

AlzeCure presents new clinical data with NeuroRestore ACD856 at the Alzheimer's conference AAIC

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's presentation at the Alzheimer's conference AAIC 2022, regarding new clinical data with its leading drug candidate NeuroRestore ACD856, which is being developed with a focus on Alzheimer's disease, is now available in its entirety on the company's website.

The presentation, titled *Results From a Multiple Ascending Dose Study in Healthy Volunteers of ACD856, a Positive Modulator of Neurotrophin Trk-Receptors*, was held by project manager Kristin Önnestam and contains new clinical data from the phase I MAD study with the leading drug candidate in the NeuroRestore project, ACD856. The study, in which ACD856 or placebo was administered orally repeatedly for one week to 24 healthy subjects divided into 3 groups in incremental doses, had the primary aim of evaluating the safety, tolerability and pharmacokinetics of ACD856 after repeated dosing in humans.

The results show that ACD856 has a very good tolerability and safety profile without any significant safety findings in the study participants at the tested doses of 10, 30 and 90 mg. The substance also showed a good pharmacokinetic profile with high bioavailability and a clear exposure in cerebrospinal fluid which shows that the substance crosses the blood-brain barrier in highly relevant concentrations. ACD856, which is a positive modulator of both NGF/TrkA- and BDNF/TrkB-mediated signaling, has in previous preclinical studies been shown to improve cognition and memory ability and is developed primarily for the treatment of Alzheimer's disease.

"ACD856 follows the positive development that we have observed in previous clinical studies, with a very good safety profile. We have now also been able to verify that we see a dose-dependent increase in the substance in cerebrospinal fluid, which is very important as the brain is our target organ, and these results bode well for future effect studies," said Kristin Önnestam, project leader for ACD856.

"These positive data further strengthen the continued clinical development of ACD856, which is based on a new mechanism of action with great potential for symptom relief and memory-enhancing effects in diseases with cognitive impairment, such as Alzheimer's," said Martin Jönsson, CEO of AlzeCure Pharma AB.

The abstract is written by Kristin Önnestam, Dr. Johan Sandin, CSO at AlzeCure, Dr. Matthias Rother, Medical Program Director, and Dr. Märta Segerdahl, CMO at AlzeCure.

The abstract and the poster are available on AlzeCure's website (<https://www.alzecurepharma.se/en/presentations-and-interviews/>).

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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 45 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 globally in 2018. 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.

Image Attachments

Martin Jönsson CEO AlzeCure Pharma

Attachments

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