



Announcement

NeuroSearch announces results from an open-label safety extension to the Phase III MermaiHD study of Huntexil[®] in patients with Huntington's disease

- ***The results show that Huntexil[®] was well tolerated in patients with Huntington's disease over 12 months' treatment***
- ***The results further support the favourable safety profile of Huntexil[®]***

Copenhagen, 15 September 2010 – Today, NeuroSearch A/S (NEUR) announced preliminary results from the 26-week open-label extension to the Phase III MermaiHD study of Huntexil[®] (pridopidine) for the treatment of Huntington's disease. The results further support the favourable safety profile of Huntexil[®] and show that the drug is well-tolerated in patients with Huntington's disease over 12 months' treatment.

The open label extension enrolled a total of 353 patients who had completed the first 26 weeks of randomised treatment with Huntexil[®] 45 mg once or twice daily or placebo. In the study extension, all the patients were treated with Huntexil[®] 45 mg twice daily, and 305 patients completed the entire 12-month treatment.

The study objective of the open-label extension was to evaluate the long-term safety and tolerability of Huntexil[®] and to collect efficacy parameters after a 12-month treatment period to support the safety evaluation. Safety and tolerability assessments include incidence and severity of adverse events, laboratory parameters, vital signs and ECG measurements.

Based on the safety and tolerability data available and analysed at present, i.e. data on adverse events profile, vital signs and ECG, Huntexil[®] displayed a favourable safety and tolerability profile in patients with Huntington's disease over the 12 month treatment period. The most common adverse events reported during the 12-month period were falls (14% of patients), Huntington's chorea, originally reported as a worsening of pre-existing chorea (13% of patients), depression (8% of patients), dizziness, nasopharyngitis, fatigue, irritability (each reported for 7% of patients), diarrhoea, nausea and insomnia (each reported for 6% of patients). These findings are consistent with the adverse event profile seen for both the two active groups as well as the placebo group in the 6-month randomised study, and the majority of the events are considered to be related to the underlying disease. Likewise, the most frequent adverse events reported in the open label extension in patients that had previously been in the placebo arm (drug naïve patients) were similar to the adverse event profile observed in patients on active treatment in the randomised study.

When comparing patients treated with Huntexil[®] in both the randomised study and the open label extension to those treated with placebo in the randomised phase, the adverse event profile appears similar during the open-label extension, except for chorea. Huntington's chorea, i.e. a worsening of chorea was reported with a higher incidence for patients on drug for 12 months (12.5%) than for patients on drug for six months (6.2%). However, no similar pattern was observed on the chorea subscale of the Unified Huntington's Disease Rating Scale (UHDRS), indicating no general worsening of chorea at study end for the patients treated for 12 months compared to

patients treated for 6 months. Also, the drop-out rate due to a worsening of chorea was similar in both groups.

During the open label extension, serious adverse events were reported in 6% of the patients on drug for 12 months compared to 4% of the patients on drug for 6 months, with no apparent difference for any of the single events between the groups.

No clinically meaningful changes in vital signs (supine and standing blood pressure and pulse rate) and ECG were observed during the 12-month study period.

Detailed data and findings from the study will be shared and discussed in an article that is planned for publication in a peer reviewed scientific journal.

Dr. Nicholas Waters, CEO of NeuroSearch Sweden AB, commented:

"We are encouraged by these results as they support earlier findings that Huntexil[®] has a favourable safety profile and is well tolerated in patients with Huntington's disease over a treatment period of 12 months. Furthermore, the safety findings from the open-label extension are similar to what has previously been observed and reported in clinical studies with Huntexil[®] in this patient population. "

NeuroSearch is also evaluating Huntexil[®] in a 12-week North American Phase IIb study, the HART study, from which the first results are expected to be available in October in connection with the Clinical Symposium on Huntington's disease, in La Jolla, USA.

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About Huntexil[®] (pridopidine)

Pridopidine acts as a dopaminergic stabiliser and is the first compound in a new class of pharmaceutical agents, *dopidines* to have demonstrated clinical effect. Dopidines have the unique ability to stabilise the dopaminergic system, i.e., to either enhance or inhibit dopamine dependent functions in the brain, depending on the initial level of dopaminergic activity.

Pridopidine inhibits dopamine activation of the D2 receptor with a preference towards the high affinity (activated) receptor state and has no detectable agonist activity on this receptor. *In vivo*, pridopidine strengthens glutamate function in the frontal cortex, which may add to the agent's powerful behavioural effects in states of excessively high dopamine activity or excessively low glutamate activity, while not affecting behaviour under normal conditions. Together, these findings suggest that pridopidine stabilises psychomotor activity in states of hypo- and hyperactivity by means of functional D2 antagonism and strengthening of cortical glutamate functions.

About Huntington's disease

Huntington's disease is a highly disabling, fatal and incurable genetic disorder, which leads to damage of the nerve cells in certain areas of the brain including the basal ganglia and the cerebral cortex. The disease is hereditary and every child of someone with Huntington's disease has a 50% chance of inheriting the disease.

Patients with Huntington's disease experience a wide variety of symptoms, which typically can be grouped into three categories: *motor dysfunction* includes loss of muscle co-ordination, parkinsonism, chorea, dystonia, and abnormal gait and posture, which can markedly impair patients' daily functioning. *Impaired executive and cognitive functions* lead to loss of organizational and planning skills, and *psychiatric changes*, such as depression and anxiety, are typical; manic and psychotic symptoms can also be present. The onset of symptoms is typically around 35–45 years of age, after which patients deteriorate gradually and have a life expectancy of 10–20 years.

Patients with Huntington's disease will eventually require full-time care, and the therapy area has high unmet medical needs. No cure or effective treatment is available and only a limited number of novel drugs are in development. The prevalence of Huntington's disease is about 1: 10 000 in most western countries, corresponding to an estimated 70 000 affected patients in North America and Europe combined. In other parts of the world, the prevalence varies substantially and is generally lower.

About NeuroSearch – Company profile

NeuroSearch A/S is a leading CNS focused and European based biopharmaceutical company listed on NASDAQ OMX Copenhagen A/S (NEUR). The company's core business is development of novel drugs to treat diseases of the central nervous system, and the pipeline comprises eight products in clinical development (Phase I-III). These include Huntexil® (pridopidine), a unique orphan drug in Phase III development for the treatment of Huntington's disease, and tesofensine ready for Phase III development as a novel treatment of obesity.

NeuroSearch is founded on a well-established drug discovery platform in the field of ion channels and monoamine transporters, holding also a broad portfolio of preclinical drug candidates. The company has strategic drug discovery alliances with Janssen Pharmaceutica and Eli Lilly as well as a licence collaboration with Abbott. Further, NeuroSearch has equity interests in a number of private health care companies.

