AlzeCure's Alzheimer's project receives approval to start next clinical phase I study with ACD856

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a pharmaceutical company that develops a broad portfolio of candidate drugs for diseases affecting the central nervous system, with projects in both Alzheimer's disease and pain, today announced that the company has received approval from the regulatory authorities in Sweden to begin the next clinical phase I study (multiple ascending dose, MAD) with the candidate drug ACD856 focused on Alzheimer's disease.

The MAD Phase I study is AlzeCure's third clinical study with ACD856, the lead candidate drug within the company's NeuroRestore platform. ACD856 is being developed as a symptom-relieving treatment for disease states where the cognitive ability is impaired, such as in Alzheimer's disease. The primary study goal is to evaluate ACD856's tolerability and safety after repeated dosing, as well as to examine early signals on brain activity.

The substances in the NeuroRestore platform stimulate several important signaling pathways in the brain, which, among other things, leads to improved cognition. Preclinical studies have shown that AlzeCure's candidate drugs strengthen the communication between nerve cells and improve cognitive ability including memory functions.

"I'm very pleased that we have all regulatory approvals in place to be able to start the next study with ACD856. This means we will be able to start the MAD study during the fall, which is in line with our previously communicated goals," said Johan Sandin, CSO at AlzeCure Pharma.

"This is a statement of strength that shows that AlzeCure continues to deliver according to plan," said Martin Jönsson, CEO of AlzeCure Pharma AB. "Diseases with cognitive disorders, and especially Alzheimer's disease, are areas with high need of new, more effective treatments and I am very much looking forward to the continued development of this important candidate drug".

AlzeCure Pharma will give a strategic update on Alzheimer's disease and the NeuroRestore platform on September 1 at 9 a.m. CET at Redeye. Watch the livestream via:
https://www.redeye.se/events/816325/strategy-update-alzecure-pharma-2

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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 to 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. 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 $10 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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