

PRESS RELEASE 25 May 2022 09:30:00 CEST

AlzeCure gets approval to start Phase II clinical trial with non-opioid pain project ACD440

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a pharmaceutical company that develops a broad portfolio of small molecule drug candidates for diseases affecting the central nervous system, with projects in both Alzheimer's disease and pain, today announced that it has received approval from the regulatory authorities in Sweden to initiate its clinical phase IIa study with the drug candidate ACD440 in patients with peripheral neuropathic pain.

The Phase IIa study is AlzeCure's second clinical study with ACD440, the company's leading drug candidate in the Painless platform. ACD440 is under development as a local treatment for peripheral neuropathic pain, such as long-term pain after shingles and diabetic neuropathy. The aim of the study is to evaluate the analgesic effects of the drug candidate in patients with peripheral neuropathic pain, but also its tolerability after repeated dosing.

ACD440 is a TRPV1 antagonist that originated in Big Pharma and is based on a strong scientific foundation. The discovery and insight into TRPV1, the biological system that underlies ACD440 and is central to, among other things, temperature regulation and pain, was awarded the Nobel Prize in Physiology or Medicine 2021. ACD440 is developed for local treatment as a gel and has previously been studied in a clinical phase lb study, which showed both good tolerability and good pain-relieving effect.

"We now have all regulatory approvals in place to be able to start the phase IIa study with ACD440. We expect to be able to initiate the study soon and present results in 2023", said Märta Segerdahl, CMO at AlzeCure Pharma.

"This shows that AlzeCure continues to deliver according to plan", said Martin Jönsson, CEO of AlzeCure Pharma AB. "Neuropathic pain is an area that is in great need of new, more effective and safer treatments, including alternatives to opioids, and I am very much looking forward to the results of this important study".

For more information, please contact

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About AlzeCure Pharma AB (publ)

AlzeCure® is a Swedish pharmaceutical company that develops new innovative small molecule 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 other types of 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 solutions for license agreements 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 neuropathic pain

Neuropathic pain affects approximately 7–8 percent of the total adult population, corresponding to roughly 600 million people globally. Some patients, with indications such as diabetes and HIV, are affected to a greater extent, where approximately 25 and 35 percent respectively of the patients experience neuropathic pain.

Peripheral neuropathic pain is the result of various types of damage to the nerve fibers, such as toxic, traumatic or nerve compression injuries as well a metabolic and infectious diseases. Common symptoms are painful tingling that can be described as "pins and needles", or choking or burning pain, as well as the feeling of getting an electric shock. Patients may also experience allodynia (pain caused by a stimulus that usually does not cause pain) or hyperalgesia (increased pain from a stimulus that normally provokes pain).

The market for neuropathic pain is characterized by a major medical need in all indications and in all major markets, where about 70-80 percent of patients do not get effective pain relief with existing treatment. The patient population will grow, among other things, due to an aging population and increased number of long-term cancer survivors and increasing prevlance of type-2 diabetes. The global market for neuropathic pain was valued at \$11 billion in 2020 and is expected to grow to \$25 billion by 2027.

Image Attachments

Martin Jönsson CEO AlzeCure Pharma



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Attachments

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