

Last Patient Last Visit (LPLV) Milestone achieved for AlzeCure's phase II clinical trial of the non-opioid ACD440 in neuropathic pain

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LINK Medical, the Northern European clinical research organization (CRO) can announce that another significant milestone is achieved for AlzeCure® Pharma AB's (publ) (FN STO: ALZCUR) phase II clinical trial of the non-opioid ACD440 (TRPV1-antagonist) in neuropathic pain.

The Patient Last Visit (LPLV) has been achieved and this marks the successful milestone achieved through great collaboration, the flexible and customized decentralized approach that was set up using Viedoc®. Patients had the ability to be pre-screened via a web tool, see study information and receive information around study participation within Viedoc and have their follow up (FU) visits via video.

AlzeCure Pharma AB, 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, has announced that the LPLV has been completed in the ongoing phase II clinical trial with ACD440, the lead non-opioid drug candidate in the Painless platform, which is being developed against peripheral neuropathic pain.

"We look forward to seeing the results of this important phase II trial in peripheral neuropathic pain, an area of very high medical need where up to 80% of patients are not responding satisfactorily with their current treatments and where many are still prescribed opioids", said Märta Segerdahl, project leader and CMO at AlzeCure Pharma.



Märta Segerdahl, MD, PhD
at AlzeCure

This double-blind, placebo-controlled, randomized cross-over study, which is carried out in collaboration with LINK Medical Research in Sweden, is aimed at evaluating the efficacy, safety and pharmacokinetics of AlzeCure's lead drug candidate in pain, ACD440. The main results from the study are expected by the summer of 2023 at the latest.

AlzeCure's 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, which is also the company's leading drug candidate within the Painless platform, 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.

The medical need in neuropathic pain is very great, not least to find alternatives to opioids. The neuropathic pain market is the single largest market segment in pain management with annual sales exceeding \$11 billion. Up to 80% of patients do not get a satisfactory effect with their current treatments.

"The lack of effective and safe drugs, combined with the fact that upwards of 8% of the adult population suffers from neuropathic pain, makes clear the great medical need and the enormous potential of our project. ACD440 can become a first-in-class drug and meet a very large patient need, which of course is a value driver in connection with the outlicensing of the project", said Martin Jönsson, CEO of AlzeCure Pharma.



*Martin Jönsson, CEO of
AlzeCure Pharma*



*Sissel Lønning Andresen,
CEO of LINK Medical*

"We are honored and thrilled to be part of this study supporting AlzeCure in this important study to provide a new innovative option for patients with neuropathic pain. This is a great example of how providing our experienced team, technology, and infrastructure turns into an efficient collaboration with the site and patients. We look forward to the positive results and supporting them on the next milestone", said Sissel Lønning Andresen, CEO LINK Medical.



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PRESS RELEASE

About LINK Medical

LINK Medical is a full-service contract research organization (CRO) providing product development services for the pharmaceutical and medical device industries across Northern Europe. LINK Medical offers a well-integrated local presence in all Nordic countries, UK and Germany. Reaching from early phase development to post-marketing and provides expert guidance across every aspect of a project – all from ONE source. LINK Medicals promise is to improve and accelerate your product development through transformative methods, active communication, and optimal solutions. As a strategic partner, LINK Medical provides expert competence and technology to enable evidence-based decision-making that supports the delivery of superior clinical outcomes.

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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, +46(0)8 528 00 399 info@fnca.se, is the company's Certified Adviser. For more information, please visit www.alzecurepharma.se.



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PRESS RELEASE

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.

For more information, please contact

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