

## AlzeCure receives positive FDA response regarding Phase II/III studies with ACD440 in a rare disease

**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 it has received a positive response from the US Food and Drug Administration (FDA) regarding the preIND application submitted in advance of a planned application for orphan drug status.**

"We are very pleased with the meeting and interaction with the FDA, and with the positive response from the agency, we can now move forward with our planning for the continued clinical development program. The response we have received from the FDA has provided us with good guidance for the project, where our ACD440 project team has done an excellent job," said Märta Segerdahl, CMO at AlzeCure Pharma.

ACD440, the company's lead drug candidate within the Painless platform, has previously completed a positive Phase IIa clinical trial in patients with chronic peripheral neuropathic pain. Ahead of the next clinical development stage, AlzeCure applied for a preIND meeting with the FDA regarding the further development of ACD440 as a drug for the treatment of this rare disease.

AlzeCure has now received a positive guidance response after a meeting with the FDA that supports the continued development program for ACD440 in the treatment of the rare pain disorder erythromelalgia. In the meeting, the FDA confirmed that there is a significant medical need in the indication, which affects both children and adults. The scientific rationale was also supported by the authority. The results of the meeting provide strong support for the continued development of the registration-based program with ACD440.

Erythromelalgia is a rare chronic disease that affects an average of 1-4 out of 100,000 people and is characterized by intense burning pain and severe redness of the skin. The disease most often occurs in the extremities such as the feet, hands, ears and nose, but can also occur in other parts of the body. The affected part of the body often swells and the skin becomes very hot. There is currently no approved treatment available for patients suffering from erythromelalgia, so the medical need is very great.

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.

"This is very good news, as the medical need in erythromelalgia is very great and there are currently no approved drugs for this indication and patient group. An orphan drug as this one, also often has a faster path to market via a limited study program, and extended market exclusivity is granted upon approval, which generates interest among potential recipients and increases the possibilities for out-licensing," said Martin Jönsson, CEO of AlzeCure Pharma.

For more information, please contact

---

Martin Jönsson, CEO  
Tel: +46 707 86 94 43  
[martin.jonsson@alzekurepharma.com](mailto:martin.jonsson@alzekurepharma.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 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](http://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

---

Märta Segerdahl AlzeCure 1 Sv

## Attachments

---

AlzeCure receives positive FDA response regarding Phase II/III studies with ACD440 in a rare disease