AlzeCure announces positive data from clinical study with ACD856

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 the company has received positive results from the first clinical study with ACD856, aiming to evaluate half-life in humans. ACD856 is currently under development for e.g. Alzheimer's disease.

The results demonstrate that ACD856, the lead drug candidate within the company's NeuroRestore platform, has a good pharmacokinetic profile with a significantly shorter human half-life than its predecessor ACD855, as well as a suitability for further clinical development, e.g. in oral treatment of Alzheimer's disease.

"We are very pleased that ACD856 has a suitable profile for further clinical development", said Johan Sandin, CSO at AlzeCure Pharma. "The compound has previously shown potent cognitive and memory enhancing properties in our preclinical studies, such as the results we presented in April together with researchers from Karolinska Institutet. With its potential to improve memory functions in a variety of disorders, ACD856 can play a significant role in treating indications where these key functions are impaired, such as Alzheimer's disease, sleep apnea, traumatic brain injury and Parkinson's disease."

AlzeCure Pharma initiated the study in December 2019 and now presents the results of this first clinical study with ACD856 according to plan. Preparations are ongoing to initiate further clinical trials, with a planned start by the end of 2020. These upcoming Phase I studies are aimed to evaluate tolerability in humans, as well as early efficacy signals.

"The results of the NeuroRestore candidate ACD856 are demonstrating the great value of AlzeCure's broad portfolio of candidates, which together with the company's strong financial position, enables a strategy where we can develop several candidates in parallel. Due to the fact that AlzeCure is not centered around one single drug candidate, a quick follow-up strategy is possible while opening up opportunities for multiple indications," said Martin Jönsson, CEO of AlzeCure. "We are now looking forward to taking ACD856 further into the planned clinical studies. This will also stimulate potential partnership and out-licensing discussions as well as increase interest in the NeuroRestore platform."

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This is information that AlzeCure Pharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above at 10.30 am CET on June 4, 2020.

About AlzeCure® Pharma

AlzeCure Pharma AB is a Swedish pharmaceutical company that develops new innovative drug therapies for the treatment of severe disorders 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 parallell drug candidates based on the three research platforms, NeuroRestore®, Alzstatin® and Painless.

NeuroRestore comprises three symptom-relieving drug candidates where the unique target mechanism opens up for multiple indications – Alzheimer's disease, but also cognitive dysfunction in traumatic brain injury, sleep apnea and Parkinson's disease.

Alzstatin is comprised of two disease modifying and preventive drug candidates for treatment of early Alzheimer's disease. Painless, which is the company's research platform in the field of pain, contains two projects: VR1/ACD440 which is a clinical candidate for the treatment of neuropathic pain, and TrkA-NAM that is targeting pain disorders such as osteoarthritis. AlzeCure aims to pursue its own projects through preclinical research and development to an early clinical phase.

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About NeuroRestore

NeuroRestore is a platform of symptom-relieving drug candidates for disease states in which cognitive ability is impaired, e.g. Alzheimer's Disease, sleep apnea, traumatic brain injury and Parkinson's disease. NeuroRestore stimulates several important signaling pathways in the brain, which among other things leads to improved cognition. In preclinical studies with NeuroRestore we

have been able to show that our drug candidates enhance communication between the nerve cells and improve cognitive ability. NeuroRestore stimulates specific signaling pathways in the central nervous system known as neurotrophins, the most well-known being NGF (Nerve Growth Factor) and BDNF (Brain Derived Neurotrophic Factor). The levels of NGF and BDNF are disturbed in several disease states and the signaling is reduced. The impaired function impairs communication betweenthe synapses, i.e. the contact surfaces of the nerve endings, as well as reducing the possibility of survival for the nerve cells, which gives rise to the cognitive impairments. Neurotrophins play a crucial role for the function of nerve cells, and a disturbed function of BDNF has a strong genetic link to impaired cognitive ability in several different diseases, such as Alzheimer's, Parkinson's disease, traumatic brain injury and sleep apnea.

About Alzheimer's disease

Alzheimer's disease is the most common form of dementia, affecting approximately 45 million people worldwide. Alzheimer's disease is a lethal disorder that also has a large impact on both relatives and the society. Today, preventive and disease modifying treatments are missing. The main risk factors to develop Alzheimer's are age and genetic causes. Even though the disease can start as early as between 40 and 65 years of age, it is most common after 65 years. Significant investments in Alzheimer research are being made because of the significant unmet medical need and the large cost of this disease for healthcare and society. The total global costs for dementia related diseases is estimated to about 1,000 billion USD globally in 2018. Given the lack of both effective symptomatic treatments and disease modifying treatments, the need for new effective therapies is acute.The few approved drugs on the market today have only a limited symptomatic effect and can produce dose limiting side effects. A disease modifying treatment for Alzheimer's disease is estimated to reach more than 10 billion USD in annual sales. In Sweden, approximately 100,000 people suffer from Alzheimer's disease with a healthcare cost of about 63 billion SEK yearly, which is more than for cancer and cardiovascular diseases combined.