PRESS RELEASE
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Pain project ACD440 granted orphan drug status in the EU

AlzeCure Pharma AB (publ) (FN STO: ALZCUR), a biotech company that develops candidate drugs for diseases affecting the nervous system, focusing on Alzheimer's disease and pain, today announced that the European Medicines Agency (EMA) has granted the company's application for orphan drug status for the clinical pain medication ACD440 as treatment in erythromelalgia.

"This positive news from the EMA regarding orphan drug status for ACD440, combined with the positive interaction and message we have received from the FDA, gives us increased opportunities to offer an effective treatment to these very severely affected patients," said Märta Segerdal, CMO at AlzeCure Pharma.

ACD440, the company's lead pain drug candidate within the Painless platform, has previously completed a positive Phase IIa clinical trial in patients with chronic peripheral neuropathic pain. The compound received orphan drug designation from the US Food and Drug Administration (FDA) in 2025. In addition to the grant of orphan drug designation, the company also received positive guidance from the FDA supporting the continued development of the compound in a Phase II/III trial in peripheral neuropathic pain for regulatory approval.

Erythromelalgia is a rare chronic disease that affects an average of just over 13 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 painful 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.

"The fact that we have now been granted orphan drug status in the EU also, strengthens our competitive advantages and the conditions for out-licensing this important and promising project. Orphan drug status entails a number of very important advantages, with the possibility of obtaining a faster path to approval through processes, such as accelerated or conditional approval, and prioritized review. In addition, a stronger and extended market exclusivity is provided during a 10 year period, which strengthens our competitive advantages. Also, the price of orphan drugs in general is very high, e.g. the USA with a median price of around SEK 2 million for an annual treatment*," said Martin Jönsson, CEO of AlzeCure Pharma.

*) ***Althobaiti*** *H et al, Disentangling the Cost of Orphan Drugs Marketed in the United States, Healthcare (Basel), 2023 Feb 13;11(4):558;* ***https://pmc.ncbi.nlm.nih.gov/articles/PMC9957503/***

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About AlzeCure Pharma AB (publ)

AlzeCure® is a Swedish clinical stage biotech 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. NeuroRestore has received an EU grant from the European Innovation Council and is being prepared for phase 2. Alzstatin focuses on developing disease-modifying and preventive drug candidates for early treatment of Alzheimer's disease. Painless contains two projects: ACD440, which is a drug candidate for the treatment of neuropathic pain with positive phase 2 results and orphan drug designation from the FDA for the rare disease erythromelalgia, 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.

About erythromelalgia

Erythromelalgia is a rare condition that affects just over 13 in 100,000 people and causes burning pain, redness, warmth and swelling, most often in the feet or hands. The symptoms are worsened by heat and relieved by cold. The disease can be primary (inherited) or secondary to other conditions, as part of autoimmune diseases, as a side effect of certain medications, or an effect of certain blood disorders (e.g. polycythemia vera or essential thrombocythemia). The cause is believed to be a combination of disturbances in the nervous system's pain signaling and the function of the thinnest blood vessels. Treatment focuses on relieving symptoms, often with cooling, pain medications and sometimes drugs that affect blood flow or nerve signals.

Erythromelalgia is a very painful condition characterized by burning pain, which occurs in sudden attacks triggered by heat, either in the environment or locally. These attacks can last for several hours, and recur from a few times a week to several times a day. Patients often describe the pain as if the skin is "burning".

Cooling the painful area is the most effective relief, while despite the frequent trials of many drugs, there is no established effective treatment. Frequent or prolonged cooling as a treatment often leads to severe frostbite and infection, which can be life-threatening.

The disease greatly affects quality of life. Walking, standing or just being in warm environments or wearing shoes that get hot can be unbearable. Many have difficulty managing their jobs, experience sleep problems and suffer from isolation.

About orphan drugs

Orphan drugs are used to treat, prevent or diagnose a rare disease – that is, a disease that affects no more than 5 in 10,000 people in the EU. In the US, the limit is a maximum of 200,000 people with the disease.

To encourage the development of such drugs, authorities offer special benefits, e.g.:

- Prolonged market exclusivity
- Scientific advice from pharmaceutical authorities
- Reduced fees for approval applications

Orphan drugs are important because they make it possible to treat patients with rare and often serious diseases who might otherwise not have received treatment. Furthermore, the price of orphan drugs is often significantly higher than that of other medicines.

Image Attachments

Martin Jönsson O Märta Segerdahl AlzeCure Pharma

Attachments

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