

KARO BIO ANNOUNCES SUCCESSFUL PHASE II STUDY WITH EPROTIROME IN COMBINATION WITH STATIN

Karo Bio has successfully completed a 12 week phase IIb study of eprotirome (KB2115) given to patients with dyslipidemia (elevated blood lipids). These patients were already on statin treatment. Data show that eprotirome induced a statistically significant and clinically relevant lowering of serum LDL-cholesterol, triglycerides and lipoprotein (a) and was safe and well tolerated. The data indicate that eprotirome has the potential to become an important new medicine for treatment of dyslipidemia.

Eprotirome is a novel, selective, thyroid hormone receptor agonist, developed for treatment of dyslipidemia. To explore the potential for eprotirome as an add–on to standard statin treatment, Karo Bio conducted a phase IIb placebo controlled, randomized, double blind, 12 week study in 189 patients, each with high levels of serum cholesterol. Three different doses of eprotirome were tested on a background of statin treatment.

The results show that eprotirome, in a dose–dependent manner, significantly lowered LDL–cholesterol, triglycerides and lipoprotein(a) when added to statin. The additional reductions are clinically relevant and of the same magnitude as eprotirome given alone. Eprotirome was safe and well tolerated. Sensitive markers of the body s thyroid hormone status were unaffected by eprotirome.

The profile of eprotirome is unique in producing simultaneous and powerful reductions of three independent risk factors for the development of atherosclerotic cardiovascular disease. This combined effect on LDL-cholesterol, triglycerides and lipoprotein(a) indicates that eprotirome has the potential for being an important drug for dyslipidemia. Scientific data from the study will be presented at upcoming conferences during the fall of 2008.

The study shows that eprotirome can be given safely with statins, and has significant therapeutic efficacy on LDL-cholesterol, triglycerides and lipoprotein(a) over and above the effect of statin. The unique clinical efficacy, tolerability and safety make this combination a potentially attractive therapy for patients who cannot achieve their treatment goals with statin alone. Karo Bio will proceed with its communicated strategy with the aim to develop eprotirome through phase III with a partner says Per Olof Wallström, President of Karo Bio.

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About dyslipidemia treatment and opportunities for eprotirome Consequences of atherosclerotic cardiovascular disease such as coronary heart disease and stroke are major medical problems, and there is a need to develop improved means to treat these disorders by reducing important risk factors such as serum LDL-cholesterol, triglycerides and lipoprotein(a).

Statins are a class of compounds that are widely used for treatment of elevated LDL-cholesterol. The global sales of statins were in the range of USD 15–20 billion in 2007. In spite of active treatment of high blood lipids with increasing doses of statins over the last 15 years, and achieving subsequent reductions of heart disease and stroke by some 30%, the morbidity and mortality for cardiovascular atherosclerotic disease remain high. The treatment goals for acceptable LDL-cholesterol levels have been generally lowered over the years, specifically for high risk patients. Combination therapies have become more common as it proves difficult to reach the treatment target by one medication only. Apart from LDL-cholesterol there is a growing awareness that it is important to lower additional risk factors such as triglycerides and lipoprotein(a). Recent data indicate that lipoprotein(a) is a risk factor for heart disease and stroke of the same magnitude as high blood pressure. Until now there have been limited treatment options for patients with elevated lipoprotein(a).

Eprotirome has the potential to be used as second–line therapy for patients who do not reach their treatment goal with statin alone. Due to the combined effect on LDL–cholesterol and triglycerides, eprotirome may be well suited for the treatment of mixed dyslipidemia (elevated LDL–cholesterol and triglycerides) and diabetic dyslipidemia. Further, eprotirome may provide a powerful treatment option for patients with high levels of lipoprotein(a).

About Karo Bio

Karo Bio is a drug discovery and development company specializing in nuclear receptors for the development of novel pharmaceuticals.

The Company has a strong project portfolio with innovative molecules that primarily target metabolic diseases such as diabetes, atherosclerosis and dyslipidemia. In all of these areas there are significant market opportunities and a need for pharmaceuticals with new mechanisms of action. Karo Bio intends to bring selected compounds within niche therapeutic areas into late stage clinical develop¬ment and, potentially, to the market. In addition to pursuing niche opportunities, Karo Bio continues to develop compounds aimed at treatment of broad patient populations to clinical proof of concept before out licensing.

In addition to the proprietary projects, Karo Bio has three strategic collaborations with international pharmaceutical companies for development of innovative therapies for the treatment of common diseases.

Karo Bio is listed on the OMX Nordic Exchange Stockholm since 1998 (Reuters: KARO.ST).

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