



Study plan of AlzeCure's Phase II clinical study in neuropathic pain with non-opioid ACD440 now available

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a pharmaceutical company that develops a broad portfolio of drug candidates for diseases affecting the central nervous system, with projects in both Alzheimer's disease and pain, today announced that the study plan for the planned Phase II clinical study in neuropathic pain with ACD440, the leading non-opioid drug candidate in the Painless platform, is now available on ClinicalTrials.gov.

ACD440, a TRPV1 antagonist for topical use, recently received regulatory approvals for the Phase II clinical study aimed at evaluating the efficacy, safety and pharmacokinetics of AlzeCure's leading drug candidate in pain. The planned study NCT05416931 is a double-blind, placebo-controlled, randomized cross-over study and is now available on ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/show/NCT05416931? term=NCT05416931&draw=2&rank=1

"We look forward to initiating this important Phase II study in peripheral neuropathic pain, an area with very great medical needs where up to 80% of patients do not get a satisfactory effect with their current treatments," said Martin Jönsson, CEO of AlzeCure Pharma.

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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. 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 only about 50 percent of patients respond to existing treatment. Due to the risk of abuse, overdose and secondary injuries, people are now trying to avoid opiates as first-line treatment for pain. Despite these treatment problems, these drugs are still used frequently, and therefore the need for new treatments that are not opiates is very great.

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.



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Martin Jönsson CEO AlzeCure Pharma

Attachments

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