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Announcement

NeuroSearch successfully completes End of Phase II meeting with the FDA for tesofensine, a treatment for obesity

- ***FDA endorses the overall Phase III plan for tesofensine in obesity, including the filing of an NDA based on 12 months safety and efficacy data***
- ***NeuroSearch will now finalise Phase III preparations and an SPA request for submission to the FDA, while continuing discussions with potential license partners***

Copenhagen, 8 June 2009 – NeuroSearch announces that it has successfully completed the End of Phase II meeting with the United States Food and Drug Administration (FDA) for tesofensine, a monoamine reuptake inhibitor in development as a novel treatment for obesity (weight management).

In connection with the meeting, the FDA has evaluated tesofensine's current data package and the Phase III development plan, and provided input to the pivotal programme including the plan to apply for a Special Protocol Assessment (SPA) to support the registration of tesofensine in the United States.

The main conclusions from the End of Phase II discussions with the FDA include the following:

- The proposed dose regimen of 0.25 mg or 0.5 mg tesofensine daily in Phase III was endorsed.
- The proposed pivotal Phase III programme for tesofensine in weight management was endorsed by the FDA and will consist of four placebo-controlled clinical studies, comprising a total of approximately 5,700 obese patients with and without co-morbidities, such as Type 2 diabetes, hypertension and dislipidemia.
- Two of the four trials are powered to show superior weight loss effectiveness for tesofensine compared to sibutramine (marketed as Reductil®/Meridia®), and the aim of including an adequate wording in the labelling based on final data was supported by the FDA.
- The safety and efficacy assessment within and across the Phase III studies and the filing of the New Drug Application (NDA) for tesofensine for weight management based on 12 months data were also endorsed by the FDA.

Dieter Meier, Executive Vice President and Chief Medical Officer of NeuroSearch commented:

"*We are extremely pleased with the outcome of our End of Phase II meeting with the FDA, who have been forthcoming and constructive during our interactions. We are impressed how the FDA shares our view on the development of tesofensine, and we very much look forward to continuously working with the Agency in our dedicated efforts to bring this drug to the market as a more efficacious and safe anti-obesity treatment.*"

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Flemming Pedersen, Chief Executive Officer of NeuroSearch added:
"Obesity entails a number of very serious and very costly disease conditions, including diabetes, metabolic disorders, cardiac complications, arthritis and cancer, and we believe tesofensine could effectively contribute to the global quest towards improved weight management and potentially also to the treatment of diabetes. Tesofensine is one of only very few anti-obesity drugs in late stage development, and based on the remarkable results seen in Phase II studies we believe it holds immense medical and commercial potential."

Earlier results from a Phase II Proof of Concept study with tesofensine in obesity, TIPO-1, has shown a placebo-corrected average weight loss of approximately 10% after 24 weeks of daily treatment with 0.5 mg tesofensine. The results from TIPO-1 have been published in *The Lancet* (The Lancet, Volume 372, Issue 9653, Pages 1906-1913, 29 November 2008) with the conclusion that tesofensine produces a weight loss at least twice that of currently approved anti-obesity drugs. The safety data base for tesofensine includes more than 1,500 patients having been exposed to treatment with tesofensine and hereof more than 1,300 on relevant dosing.

Based upon the outcome from the End-of-Phase II meeting with the FDA, NeuroSearch will now make final preparations for Phase III and in parallel continue discussions with interested partners regarding a license agreement on tesofensine.

Flemming Pedersen
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About NeuroSearch

NeuroSearch (NEUR) is a Scandinavian biopharmaceutical company listed on Nasdaq OMX Copenhagen. The core business of the company covers the development of novel pharmaceutical agents, based on a broad and well-established drug discovery platform focusing on ion channels and central nervous system (CNS) disorders. A substantial share of the activities is partner financed through strategic alliances with Eli Lilly and Company and GlaxoSmithKline (GSK), and license collaboration with Abbott. The drug pipeline comprises seven clinical (Phase I-III) development programmes: Pridopidine (ACR16) for Huntington's disease (Phase III), tesofensine for obesity (Phase III ready), ABT-894 for ADHD (Phase II) in partnership with Abbott, ACR325 to treat dyskinesias in Parkinson's disease (Phase II ready), ACR343 for schizophrenia (Phase I), ABT-560 for the treatment of cognitive dysfunctions (Phase I) in collaboration with Abbott and NSD-788 for anxiety (Phase I). In addition, NeuroSearch has a broad portfolio of preclinical drug candidates and holds equity interests in several biotech companies.