Last patient included in Phase II clinical trial

Categories : Pharmaceuticals

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AlzeCure Pharma 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 the last patient has now been included in the ongoing Phase II clinical study with ACD440, the lead non-opioid drug candidate in the Painless platform, which is being developed against peripheral neuropathic pain.

This double-blind, placebo-controlled, randomized cross-over study, which is carried out in collaboration with LINK Medical Research in Uppsala, 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 Dollar. Up to 80 percent of patients do not get a satisfactory effect with their current treatments.

"The study has developed well and the fact that we have now been able to include the last patient in the study means that we have good hopes that the study will also deliver the results according to what we previously communicated," said Märta Segerdahl, MD, PhD, project leader and CMO at AlzeCure. "We see an exciting potential with ACD440, where you can broaden the further development with other formulations, thereby enabling several indications."

"With the previous positive results from the phase Ib study, we look forward to the readout of this phase II study. There is already interest in the project and with phase II data, the project can generate even greater interest for out-licensing in a segment with a very high medical need," said Martin Jönsson, CEO of AlzeCure Pharma.