

AlzeCure is moving towards Phase IIa clinical trial with ACD440 based on guiding response from the FDA

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a pharmaceutical company that develops a broad portfolio of small molecule drug candidates for diseases affecting the central nervous system, with projects in both Alzheimer's disease and pain, today announced that it has received a response from the US Food and Drug Administration (FDA) regarding the preIND application that was submitted prior to the planned phase IIa study with ACD440 in neuropathic pain.

ACD440, which is the company's leading drug candidate in the Painless platform, completed a positive phase Ib study in 2021 and the company now plans to initiate a clinical phase IIa study in patients with peripheral neuropathic pain. Prior to this clinical development step, a preIND application was submitted to the FDA. AlzeCure has now received indicative answers that support the continued development program for ACD440, as well as the preparatory work for the upcoming clinical phase IIa study.

ACD440 is a TRPV1 antagonist for the topical treatment of patients with neuropathic pain. The discovery of TRPV1, which is the basis for the project, was awarded the Nobel Prize in Physiology or Medicine in 2021.

"With the responses from the FDA, we can now proceed as planned regarding the next clinical phase, a planned phase IIa study in patients. The answers we received from the FDA have given us good guidance for the project. Our project team for ACD440 for neuropathic pain has done an excellent job," said Martin Jönsson, CEO of AlzeCure Pharma.

"The medical need for neuropathic pain is enormous. Over 60% of patients in the United States have been prescribed opioids, which can be very problematic. With our project, we want to develop an efficient and safer alternative. As the medical need is so great, our ambition is to be able to get a Fast Track Designation from the FDA in order to make our potential drug available to patients more quickly."

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 adult population, corresponding to roughly 600 million people globally. 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.

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 CEO And Johan Sandin CSO AlzeCure Pharma



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Attachments

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