PRESS RELEASE
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First patient included in AlzeCure's Phase II clinical trial in neuropathic pain with non-opioid ACD440

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 first patient has been included in a Phase II clinical trial with ACD440, the leading non-opioid drug candidate in the Painless platform which is being developed for peripheral neuropathic pain.

This follows the recent approvals from regulatory authorities to begin the study. The Phase II clinical trial is a double-blind, placebo-controlled, randomized cross-over study evaluating the efficacy, safety, and pharmacokinetics of AlzeCure's leading drug candidate in pain, ACD440. Results from the study are expected in mid-2023.

ACD440 is a TRPV1 antagonist and first-in-class local treatment for patients with peripheral neuropathic pain. The discovery of TRPV1, which is the basis for the project, was awarded the Nobel Prize in Physiology or Medicine in 2021. ACD440, which is applied as a gel, is the company's leading drug candidate in the Painless platform and conducted a positive phase Ib study in 2021.

The medical need in neuropathic pain is very great, not least to find alternatives to opioids. The market for neuropathic pain is the single largest market segment in pain treatment, with annual sales of over USD 11 billion. Up to 80% of patients do not get a satisfactory effect with their current treatments.

"We are very pleased to have been able to initiate this important study with ACD440 according to plan," said Märta Segerdahl, project manager and CMO at AlzeCure Pharma. "Neuropathic pain is an area of great medical need, and we believe that ACD440 could significantly improve the quality of life for patients suffering from neuropathic pain."

"This is a big step for both the project and the company, as we are now a phase II company. With the previous positive results from the phase Ib study, we look forward to the reading of this study, which can generate even greater interest in outlicensing," 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 $5 billion in 2015 and is expected to grow to $8 billion by 2024.

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Image Attachments

Martin Jönsson CEO AlzeCure Pharma

Attachments

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