PRESS RELEASE
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AlzeCure publishes clinical results supporting continued development of NeuroRestore ACD856 against Alzheimer's

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a pharmaceutical company that develops small molecule drug candidates for CNS diseases, focusing on Alzheimer's disease and pain, today announced that another scientific article has been published on the phase I clinical results supporting the continued development of the lead drug candidate NeuroRestore ACD856.

The article, titled *ACD856, a Novel Positive Allosteric Modulator of Trk-receptors, Single Ascending Doses in Healthy Subjects: Safety and Pharmacokinetics*, was published in the European Journal of Clinical Pharmacology and the responsible author is Märta Segerdahl, MD, PhD and CMO at AlzeCure Pharma. Co-authors are Boel Nilsson, Johan Bylund, Magnus Halldin, Matthias Rother, Erik Rein-Hedin and Kristin Önnestam. AlzeCure has previously published positive data from the subsequent clinical phase I MAD study.

The article focuses on the results from the clinical phase I study (Single Ascending Dose, SAD) with ACD856, the primary drug candidate within the company's NeuroRestore platform, but also contains data from the previously performed microdose study in humans. The results of this study, which was the first clinical study of ACD856, demonstrated that the compound had suitable pharmacokinetic properties with a half-life in humans that allows for once-daily dosing. The subsequent SAD study was able to confirm the good pharmacokinetic properties with rapid absorption in the body and a linear increase in the concentration of the substance in the blood with increased oral dosage. Furthermore, it was observed that the substance has good tolerability and safety in humans.

"The clinical results from the phase I studies with ACD856 show that the substance has a very suitable profile for continued clinical development. The previously published clinical phase I MAD results with the substance show that the substance also reaches the brain and can activate neural pathways with relevance for both memory and learning, as well as depression," said Märta Segerdahl, CMO at AlzeCure Pharma.

ACD856 is a Trk-PAM and enhances BDNF and NGF signaling, which play an important role in normal neuronal function. The substance is under development as a symptom-relieving treatment for medical conditions where the cognitive ability is impaired, for example in Alzheimer's disease. New preclinical data also suggest that ACD856 has potential protective and disease-modifying effects.

“The results for NeuroRestore ACD856 are promising, and the need for new drugs in the field is very great. The substance has the potential to improve learning and memory functions in a number of different diseases and therefore ACD856 may have a significant role in the treatment of several indications where these key functions are impaired, for example in Alzheimer's disease, traumatic brain injury and Parkinson's disease," said AlzeCure Pharma’s CEO Martin Jönsson.

The article is available via the following link: https://www.researchsquare.com/article/rs-3481125/v1

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About AlzeCure Pharma AB (publ)

AlzeCure® is a Swedish pharmaceutical company that develops new innovative 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 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 outlicensing solutions with other pharmaceutical companies.

FNCA Sweden AB 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. Preclinical studies with NeuroRestore have shown that AlzeCure's drug candidates enhance communication between the nerve cells and improve cognitive ability. The NeuroRestore substances are so called Trk-PAMs which stimulate 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. In addition to cognitive-enhancing effects, new preclinical data also show that NeuroRestore substances have a positive effect on mitochondrial function and cell survival, which could indicate potential disease-modifying effects. The leading drug candidate in the platform, ACD856, has recently completed clinical phase I studies and demonstrated positive effects there that support continued development of the program.

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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 $1,300 billion globally in 2019. 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

CEO Martin Jönsson CMO Märta Segerdahl 2023

Attachments

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