

Investor News

Data from TIPO-1, a Phase IIb study with NeuroSearch's novel anti-obesity compound, tesofensine to be presented at ECO 2008, the 16th European Congress on Obesity

The principal investigator in the TIPO-1 Phase IIb study, Professor, Dr. Med. Sci. Arne Astrup¹, Department of Human Nutrition, Faculty of Life Sciences, University of Copenhagen, Denmark will present the data, showing that tesofensine is a potentially effective and safe treatment for obesity and possibly type 2 diabetes. Tesofensine is a monoamine reuptake inhibitor, increasing the pre-synaptic levels of serotonin, noradrenalin, and dopamine, and has been found to produce a dose-dependent weight loss.

The data will be presented tomorrow, Friday 16 May at the 16th Annual European Congress on Obesity (ECO 2008) from 14th- 17th May in Geneva, Switzerland, in an oral presentation under the title "*The efficacy and safety of tesofensine for weight loss in obese subjects. A 24 week randomised, double-blind, placebo-controlled Danish multi-centre trial*". In the study, obese patients (ITT population n = 203; BMI 30-40; age 18-65 years) underwent a two week diet and exercise lead-in period followed by a 24 week energy-restricted diet and treatment with 0.25 mg, 0.5 mg or 1.0 mg tesofensine or placebo, once daily.

Results demonstrate that the placebo-subtracted weight loss produced by 0.5 mg tesofensine was more than double that produced by currently approved compounds, and primarily in the form of body fat (8 out of 11 kg), resulting in an average reduction in waist circumference of 10 cm compared to an average loss of 2 cm in the placebo group. Further, treatment with tesofensine has led to important improvements in glucose metabolism and reduced insulin resistance, indicating that tesofensine may be able to treat also overweight patients with type 2 diabetes.

Adverse events were generally mild and transient. 12% (n=6) of the TE 0.5 mg group dropped out, 25% (n=13) in the placebo group and 29% (n=14) in the TE 1.0 mg group: 20.4% due to adverse events, vs. 8% in the other groups. At therapeutic doses (0.25 mg and 0.5 mg) no statistically significant increases in blood pressure occurred, while heart rate increased dose-dependently up to approx. 7 BPM on average. No cardiovascular signs of potential clinical relevance were seen in individual patients.

¹ Arne Astrup has received honoraria from NeuroSearch as a consultant and as a member of the tesofensine advisory board. Arne Astrup has informed Neurosearch that he holds 550 shares in NeuroSearch A/S

At ECO 2008, there will also be a poster presentation of results from the TIPO-1 study under the title "*The effects of tesofensine on body composition in obese subjects*". Body composition was assessed by DEXA, waist circumference and sagittal diameter, and results indicate that tesofensine is highly effective in reducing central obesity.

Tesofensine may be more effective, with similar or less risk, than currently approved drugs and warrants Phase III trials.

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NeuroSearch (NEUR) is a Scandinavian biopharmaceutical company listed on the OMX Nordic Exchange Copenhagen A/S. Our 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 part of the company's activities are partner financed through a broad strategic alliance with GlaxoSmithKline (GSK) and collaborations with Abbott and Astellas. The drug pipeline comprises 13 clinical (Phase I-III) development programmes: ACR16 in Huntington's disease (Phase III), tesofensine in obesity (Phase III in preparation), NS2359 in depression (Phase II) and ADHD (Phase II) in partnership with GSK, ABT-894 in ADHD (Phase II) and pain (Phase II) in partnership with Abbott, ACR16 in schizophrenia (Phase I) in partnership with Astellas, ACR325 in bipolar disorder (Phase I), ABT-107 as well as ABT-560 for the treatment of various CNS diseases, both (Phase I) in collaboration with Abbott, NSD-644 in pain (Phase I) in partnership with GSK, ACR343 in Parkinson's disease (Phase I) and NSD-788 in anxiety and depression (Phase I). In addition, NeuroSearch has a broad portfolio of preclinical drug candidates and holds equity interests in several biotech companies.