528 00 399 info@fnca.se, is the company's Certified Adviser. For more information, please visit www.alzecurepharma.se

About NeuroRestore

NeuroRestore is a platform of symptom-relieving drug candidates for disease states in which cognitive ability is impaired, e.g. Alzheimer's Disease, sleep apnea, traumatic brain injury and Parkinson's disease. NeuroRestore stimulates several important signaling pathways in the brain, which among other things leads to improved cognition. In preclinical studies with NeuroRestore we have been able to show that our drug candidates enhance communication between the nerve cells and improve cognitive ability. NeuroRestore stimulates specific signaling pathways in the central nervous system known as neurotrophins, the most well-known being NGF (Nerve Growth Factor) and BDNF (Brain Derived Neurotrophic Factor). The levels of NGF and BDNF are disturbed in several disease states and the signaling is reduced. The impaired function impairs communication between the synapses, i.e. the contact surfaces of the nerve endings, as well as reducing the possibility of survival for the nerve cells, which gives rise to the cognitive impairments. Neurotrophins play a crucial role for the function of nerve cells, and a disturbed function of BDNF has a strong genetic link to impaired cognitive ability in several different diseases, such as Alzheimer's, Parkinson's disease, traumatic brain injury and sleep disorders. There is also a link between BDNF signaling and depression, something that has been further strengthened in recent years.

About Alzheimer's disease

Alzheimer's disease is the most common form of dementia, affecting approximately 50 million people worldwide. Alzheimer's disease is a lethal disorder that also has a large impact on both relatives and the society. Today, preventive and disease modifying treatments are missing. The main risk factors to develop Alzheimer's are age and genetic causes. Even though the disease can start as early as between 40 and 65 years of age, it is most common after 65 years. Significant investments in Alzheimer research are being made because of the significant unmet medical need and the large cost of this disease for healthcare and society. The total global costs for dementia related diseases is estimated to about 1,000 billion USD. Given the lack of both effective symptomatic treatments and disease modifying treatments, the need for new effective therapies is acute. The few approved drugs on the market today have only a limited symptomatic effect and can produce dose limiting side effects. A disease modifying treatment for Alzheimer's disease is estimated to reach more than \$15 billion in annual sales. In Sweden, approximately 100,000 people suffer from Alzheimer's disease with a healthcare cost of about SEK 63 billion yearly, which is more than for cancer and cardiovascular diseases combined.

This information is information that AlzeCure Pharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2022-06-29 11:00 CEST.

Image Attachments

Martin Jönsson CEO AlzeCure Pharma

Attachments

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