

AlzeCure receives approval to start clinical Phase Ib trial with ACD440 in neuropathic pain

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 it has received approval from regulatory authorities in Germany to initiate a clinical Phase Ib study with the drug candidate ACD440.

ACD440 is a drug candidate for topical use, i.e. as a gel or cream, within AlzeCure's Painless platform and focused on neuropathic pain. ACD440 has previously undergone Phase I clinical trials in which the drug candidate's tolerability has been evaluated and early efficacy signals observed.

The upcoming Phase Ib study with ACD440 has the primary study objective to evaluate safety and tolerability, as well as efficacy and so-called proof-of-mechanism data with the topical preparation. Study results are expected in H1 2021.

"Our aim has been to initiate two clinical studies before year end, and it is with great pleasure that we can announce the approval to start a Phase Ib study with ACD440, just recently after we received the approval for a clinical Phase I study with ACD856 in Alzheimer's disease. Neuropathic pain is, just as Alzheimer's, a disease area with extensive undertreatment where a majority of patients are not expected to receive adequate pain relief. The need for more effective pharmaceuticals is massive, and I look forward to starting our first study with this promising drug candidate soon," said Martin Jönsson, CEO of AlzeCure Pharma AB.

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 extremely 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 three 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. Alzstatin comprises two 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 clinical candidate 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 to an early clinical phase and is continuously working with business development to find suitable out-licensing 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. 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, metabolic, infectious or compressional injuries. Common symptoms are painful tingling that can be described as 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 only about 50 percent of patients respond to existing treatment.

The patient population will grow, among other things, due to an aging population and increased incidence of cancer and type-2 diabetes.

The global market for neuropathic pain was valued at \$5 billion in 2015 and is expected to grow to \$8 billion by 2024.

Attachments

AlzeCure receives approval to start clinical Phase Ib trial with ACD440 in neuropathic pain