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Investor News

NeuroSearch responds to conclusions about tesofensine made by BiotekAnalyse Weekly

On the basis of an analysis made by the magazine BiotekAnalyse Weekly (no. 77/10.03.2007), the management of NeuroSearch has considered it necessary to respond to the conclusions about tesofensine which NeuroSearch develops for the treatment of obesity.

As a general rule, it is NeuroSearch's policy not to comment on the market participants' analyses and other media coverage. However, as BiotekAnalyse Weekly has made technically incorrect claims and conclusions without any prior dialogue with NeuroSearch, we find this press release necessary primarily out of regard for the patients enrolled in the current clinical studies in order to respond to the conclusions of the analysis regarding tesofensine's clinical side-effects and efficacy profile.

Clinical effect - loss of weight

The conclusions of the analysis regarding tesofensine's clinical effect have been made on an erroneous basis. In the pharmaceutical industry doses are calculated in mg/kg in preclinical studies (studies made with animals) whereas daily doses in human clinical studies are calculated in mg per day. When determining the doses it is also necessary to consider the duration of the effect in animals and humans respectively. Therefore it is not relevant to make direct comparisons between doses used in animal studies and doses used in patient studies. If this is done, this will lead to erroneous conclusions.

Regarding the preclinical rat studies referred to by BiotekAnalyse Weekly in which NeuroSearch has evaluated tesofensine and sibutramine, both compounds were given in the maximum tolerated doses for rats. The study showed effect not only on weight but also on the metabolism relating to type 2 diabetes, and that tesofensine demonstrated significantly better effect than sibutramine.

To draw a direct parallel between the doses of tesofensine and sibutramine used in preclinical studies to determine the dose in clinical studies is a basic and crucial failure. What is relevant is the degree of exposure of tesofensine in animals and humans to be able to evaluate the effect. In this connection it can be informed that a daily dose of 1 mg of tesofensine gives the same exposure in humans as 2.5 mg/kg in rats.

The authors themselves stress that "… the doses used are a mystery to them". This "mystery", which is a professional commonplace and standard procedure in the entire pharmaceutical industry, could have been given a prompt answer if the question had been addressed to the company.

Clinical safety profile

The analysis by BiotekAnalyse Weekly about tesofensine's safety profile is again built on the erroneous conclusion about dose levels mentioned above which results in a misleading and decidedly erroneous argumentation.

The analysis comments separately on the safety profile in connection with possible heart symptoms. We draw attention to the fact that all clinical studies with tesofensine taken into to consideration, the total number of reported heart-related symptoms in the form of rapid pulse and elevated blood pressure so far is smaller than what is reported for sibutramine. All patients enrolled in the ongoing clinical studies are carefully looked

after and monitored - heart diagram (ECG), pulse and blood pressure - which is common practice in clinical studies.

It can also be informed that NeuroSearch in its Annual Report 2006 of 5 March 2007 announced a very favourable mid-term evaluation made by an external Data Monitoring Committee which has recommended that the study continues as planned. The Data Monitoring Committee considered the observed side-effects few and insignificant and concluded that tesofensine has been well-tolerated. For statistical reasons all data must be blinded until the end of the study and therefore the mid-term evaluation is only available in the form of the main conclusions and only the Data Monitoring Committee has access to the detailed data.

Tesofensine has now been dosed in more than 1,200 humans in 23 different clinical studies of which more than 800 patients were diagnosed with Alzheimer's or Parkinson's disease. The patients in this population are between 65 to 85 years of age and generally tolerate very few side-effects. Even in this patient population, tesofensine has had a satisfactory safety profile. In addition the full preclinical safety programme necessary for regulatory approval has been terminated with a satisfactory result. Furthermore all clinical studies are approved by national authorities and an ethical committee, which evaluates safety aspects before study start is approved.

The results of the ongoing clinical studies - TIPO-1 and TIPO-2 - are expected in the second half of 2007.

NeuroSearch supports a lively and active share market with room for critical analysis and media coverage but we expect a critical analysis founded in a scientific argumentation to be based on a minimum level of scientific standard and insight.

We invite all market participants to obtain insight and transparency directly with the company to eliminate the most basal misjudgements.

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NeuroSearch is a Scandinavian biopharmaceutical company listed on the Copenhagen Stock Exchange (NEUR). Our core business covers the development of novel drugs, based on a broad and well-established drug discovery platform focusing on ion channels and transporters. 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. Eight drug programmes are in clinical development: ACR16 for the treatment of Huntington's disease (under preparation for Phase III), tesofensine for the treatment of obesity/type 2 diabetes (Phase II), NS2359 for the treatment of depression (Phase II) and ADHD (Phase II) in partnership with GSK, NS1209 for the treatment of epilepsy and pain (Phase II), ABT-894 for the treatment of ADHD (Phase II) and neuropathic pain (Phase I) in partnership with Abbott, ACR16 for the treatment of schizophrenia (Phase I) in partnership with Astellas, and ACR325 for the treatment of psychoses such as bipolar disorder (Phase I). In addition, NeuroSearch has a broad portfolio of preclinical drug candidates and has equity interests in several biotech companies.