

New scientific article published on positive clinical results with Painless ACD440 against neuropathic pain

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a pharmaceutical company that develops candidate drugs for diseases affecting the nervous system, focusing on Alzheimer's disease and pain, today announced that a scientific article has been published on the clinical phase IIa results supporting the continued development of the lead drug candidate Painless ACD440.

The article, titled *Topically applied novel TRPV1 receptor antagonist, ACD440 Gel, reduces temperature-evoked pain in patients with peripheral neuropathic pain with sensory hypersensitivity, a randomized, double-blind, placebo-controlled, crossover study*, has been published online in the Scandinavian Journal of Pain and is written by Märta Segerdahl, MD, PhD and CMO at AlzeCure Pharma. Co-authors are Adriana Miclescu, Rolf Karlsten, Ingrid Lönnstedt, and Magnus Halldin.

The article focuses on the clinical phase IIa study with ACD440 in patients with chronic peripheral neuropathic pain. The results show that ACD440 had significant analgesic effects on temperature-induced pain compared to placebo in patients with various types of nerve pain induced by, e.g., shingles, amputation and side effects of cancer treatment. The effect was significant in this group despite the use of other pain medications in parallel.

The results also showed that the product was very well tolerated as a topical gel on the skin, indicating good suitability for further clinical development, i.e. as a local treatment for nociceptive and neuropathic pain conditions. Furthermore, the results showed that the clinical bedside kit used worked very well to identify patients suitable for treatment.

ACD440 is a first-in-class TRPV1 antagonist in clinical development as a novel topical local treatment for chronic peripheral neuropathic pain. The drug candidate, which was incorporated via a strategic in-licensing, originated in Big Pharma and is based on a strong scientific foundation, which was awarded a Nobel Prize in 2021. The substance is being developed as a gel for topical use, which keeps systemic exposure very low while maintaining high local concentrations of the substance to achieve maximum analgesic effect and over a long period of time.

"The publication demonstrates proof-of-mechanism in patients for ACD440, i.e. that the product has a high and significant analgesic effect. This now strengthens the continued development opportunities for ACD440," said Märta Segerdahl, CMO at AlzeCure Pharma.

"There is a great medical need for effective and safe non-opioid treatments for neuropathic pain. 7-8 out of 10 patients do not experience a satisfactory effect from existing treatment, and the area is the single largest in pain. Our project ACD440 has very great potential," said Martin Jönsson, CEO of AlzeCure Pharma.

The article is now available online via the following link: <https://www.degruyterbrill.com/document/doi/10.1515/sjpain-2025-0011/html>



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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 and is being prepared for phase 2. The Alzstatin platform focuses on developing disease-modifying and preventive drug candidates for early treatment of Alzheimer's disease. 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 with positive phase 2 results, 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 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.

Image Attachments

Martin Jönsson O Märta Segerdahl AlzeCure Pharma

Attachments

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