PRESS RELEASE
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AlzeCure publishes the positive clinical results from the phase I trial of NeuroRestore ACD856 against Alzheimer's

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 a new scientific article has been published on the Phase I clinical results supporting the continued development of the lead candidate drug NeuroRestore ACD856.

The article, titled Safety, Tolerability, Pharmacokinetics and Quantitative Electroencephalography Assessment of ACD856, a Novel Positive Allosteric Modulator of Trk-Receptors Following Multiple Doses in Healthy Subjects, was published in The Journal of Prevention of Alzheimer's Disease and the corresponding author is Märta Segerdahl, MD, PhD and CMO at AlzeCure Pharma. Co-authors are Kristin Önnestam, Boel Nilsson, Matthias Rother, Erik Rein-Hedin, Johan Bylund, Peter Anderer, Manuel Kemethofer, Magnus Halldin and Johan Sandin.

The article focuses on the results from the clinical phase I study (Multiple Ascending Dose, MAD) which shows that ACD856, the primary drug candidate within the company's NeuroRestore platform, has good tolerability and safety. Furthermore, it was observed that the substance has suitable pharmacokinetic properties with rapid absorption in the body and relevant and dose-dependent exposure in the CNS. In addition, AC856 was shown to increase EEG activity in the brain, indicating that the substance reaches and activates regions of the brain that are central for cognitive-enhancing and antidepressive therapies.

"The results presented in the article show that ACD856 has a very good profile for further clinical development. With its potential to improve memory functions in a variety of diseases, ACD856 may have a significant role in the treatment of indications where these key functions are impaired, such as Alzheimer's disease, traumatic brain injury and Parkinson's disease," 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 potentially protective and disease-modifying effects.

"The clinical phase I data we have obtained with ACD856 are very promising and the need for new drugs in the Alzheimer's field is great. The results with the substance which support treatment to improve learning and memory abilities as well as depression are clearly positive with regard to partnership and out-licensing discussions and increases interest in the NeuroRestore platform," said Martin Jönsson, CEO of AlzeCure Pharma.

The article is available via the following link: https://rdcu.be/dijyU

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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, +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. 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 protective and 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 55 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 1.3 trillion USD 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

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Attachments

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