NEUROSEARCH

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Announcement

NeuroSearch announces the dosing of the first patients in the US HART study, a part of the ongoing ACR16 pivotal programme in Huntington's disease

NeuroSearch is pleased to announce that the first patients have now been treated in the US HART (Huntington's disease ACR16 Randomised Trial) study with ACR16, a dopaminergic stabiliser and the company's unique and novel compound for the treatment of Huntington's disease. The HART study is a randomised, placebo-controlled, double-blinded study expected to include a total of 220 patients with Huntington's disease. The patients will be randomised to three months treatment with one of three doses of ACR16 (10 mg BID, 22.5 mg BID and 45 mg BID) or placebo. The study will be conducted in a number of centres in the United States and Canada.

The ongoing European MermaiHD (Multinational EuRopean Multi-centre ACR16 study In Huntington's Disease) Phase III study with ACR16 in Huntington's disease, in which the first patients were dosed in April 2008, is progressing satisfactorily. Almost all the centres participating in the study are now enrolling patients, and also the first patients that have finalised the six months blinded treatment period are now entering into the six months open-label extension to the study.

The primary efficacy endpoint for both HART and MermaiHD is the effect of ACR16 on Huntington patients' motor function (such as gait/balance, hand functionality and parkinsonism) 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 and the severity of neuropsychiatric symptoms such as depression and anxiety.

For further information on both the HART study and the MermaiHD study, please see www.clinicaltrials.gov.

Flemming Pedersen, CEO of NeuroSearch comments:

"*The initiation of the HART study represents a very important milestone for us in our efforts to get ACR16 on the market and make this promising drug available for the patients suffering from Huntington's disease. We now have a full pivotal programme running and with the European MermaiHD study progressing according to plan, we remain confident that we will have the first key data in the second half of 2009 and be able to apply for market registration as soon as possible thereafter.*"

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

The initiation of the HART study with ACR16 does not change NeuroSearch's financial guidance for 2008 of an expected loss before tax in the region of DKK 400 million.

Thomas Hofman-Bang
Chairman of the Board

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ACR16 – A dopaminergic stabiliser

ACR16 belongs to a novel class of active agents called dopaminergic stabilisers, which have the unique ability to either enhance or counteract dopamine dependent functions in the brain, depending on the level of dopaminergic activity. Dopamine is an important neurotransmitter in the brain, and the dopaminergic system plays a central role in the control of motor and mental functions. In preclinical studies dopaminergic stabilisers have demonstrated the ability to stabilise motor, cognitive and psychiatric dysfunction, and they do this without compromising normal brain functions.

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.

Both the European (EMEA) and the US (FDA) Health Authorities have granted ACR16 orphan drug designation for the treatment of Huntington's disease.

Huntington's disease

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, including severe motor disturbances, cognitive impairment and psychiatric disorders. The disease occurs at a rate of about one in every 10,000 in most western countries with symptoms onset typically around 35 and 45 years of age and 10 to 20 years of life expectancy hereafter. Eventually, every person afflicted by Huntington's disease requires full-time care. There is currently no cure or effective treatment for Huntington's disease. Several medications are prescribed off label, with the sole exception of tetrabenazine, but most drugs used have limited effect and are associated with undesirable side effects.

NeuroSearch company profile

NeuroSearch (NEUR) is a Scandinavian biopharmaceutical company listed on Nasdaq OMX Copenhagen. The company's 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 share of its activities is partner financed through a broad alliance with GlaxoSmithKline (GSK) and collaborations with, among others, Abbott and Astellas. NeuroSearch's drug pipeline comprises 14 clinical (Phase I-III) development programmes: ACR16 for Huntington's disease (Phase III), tesofensine for obesity and in Type 2 diabetes (Phase III in preparation), NS2359 for depression (Phase II) and ADHD (Phase II) in partnership with GSK, ABT-894 for ADHD (Phase II) and pain (Phase II) in partnership with Abbott, ACR16 for schizophrenia (Phase I) in partnership with Astellas, ACR325 for Parkinson's disease (Phase II in preparation) and bipolar disorder (Phase II in preparation), ABT-107 and ABT-560 for the treatment of various CNS disorders – both (Phase I) in collaboration with Abbott, NSD-644 for pain (Phase I) in partnership with GSK, ACR343 for Parkinson's disease (Phase I) and NSD-788 for anxiety/depression (Phase I). In addition, NeuroSearch has a broad portfolio of preclinical drug candidates and holds equity interests in several biotech companies.