Investor News

Supportive clinical data on tesofensine, NeuroSearch’s late-stage anti-obesity drug, presented at the 17th European Congress on Obesity

- Results from three previously reported clinical studies with tesofensine are presented in an oral presentation, a “hot topic” presentation and a poster presentation

Copenhagen, 7 May 2009 – NeuroSearch announces that results from three clinical studies with tesofensine, the company’s highly efficacious anti-obesity drug in Phase II/III, are presented today and tomorrow at the 17th annual European Congress on Obesity, which is being held from 6-9 May in Amsterdam, the Netherlands.

The results from TIPO-5, a clinical study of tesofensine’s abuse liability potential, will be presented today 7 May at 1.30 pm – 3.00 pm CET in a hot topic poster presentation:

“Tesofensine, a novel weight management drug, has no or minimal abuse potential”

The conclusions from the TIPO-5 hot topic poster presentation:
- Tesofensine was not associated with significant positive effects at doses ranging from 1 mg (the maximum therapeutic dose) up to 9 mg.
- Abuse-related effects of tesofensine were lower than d-amphetamine on most measures, as well as unscheduled controls bupropion and atomoxetine on some measures.
- Tesofensine has minimal or no abuse potential in recreational stimulant users.

The results from TIPO-2, a clinical study of the metabolic effects of two weeks’ treatment with tesofensine in 32 overweight and obese subjects, will be presented tomorrow 8 May at 9.30 am – 11.00 am CET in an oral presentation:

“The effect of the triple monoamine reuptake inhibitor tesofensine on energy metabolism and appetite in overweight and moderately obese men”
- by Anders Sjödin, MD, Dr.Med.Sci. Department of Human Nutrition, University of Copenhagen, Denmark.

Summary and conclusion from the oral presentation on results from TIPO-2:
- Study subjects experienced a significant weight-loss after two weeks, despite efforts to maintain body weight.
- The weight reducing effect of tesofensine is mainly caused by its decreasing appetite effect but probably also to some extent by its stimulation of thermogenesis.
Furthermore, a poster presentation will be given tomorrow 8 May at 13.30 pm – 15.00 pm CET with results from TIPO-4, a 48-week Phase II extension study to TIPO-1, a Proof of Concept study:

“The effect of tesofensine on weight loss: Results from a one-armed, open-labeled extension study”

Conclusions from the presentation of results from TIPO-4:
- This one-armed, open-labelled, extension study confirms previously reported efficacy of tesofensine, i.e. a weight loss of > 10 kg over 24 weeks and ≈ 14 kg over 48 weeks, with good tolerability and acceptable hemodynamic effects as well as adverse events.

Earlier presented results from TIPO-1 demonstrated that 24-week treatment resulted in an average placebo-corrected weight loss of approximately 10% and a good safety and tolerability profile for the drug.

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Tesofoensine – A novel anti-obesity drug
Tesofensine is a monoamine reuptake inhibitor, which NeuroSearch has evaluated in Phase II studies with out-standing effect for the treatment of obesity. After six months of treatment, a weight loss of approx. 10% was obtained (TIPO-1 study) and a weight loss of 13-14% was seen after 12 months of treatment (TIPO-4 study). NeuroSearch believes that these results make tesofensine one of the most effective anti-obesity products in late-stage development. In October 2008, the results from TIPO-1 were published in the highly reputed international scientific journal The Lancet with the conclusions that tesofensine can produce a weight loss at least twice that of currently approved anti-obesity drugs and that it should be further evaluated in Phase III studies in order to prepare for market registration.

NeuroSearch has built up a substantial data package supporting the strong profile of tesofensine. This includes safety data from more than 1,300 individuals having received treatment with tesofensine and of these approx. 1,150 have received relevant therapeutic doses.

NeuroSearch will decide on the final Phase III development plan following interactions with both the FDA and EMEA in 2009.

NeuroSearch – Company profile
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 and a license collaboration with Abbott. The drug pipeline comprises seven clinical (Phase I-III) development programmes: ACR16 for Huntington’s disease (Phase III), tesofensine for obesity (Phase III ready), ABT-894 for ADHD (Phase II) in partnership with Abbott, ACR25 to treat dyskinesias in Parkinson’s disease (Phase II ready), ACR343 for schizophrenia (Phase II ready), ABT-560 for the treatment of various CNS disorders (Phase I) in collaboration with Abbott, and NSD-788 for anxiety/depression (Phase I). In addition, NeuroSearch has a broad portfolio of preclinical drug candidates and holds equity interests in several biotech companies.