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Announcement

NeuroSearch receives an IND approval from the FDA for ACR16 as part of an ongoing pivotal clinical programme in Huntington's disease

NeuroSearch announces that the United States' Food and Drug Administration (FDA) has approved the company's Investigational New Drug (IND) application for ACR16, a dopaminergic stabiliser and a novel drug candidate for the treatment of Huntington's disease (HD). The IND application approval allows NeuroSearch to initiate a planned US study, named HART (Huntington's disease ACR16 Randomized Trial), as part of the ongoing clinical programme with ACR16. NeuroSearch expects that the HART study will begin in the second half of 2008.

Flemming Pedersen, CEO of NeuroSearch, comments:
"The FDA acceptance of our IND application for ACR16 and of the protocol for the US HART study is an important milestone for NeuroSearch. With the European Phase III MermaiHD (Multinational European Multicentre ACR16 study in Huntington's Disease) study ongoing, we now look forward to completing our international development programme for ACR16 in the treatment of Huntington's disease. Currently, patients suffering from Huntington's disease have very limited treatment options. Bringing this promising novel treatment concept to the market to help alleviate the burden of a serious and very disabling disease would therefore be a highly valuable step forward for both patients and their relatives, as well as for NeuroSearch as a company."

The HART study is planned as a randomised, double-blinded and placebo controlled study expected to include 220 patients. In the study, patients will receive daily doses of either 22.5 mg (QD), 45 mg (QD) or 45 mg (BID) ACR16 or placebo to evaluate the efficacy and safety of ACR16 over three months' treatment. The primary efficacy endpoint of this study will be the effect of ACR16 on Huntington patients' voluntary motor function (parkinsonism, gait/balance, hand functionality, bradykinesia) measured by the modified Motor Score, mMS - a subscale of the Unified Huntington's Disease Rating Scale (UHDRS). Secondary endpoints include the overall clinical impression of the patients, their cognitive function, neuropsychiatric symptoms such as depression and anxiety. The efficacy endpoints in the HART study are the same as in the ongoing European MermaiHD study.

ACR16 belongs to a novel class of active agents called dopaminergic stabilisers, which have the unique ability to either enhance or inhibit dopamine controlled functions depending on the initial level of dopaminergic activity.

ACR16 was previously evaluated in four clinical Phase I/II studies with patients suffering from Huntington's disease, Parkinson's disease and psychoses, and demonstrated a good safety and tolerability profile. In a Phase II study with ACR16 in Huntington's disease, the results showed that 28 days' treatment with ACR16 resulted in a statistically significant improvement in the patients' voluntary movements including parkinsonism and gait function.

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Huntington's disease is a fatal, hereditary neurodegenerative genetic disorder, which leads to damage of the nerve cells in certain areas of the brain including the basal ganglia and cerebral cortex. Patients suffering from Huntington's disease experience a wide variety of symptoms typically grouped into three categories (the "symptoms triad"): motor, cognitive and psychiatric disorders. The motor symptoms include muscle spasms and rigidity, tics, gait and balance problems as well as chorea and in the later stage of the disease also difficulties in swallowing. The most significant cognitive symptoms are slowed processing of information in the brain, resulting in communicational and planning difficulties, while depression is the most common of the psychiatric symptoms of Huntington's disease.

The disease occurs at a rate of about one in 10,000 in most Western countries with symptoms onset typically around 35-45 years of age. There is currently no cure or effective treatment for Huntington's disease and the disease progresses without remission over an expected lifespan of 10 to 25 years after symptoms onset. Eventually, every person afflicted by Huntington's disease requires full-time care.

Both the EMEA (European Medicines Agency) and the FDA have granted ACR16 orphan drug status for the treatment of Huntington's disease.

ACR16 was discovered and is developed internally by NeuroSearch, which has the rights to develop and commercialise the compound for the treatment of Huntington's disease in the European Union, Norway, Switzerland and North America. All other rights to the compound have been outlicensed to Astellas Pharma Inc.

The FDA approval of the IND application for ACR16 and the planned US HART study do not change NeuroSearch's financial expectations for 2008 of an operational loss in the region of DKK 450 million.

Thomas Hofman-Bang
Chairman of the Board

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NeuroSearch (NEUR) is a Scandinavian biopharmaceutical company listed on the OMX Nordic Exchange Copenhagen A/S. The core business covers the development of novel drugs, based on a broad and well-established drug discovery platform focusing on ion channels and CNS disorders. A substantial part of NeuroSearch's activities are partner financed through a broad alliance with GlaxoSmithKline (GSK) and collaborations with among others Abbott and Astellas. The drug pipeline comprises 13 clinical (Phase I-III) development programmes: ACR16 in Huntington's disease (Phase III), tesofensine in obesity and in type II diabetes (Phase III in preparation), NS2359 in depression (Phase II) and ADHD (Phase II) in partnership with GSK, ABT-894 in ADHD (Phase II) and pain (Phase II) in partnership with Abbott, ACR16 in schizophrenia (Phase I) in partnership with Astellas, ACR325 in Parkinson's disease (Phase II in preparation) and bipolar disorder (Phase II in preparation), ABT-107 as well as ABT-560 for the treatment of various CNS disorders – both (Phase I) in collaboration with Abbott, NSD-644 in pain (Phase I) in partnership with GSK, ACR343 in Parkinson's disease (Phase I) and NSD-788 in anxiety/depression (Phase I). In addition, NeuroSearch has a broad portfolio of preclinical drug candidates and holds equity interests in several biotech companies.