

AlzeCure receives EU grant for Phase 2 clinical trial of NeuroRestore ACD856 for Alzheimer's disease

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a pharmaceutical company that develops candidate drugs for diseases affecting the nervous system, focusing on Alzheimer's disease and pain, today announced that its project NeuroRestore ACD856 has received €2.5m from the EU's European Innovation Council.

This funding will support AlzeCure's planned Phase IIa study of NeuroRestore ACD856 in Alzheimer's patients. In addition, higher doses of ACD856 will be evaluated in humans, as the good safety profile allows for further dosing. ACD856 has the potential to be the first drug in a new category of Alzheimer's drugs – positive allosteric modulators of Trk receptors (Trk-PAMs), which increase BDNF and NGF signaling.

"We are delighted to have been awarded a €2.5m grant from the European Innovation Council (EIC) for our innovative Alzheimer's treatment. The support from the EIC Accelerator program is a recognition of the project and will be crucial in advancing our clinical trials and bringing this much-needed Alzheimer's treatment to patients," said Johan Sandin, Chief Scientific Officer at AlzeCure Pharma

ACD856 is a first-in-class drug candidate for Alzheimer's disease with possible positive effects on both memory function and the course of the disease. Phase I clinical studies have shown good safety and tolerability with the substance and that it enters the brain to a high extent and activates regions of the brain with relevance for both cognition and depression. Previous preclinical studies have also shown that AlzeCure's drug candidate ACD856 in the NeuroRestore platform strengthens communication between nerve cells and improves cognitive ability, including learning and memory functions. Furthermore, preclinical results also show neuroprotective, anti-inflammatory and disease-modifying effects in various models with these so-called Trk-PAM substances, which increase BDNF and NGF signaling in the brain.

"The grant we received from the European Innovation Council is a strong validation of NeuroRestore ACD856, which has a unique pharmacological mechanism that enables multiple indications, both neurodegenerative diseases such as Alzheimer's and Parkinson's disease, but also, for example, depression," said Martin Jönsson, CEO of AlzeCure Pharma. "That ACD856 has the potential to both improve learning and memory capacity, as well as being disease-modifying and improving brain health is unique and significant".

Link to the EIC Accelerator announcement: https://eic.ec.europa.eu/news/eic-accelerator-71-companies-selected-most-competitive-funding-round-so-far-2025-02-17_en

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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 and is being prepared for phase 2. 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 with positive phase 2 results, 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. This results in a number of indication possibilities for NeuroRestore, both in neurodegenerative diseases as well as depression.

In addition to cognitive-enhancing effects, new preclinical data also show that NeuroRestore substances have a positive effect on mitochondrial function and display neuroprotective as well as anti-inflammatory effects, 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 and are being prepared for phase 2. Read more at: <https://www.alzecurepharma.se/en/neurorestore/>

About Alzheimer's disease

Alzheimer's disease is the most common form of dementia, affecting approximately 55 million people worldwide, and the number is estimated to triple in the next 30 years if nothing is done. 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 are estimated to about 1,300 billion USD globally in 2019. Given the lack of both effective symptomatic treatments and disease modifying treatments, including preventive treatments, the need for new effective therapies is acute. The few approved drugs on the European 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 And Johan Sandin CSO AlzeCure Pharma

Attachments

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