

AlzeCure announces positive Phase IIa clinical study data in neuropathic pain with the non-opioid ACD440

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a pharmaceutical company that develops a broad portfolio of small molecule candidate drugs for diseases affecting the central nervous system, with projects in both Alzheimer's disease and pain, today announced that the company has received positive data from the Phase IIa clinical study with the non-opioid drug candidate ACD440, which is developed against peripheral neuropathic pain.

- The phase II data show that ACD440 was able to demonstrate positive proof-of-mechanism (PoM) results in patients with chronic peripheral neuropathic pain, i.e. the drug candidate has an effect on the intended target mechanism.
- A significant analgesic effect was observed on pain induced by cold and heat. This temperature hypersensitivity is very common in the skin area, where the patients have their neuropathic pain, and is a major problem in everyday life for these individuals.
- These positive phase II results are in line with previously reported Phase I results.
- ACD440 was well tolerated as a topical gel on the skin, which shows good suitability for continued clinical development, i.e. as a local treatment against neuropathic pain conditions.

"We are very pleased that in this pilot study, ACD440 was both well tolerated and able to demonstrate a good effect on the common factors that patients with peripheral neuropathic pain often experience as painful," said Märta Segerdahl, project leader 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 this type of pain."

The Phase II clinical study, which was initiated in June 2022 and is being conducted in collaboration with LINK Medical Research, is a double-blind, placebo-controlled, randomized cross-over study to evaluate the efficacy and safety of AlzeCure's lead drug candidate in pain, ACD440.

"The medical need in this area is immense, not least to find alternatives to opioids. Neuropathic pain is the single largest market segment in pain management, generating over \$11 billion in annual revenues. Up to 80 percent of all patients do not get a satisfactory effect with their current treatments," said AlzeCure Pharma's CEO Martin Jönsson. "These new clinical data will help us increase interest in a license agreement with ACD440."

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 of the project, was awarded the Nobel Prize in Physiology or Medicine 2021. ACD440, which is applied as a gel, is the company's leading drug candidate within the Painless platform and completed a positive phase Ib study in 2021.

For more information, please contact

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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. 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 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 ACD440

The candidate drug ACD440, which is a TRPV1 antagonist, was licensed in January 2020 and is in clinical development for neuropathic pain. The project, which originated in Big Pharma, is based on a strong scientific foundation. The discovery of 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 in 2021. The substance, which is being developed as a gel for local treatment, has previously undergone clinical studies, but then as oral treatment. AlzeCure has previously reported positive results from a clinical phase Ib study with the drug candidate that was conducted in 2021. The effects of ACD440 were clearly significant there compared to placebo. The substance was also well tolerated as a topical gel on the skin, indicating good suitability for further clinical development as a local treatment for neuropathic pain conditions. During first quarter of 2022, feedback was received from the FDA on the material and documentation submitted for a pre-IND meeting. The response was informative and has resulted in the company initiating the now ongoing phase IIa study with ACD440 in patients with peripheral neuropathic pain.

About neuropathic pain

Neuropathic pain affects approximately 7–8 percent of the total global adult population, approximately 600 million individuals. 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 as 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. Due to the risk of abuse, overdose and secondary damage, people now try to avoid opiates as first-line treatment for pain conditions. Despite this treatment problem, these preparations 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 prevalence 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.

This information is information that AlzeCure Pharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-05-24 12:00 CEST.

Image Attachments

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Attachments

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