

KARO BIO INITIATES PHASE IIb CLINICAL STUDY WITH KB2115

Karo Bio has received approval for initiation of a phase IIb clinical study with KB2115. This study will be conducted in dyslipidemia patients receiving concomitant statin treatment. Patient recruitment has been initiated for the three month study which in total will include 172 patients.

Elevated blood lipids significantly correlate with development of cardiovascular disease. In particular high plasma levels of the harmful LDL-cholesterol contribute to disease development. There is a great need for new dyslipidemia drugs that can be used together with statins since a significant part of the patients do not reach the treatment goals on single therapy.

KB2115 is a novel, selective, thyroid hormone agonist for treatment of dyslipidemia. Recently Karo Bio presented positive data from a first phase IIa study. In summary, the compound was efficacious and safe given as 100 or 200 µg as monotherapy to dyslipidemic patients. A significant LDL lowering of approx. 30% was obtained after KB2115 administration. Furthermore, KB2115 has significant effects on other risk factors for development of cardiovascular disease such as triglycerides and lipoprotein(a).

Statins are an effective class of drugs that is widely used for treatment of dyslipidemia. Still, in a significant part of the patients, statin treatment is not sufficient and the trend is to combine new drugs with statins in order to reach the treatment goals. In the new clinical study, KB2115 will be added on top of statin treatment in order to explore the potential for additional effects regarding lowering of plasma LDL-levels. Karo Bio has preclinical evidence supporting such possibilities.

The phase IIb study is a placebo controlled, parallel group, double blind randomized 12 week study in 172 patients. The study contains four arms with 43 patients per arm. KB2115 will be given in doses of 25, 50 and 100 µg on top of statin treatment. A corresponding placebo control receiving statin only will constitute the fourth treatment group. The results from the study is planned to be presented in Q3 2008.

“The KB2115 development is progressing in accordance with our previously communicated plan. The results obtained to date regarding efficacy, clinical safety and tolerability are very encouraging as we are continuing clinical development”, says Per Olof Wallström, President of Karo Bio.

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Facts about Karo Bio

Karo Bio is a drug discovery and development company specializing in nuclear receptors for the development of novel pharmaceuticals with focus on metabolic diseases.

The company has expanded from being a drug discovery company by adding in-house preclinical and clinical development resources and competence for development of drugs to treat metabolic diseases. The company has a strong project portfolio with innovative molecules that primarily targets diseases such as diabetes, atherosclerosis and dyslipidemia. In all of these areas there are significant market opportunities and a growing need for new pharmaceuticals with new mechanisms of action.

In addition to the proprietary projects Karo Bio has two strategic collaborations with international pharmaceutical companies and one biotech collaboration for development of innovative therapies for the treatment of common diseases.

Karo Bio is listed on the OMX Nordic Exchange Stockholm AB since 1998 (Reuters: KARO.ST). This press release is also available online at: www.karobio.se and www.newsroom.cision.com