

SUCCESSFUL PHASE II STUDY EXPANDS THE POTENTIAL FOR EPROTIROME IN DYSLIPIDEMIA TREATMENT

Karo Bio has successfully completed a 10 week phase IIb study with eprotriome given to dyslipidemia patients undergoing treatment with the cholesterol absorption inhibitor ezetimibe. Eprotriome induced a statistically significant and clinically relevant lowering of serum LDL-cholesterol, triglycerides and lipoprotein(a) and was safe and well tolerated. Data show that eprotriome in combination with ezetimibe can become an important treatment option for patients with dyslipidemia.

Karo Bio's compound eprotriome is a novel, liver selective, thyroid hormone receptor agonist with a promising profile for treatment of dyslipidemia. In previous phase II studies eprotriome, alone or in combination with statins, induced a significant lowering of LDL-cholesterol in dyslipidemia patients. Furthermore, eprotriome significantly reduced other important risk factors for development of cardiovascular disease such as triglycerides and lipoprotein(a), and was well tolerated.

The intention with the new phase IIb dose ranging study was to expand the clinical and commercial potential for eprotriome in dyslipidemia treatment by exploring whether eprotriome in combination with ezetimibe can serve as an alternative to statin treatment. Ezetimibe is a well documented cholesterol absorption inhibitor and thus complements eprotriome well with a different mechanism of action.

The study was a placebo controlled, parallel group, double blind, 10 week dose ranging study in 109 patients. Eprotriome was given once daily in doses of 25, 50, or 100 µg in patients who were on a stable ezetimibe treatment, of 10 mg per day. Top line data show that there was a statistically significant lowering of LDL-cholesterol in the range of 15-25 % on top of ezetimibe treatment, which is in line with previous monotherapy and statin combination studies. Pronounced and clinically relevant reductions of triglycerides and lipoprotein(a) were also documented.

"We have, in three consecutive phase II studies, treated a total of 391 patients with eprotriome. The data are consistent and robust across the three studies. Firstly, the compound has been well tolerated. Secondly, eprotriome induced a profound lowering of several important risk factors for development of atherosclerotic cardiovascular diseases. For the dose range 25-100 µg per day of eprotriome we observed reduction in serum LDL cholesterol from 14 - 26%, reduction of triglycerides from 23-44% and reduction of Lp(a) from 22-39%. These effects were of the same magnitude regardless of whether eprotriome was given as monotherapy or to patients who were on stable treatment with statins or ezetimibe. With these phase II results we have built up a strong position for partner discussions and upcoming phase III studies", says Per Olof Wallström, President of Karo Bio.

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About dyslipidemia treatment and opportunities for eprotriome

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).

Eprotriome 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, eprotriome may be well suited for the treatment of mixed dyslipidemia (elevated LDL-cholesterol and triglycerides) and diabetic dyslipidemia. Further, eprotriome 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 project portfolio with innovative molecules that primarily targets metabolic diseases such as diabetes, atherosclerosis and dyslipidemia. In all of these areas there are significant market opportunities and a need for new pharmaceuticals with new mechanisms of action. Karo Bio intends to bring selected compounds within niche therapeutic areas into late stage clinical development 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 AB since 1998 (Reuters: KARO.ST).

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