NEUROSEARCH

Announcement

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NeuroSearch reports on scientific advice from the EMA on the clinical development programme for Huntexil®

- ***NeuroSearch has received written scientific advice from the EMA regarding the clinical development programme for Huntexil® in the treatment of Huntington's disease***
- ***Based on the scientific advice, a new confirmatory Phase III study is needed prior to submission of a Marketing Authorisation Application in Europe***
- ***NeuroSearch plans to announce a revised timeline for the global development programme for Huntexil®, based on the consolidated advice from the FDA and EMA, by end of June 2011***

NeuroSearch (NEUR) has now received scientific advice from both the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) on the clinical development plans for Huntexil® in Huntington's disease. Based on the advice from both the FDA and EMA, additional confirmatory data is needed to support the regulatory submission. The design of the new confirmatory clinical study will be defined based on the consolidated advice from the FDA and EMA.

The new Phase III study will have the Total Motor Score (TMS) as the primary efficacy endpoint.[1] Additional supportive measures of clinical relevance will also be included to characterise the overall benefit/risk assessment. Timelines for the development programme will be announced by the end of June 2011.

Patrik Dahlen, CEO of NeuroSearch commented on the feedback from the FDA and EMA:
"*Having received the feedback from both the FDA and the EMA, we can now finalise the design of the development programme for Huntexil® to meet the needs of the regulatory authorities and thus bring Huntexil® towards filing. We are pleased that the Total Motor Score is the agreed primary endpoint and that we can accommodate the advice given by both the US and European Authorities in a common global programme.*"

NeuroSearch maintains the company's financial expectations for the full financial year 2011, with an expected loss before financials and other shares of result in the region of DKK 325 million.

Patrik Dahlen
CEO

[1] The TMS is the motor part of the Unified Huntington's Disease Rating Scale (UHDRS)

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About NeuroSearch

NeuroSearch A/S is a European based biopharmaceutical company, specialising in CNS diseases, and listed on NASDAQ OMX Copenhagen A/S (NEUR). The company has a pipeline of speciality CNS drugs, including Huntexil® (pridopidine), a unique orphan drug in Phase III for the treatment of Huntington's disease. NeuroSearch is building commercial competences with a view to commercialising Huntexil® through an in-house marketing and sales organisation.

NeuroSearch has a well-established drug discovery division, NsDiscovery, with unique capabilities in the field of ion channels and CNS diseases. The company has strategic drug discovery and development alliances with Janssen Pharmaceutica and Eli Lilly as well as a licence collaboration with Abbott. NeuroSearch also has equity interests in a number of unlisted companies in the Life Science industry.