



## Announcement

### **NeuroSearch announces the issuance of an EHDN statement supporting the statistical conclusions on the primary endpoint of the MermaiHD study**

*Copenhagen, 4 September 2010* – Today, NeuroSearch A/S (NEUR) announced that the European Huntington's Disease Network, EHDN, has issued a supportive statement on the reported conclusions regarding the primary endpoint, the modified Motor Score, mMS, of the MermaiHD study, following an independent EHDN panel review of the statistical data and the analyses performed. The MermaiHD study is a European Phase III study of Huntexil<sup>®</sup> (pridopidine) for Huntington's disease, from which NeuroSearch reported the results earlier this year, consistent with a beneficial effect on Huntington patients' motor function after 26 weeks' treatment with Huntexil<sup>®</sup> (45 mg. twice daily).

To ensure full transparency about the reported analyses of the primary endpoint, NeuroSearch has agreed to make all data from the MermaiHD study and the statistical analyses performed available to a panel of EHDN-associated researchers for independent review. The review has been based on a quality controlled draft of the statistical study report and led to the following conclusions from the panel:

1. The data were comprehensively described and found to be internally consistent.
2. The statistical methods used to describe and to interpret the study data were overall adequate.
3. The analysis of the primary endpoint in both the 'full analysis set' (FAS) population as well as in the 'per protocol' (PP) population was correctly reported in the NeuroSearch announcement from 28 March 2010.

The statement was issued today in connection with the 6<sup>th</sup> Plenary Meeting of the EHDN, which is being held in Prague, Czech Republic from 3 – 5 September and is available on the EHDN homepage in the section on Huntexil<sup>®</sup> (designated by the project name; ACR16): [www.euro-hd.net/html/projects/acr16](http://www.euro-hd.net/html/projects/acr16).

Prof. Bernhard Landwehrmeyer, Chairman of the EHDN, commented:  
*"I have confidence in NeuroSearch and the work they do in the area of Huntington's disease. EHDN will remain committed to working with the company in our shared aim to establish a better therapeutic offering for patients suffering from this devastating disease."*

A publication committee has drafted a manuscript containing a full account of the findings from the MermaiHD study and intended for publication in a peer reviewed journal. Once the final statistical report is available, the manuscript will be reviewed, revised (as appropriate) and submitted.

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**About the MermaiHD study**

The MermaiHD study is a randomised, double-blinded and placebo-controlled Phase III study conducted at 32 clinical centres across Europe to examine the effects of Huntexil<sup>®</sup> on a number of Huntington's disease parameters. The study included 437 patients with Huntington's disease from Austria, Belgium, France, Germany, Italy, Portugal, Spain and the UK.

In the study, patients were randomly allocated to receive treatment with one of two Huntexil<sup>®</sup> doses (45 mg. once or twice daily) or placebo during a 26-week period. Patients completing the randomised phase have been offered to continue into a 26-week open-label extension phase, in which they receive treatment with 45 mg. Huntexil<sup>®</sup> twice daily, only.

The primary study endpoint is voluntary motor function in Huntington patients, measured on *the modified Motor Score (mMS)*, which is defined as the sum score of voluntary motor items (items 4-10 and items 13-15) from *the Total Motor Score (TMS)*. The TMS includes 15 items of motor assessment and comprises the motor part of the Unified Huntington's Disease Rating Scale (UHDRS), including both voluntary motor function (mMS and eye movements) and involuntary movements such as dystonia and chorea. TMS is also included as endpoint in the MermaiHD study. Other endpoints include cognitive function, behaviour and symptoms of depression and anxiety.

**About Huntexil<sup>®</sup> (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 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<sup>®</sup> (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, ensuring the continuous production of novel preclinical development 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 companies in the Life Science industry.

