

AlzeCure presents positive phase II clinical data with ACD440 against neuropathic pain at EFIC 2023 Conference

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 company's presentation at the pain conference EFIC 2023 is now available in its entirety on the company's website. The presentation contains clinical phase II data with the company's leading clinical candidate drug in pain, Painless ACD440, which is being developed with a focus on neuropathic pain.

"The results from the phase II study with ACD440 showed that the substance reduces temperature-evoked pain by approximately 50%, a significant and clinically relevant reduction. These positive data are in line with the results from the phase Ib study, and with this, we have also demonstrated proof-of-mechanism in patients," said Märta Segerdahl, MD, PhD, project leader and CMO at AlzeCure.

The presentation, entitled *A study of ACD440 gel for the treatment of patients with peripheral neuropathic pain with sensory hypersensitivity*, was given by Dr. Märta Segerdahl, project manager and CMO at AlzeCure, and contains results from the phase II clinical study with ACD440, the lead candidate drug in the Painless platform.

The presentation showed the results of the completed phase II clinical trial of ACD440 in patients with peripheral neuropathic pain. The study was a double-blind, placebo-controlled, randomized study aimed at evaluating the efficacy, safety and pharmacokinetics of AlzeCure's lead candidate drug in pain, ACD440. The patients, who were treated for 7+7 days in a cross over design, were between 50-85 years old and suffered from chronic neuropathic pain. The majority of them also were on existing pain treatment. Data from the study showed a clear and significant effect ($p=0.0166$) of ACD440 gel on temperature-induced pain in the patients. A very good safety and tolerability of the product in the patients was also observed.

AlzeCure's non-opioid drug candidate ACD440 is a TRPV1 antagonist for the local treatment of patients with peripheral neuropathic pain. The discovery of TRPV1 that underlies the project was awarded the Nobel Prize in Physiology or Medicine in 2021. There is thus a strong scientific basis for this biological mechanism, including its relationship to pain signaling. ACD440 has previously completed a positive phase Ib study in 2021. It showed both very good tolerability and safety, but also a potent, long-lasting pain-relieving effect of the substance that is applied as a gel to the skin.

"We are of course very happy about these positive data which show both significant effect and good tolerability. These data support further development of ACD440 and strengthens both the project scientifically and the interest from potential partners. This in an area of huge unmet medical need and an ongoing opioid crisis," said Martin Jönsson, CEO of AlzeCure Pharma.

The poster is available on AlzeCure's website: <https://www.alzecurepharma.se/en/presentations-and-interviews/>



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As well as directly here: <https://www.alzecurepharma.se/sv/wp-content/uploads/sites/3/2023/09/alzecure-acd440-trpv1-antagonist-ph-2-data-efic-2023-poster-final.pdf>

For more information, please contact

Martin Jönsson, CEO
Tel: +46 707 86 94 43
martin.jonsson@alzecurepharma.com

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, +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 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.



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Image Attachments

CEO Martin Jönsson CMO Märta Segerdahl 2023

Attachments

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