

Positive results from the Phase Ib clinical study of NeuroRestore ACD856, under development for Alzheimer's

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a biotech company that develops candidate drugs for diseases affecting the nervous system, focusing on Alzheimer's disease and pain, today announced that the Phase Ib clinical study of ACD856, the lead drug candidate in the NeuroRestore platform being developed for Alzheimer's disease and other indications, has been completed on schedule with positive results.

"Consistent with previous clinical data, the results show that ACD856 was well-tolerated and no substance-related safety findings were observed. Furthermore, an expected increase in the concentration of ACD856 was seen in both blood and cerebrospinal fluid. These data further strengthen the continued development of ACD856, broaden the therapeutic window, and provide a solid foundation for dose selection in future clinical studies," said Märta Segerdahl, CMO at AlzeCure Pharma.

The Phase Ib clinical study aimed to evaluate the safety and tolerability of ACD856 following repeated administration of higher doses than previously studied, as well as to measure the substance's concentration in the body. This could broaden the opportunities for ACD856, including in depression.

AlzeCure has previously obtained key clinical data showing that ACD856 crosses into the brain at relevant concentrations and activates neural pathways important for both cognition and depression. This supports the ongoing development program for the drug candidate as an oral treatment for Alzheimer's disease and other indications.

Preclinical studies have previously shown that AlzeCure's drug candidates in the NeuroRestore platform strengthen communication between nerve cells and improve cognitive function, including learning and memory. Previous preclinical results from AlzeCure also demonstrate neuroprotective, anti-inflammatory, and disease-modifying effects in various models with these so-called Trk-PAM substances, which enhance BDNF and NGF signaling.

Furthermore, NeuroRestore's unique pharmacological mechanism enables its use across several different indications, such as Alzheimer's and Parkinson's disease, as well as depression. ACD856 is a first-in-class drug candidate for Alzheimer's disease and is currently being prepared for upcoming Phase II clinical studies in patients; it was also awarded a major EU grant from the European Innovation Council (EIC) in 2025. This study is expected to start in 2026.

"The fact that the study progressed according to plan is excellent news, and we see that a wide therapeutic window further strengthens our commercial opportunities for this promising compound, including in other areas with very high unmet medical needs, such as depression," said Martin Jönsson, CEO of AlzeCure Pharma.

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About AlzeCure Pharma AB (publ)

AlzeCure® is a Swedish clinical stage biotech 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 one symptomatic drug candidate 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. NeuroRestore has received an EU grant from the European Innovation Council and is being prepared for phase 2. Painless contains two projects: ACD440, which is a drug candidate for the treatment of neuropathic pain with positive phase 2 results and orphan drug designation from the FDA in the USA and from EMA in Europe for the rare pain disease erythromelalgia, and TrkA-NAM, which targets severe pain in conditions such as osteoarthritis. Within the Alzstatin platform, the company has entered into a collaboration and out-licensing agreement with Lilly regarding the global rights to the Alzheimer's project Alzstatin ACD680. 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 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. ACD856 is in preparation for Phase II clinical trials, funded by a substantial EIC grant from 2025. 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 O Märta Segerdahl AlzeCure Pharma

Attachments

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