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Investor News

NeuroSearch announces publication in The Lancet of tesofensine Proof-of-Concept results from TIPO-1

- **Tesofensine can produce weight loss twice that of currently approved obesity drugs**

NeuroSearch announces publication in The Lancet of the results from a Phase II Proof-of-Concept study, TIPO-1, of its anti-obesity compound, tesofensine.

Tesofensine can produce a weight loss twice that of currently approved obesity drugs, and should be studied in Phase III trials. These are the conclusions of an article published early Online and in an upcoming edition of The Lancet written by Professor Arne Astrup, Department of Human Nutrition, Faculty of Life Sciences, University of Copenhagen, Denmark, and colleagues.

Increased obesity prevalence worldwide, in both developed and developing countries, results in more people with cardiovascular disease, diabetes, musculoskeletal disorders and cancer. Whilst gastric bypass surgery substantially reduces bodyweight and obesity-related disease, the researchers believe a treatment gap exists between the effectiveness of currently marketed obesity drugs and gastric-bypass surgery. Tesofensine – which inhibits the presynaptic uptake of the neurotransmitters noradrenaline, dopamine and serotonin in the brain – has been shown to be safe and effective in animal models. It also caused unintended weight loss when it was given obese patients with Parkinson's or Alzheimer's disease when it was researched for those conditions. The drug works by suppressing hunger, leading to an energy deficit, which burns off excess body fat.

Tesofensine was investigated in a randomised, placebo-controlled Phase II study, named TIPO-1, in five Danish obesity management centres, involving 203 obese patients, weighing a mean of just over 100 kg at baseline (body mass index 30-40 kg/m2). The patients were prescribed a limited-energy diet and assigned to tesofensine 0.25 mg (52 patients), 0.5 mg (50 patients), 1.0 mg (49 patients) or placebo (52 patients), all once daily for 24 weeks. The primary outcome was percentage change in bodyweight. A total of 161 patients completed the study, and mean weight loss recorded for placebo and diet was 2.2 kg and for tesofensine 0.25 mg, 0.5 mg and 1.0 mg was 6.7 kg, 11.3 kg, and 12.8 kg respectively. For the 0.5 mg and 1.0 mg doses, this represented a weight loss around twice that attained using sibutramine (Reductil®/Meridia®) or rimonabant (Accomplia®), the currently-approved therapies in Europe – and in half the treatment time. Blood pressure was increased in the 1.0 mg group. The most common side-effects caused by tesofensine were dry mouth, nausea, constipation, hard stools, diarrhea and insomnia.

The authors conclude that the 0.5 mg dose of tesofensine is more promising than the 1.0 mg dose because it produces a similar weight loss with less side-effects. They say: *"We conclude that tesofensine 0.5 mg, once daily for 6 months, has the potential to produce twice the weight loss as currently approved drugs; however, larger Phase III studies are needed to substantiate our findings."*

Professor Arne Astrup says*):

"The results indicate that obese patients who typically obtain a weight loss of 3-5 kg with existing drugs on the market, can now expect a weight loss of 10 kg with tesofensine alone. If, in addition, the treatment is combined with the right diet, the total weight loss can amount to 20 kg."

*) Arne Astrup owns 966 shares in NeuroSearch.

Flemming Pedersen, CEO of NeuroSearch, comments:

"We are very pleased to see our TIPO-1 results published in The Lancet and with firm suggestion that tesofensine has a superior profile as a new treatment within weight management and that such a treatment offering is strongly needed. Tesofensine has been studied in more than 1,000 patients at relevant therapeutic doses, and we are highly satisfied with the efficacy and safety profile of the drug. Following the outstanding weight loss results from the TIPO-1 Proof-of-Concept study, we have reported interim results from a 48-week extension study showing a placebo-controlled average weight loss of 13 kg after 48 weeks of treatment with tesofensine. This is almost tripple the effect seen with existing anti-obesity drugs and even comparable to the weight loss effect of surgical procedures such as gastric by-bass."

NeuroSearch has succesfully completed all Phase III preparatory work with tesofensine and expects to initiate pivotal studies with the drug.

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NeuroSearch (NEUR) is a Scandinavian biopharmaceutical company listed on Nasdaq OMX Copenhagen. The company's 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 share of its activities is partner financed through a broad alliance with GlaxoSmithKline (GSK) and collaborations with, among others, Abbott and Astellas. NeuroSearch's drug pipeline comprises 14 clinical (Phase I-III) development programmes: ACR16 for Huntington's disease (Phase III), tesofensine for obesity and in Type 2 diabetes (Phase III in preparation), NS2359 for depression (Phase II) and ADHD (Phase II) in partnership with GSK, ABT-894 for ADHD (Phase II) and pain (Phase II) in partnership with Abbott, ACR16 for schizophrenia (Phase I) in partnership with Astellas, ACR325 for Parkinson's disease (Phase II in preparation) and bipolar disorder (Phase II in preparation), ABT-107 and ABT-560 for the treatment of various CNS disorders – both (Phase I) in collaboration with Abbott, NSD-644 for pain (Phase I) in partnership with GSK, ACR343 for Parkinson's disease (Phase I) 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.