NEUROSEARCH

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Announcement

NeuroSearch publishes positive and confirmatory results from TIPO-2, a clinical metabolic study with tesofensine for the treatment of obesity

NeuroSearch has finalised a clinical metabolic study ("TIPO-2") with tesofensine for the treatment of obesity. TIPO-2 is a randomised, double-blind, placebo-controlled study in which 32 overweight volunteers with a BMI (Body Mass Index) of 28 - 35 were treated for 14 days with either tesofensine (with accelerated dosing up to 1 mg exposure) or placebo. The aim of the study was to evaluate tesofensine's effect on selected metabolic parameters.

Even though the TIPO-2 study was designed with short term treatment and the study subjects were urged not to change their lifestyle while in the study (no diet and exercise programme), a statistically significant mean weight loss of 2.2 kg (maximum weight loss of 4.7 kg) was seen in the tesofensine-treated group compared to a mean weight loss of 0.4 kg in the placebo group.

	Tesofensine	Placebo
Population (ITT)	n = 16	n = 16
Baseline average BMI	30.7	31.1
Baseline average weight (kg)	102.6	102.6
Total body weight loss (kg)	2.2	0.4
Maximum weight loss (kg)	4.7	1.5

Professor, Dr. Med. Sci. Arne Astrup*, Head of Department of Human Nutrition at the University of Copenhagen Faculty of Life Sciences, lead investigator in TIPO-2, commented:

"Normally we don't see any significant weight loss within two weeks' treatment, so the findings in TIPO-2 underpin the superiority of tesofensine compared to existing weight loss compounds. These results are therefore quite re-assuring after the weight loss results seen in the TIPO-1 study."

* Arne Astrup holds 425 shares in NeuroSearch A/S

The results from TIPO-2 showed no measurable changes in energy expenditure, metabolic rate and respiratory quotient while there was an increase in fat oxidation in the tesofensine-treated group compared to the placebo-group. Fat oxidation is a key aspect of improving insulin sensitivity in obese individuals. Normally, changes in energy expenditure and metabolic rate correlate with changes in body weight and further detailed data evaluation of the relationship between the different study endpoints is ongoing. No changes in physical activity in either the active group or the placebo group were observed.

Safety results from TIPO-2 are fully consistent with previous findings, and the most frequently reported adverse events in the study were mild to moderate. The most prominent adverse events were dry mouth and insomnia. Considering the subjects' accelerated exposure to tesofensine these safety results are highly confirmatory.

NeuroSearch considers the TIPO-2 results highly supportive for the continued development of tesofensine both in terms of superior efficacy and safety. Notably the fast induced weight loss seen after two weeks of tesofensine treatment is important both from a medical point of view and with a view to ensuring a high patient compliance.

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NeuroSearch (NEUR) is a Scandinavian biopharmaceutical company listed on the OMX Nordic Exchange Copenhagen A/S. The 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 alliance with GlaxoSmithKline (GSK) and collaborations with among others Abbott and Astellas. The drug pipeline comprises 13 clinical (Phase I-III) development programmes: ACR16 in Huntington's disease (Phase III in preparation), tesofensine in obesity (Phase III in preparation), NS2359 in depression (Phase II) and ADHD (Phase II) in partnership with GSK, NS1209 in epilepsy/pain (Phase II), 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/Parkinson's disease (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 a.o. (Phase I) in partnership with GSK and ACR343 in Parkinson's disease (Phase I). In addition, NeuroSearch has a broad portfolio of preclinical drug candidates and holds equity interests in several biotech companies.