KARO BIO

Press release

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SUCCESSFUL KB2115 PHASE II STUDY MEETS PRIMARY OBJECTIVES

The 12 week proof of concept phase II study with KB2115 in patients with dyslipidemia has been successfully completed. KB2115 is efficacious in LDL lowering and safe with respect to a broad range of parameters reflecting effects on heart, bone, muscle and thyroid function.

The thyroid hormone receptor (TR) is a key regulator of metabolic pathways and holds the promise of a new target for the treatment of dyslipidemia. KB2115 is an innovative and first in class liver selective agonist for the TR. Unlike the natural thyroid hormones, KB2115 is a liver selective TR agonist that can induce pharmacological effects in the liver, while a normal thyroid state is preserved in the rest of the body.

The completed 12 week, placebo controlled, double blind, randomised, clinical phase II study in 99 patients with high cholesterol levels was designed to explore whether a clinically relevant LDL-cholesterol lowering effect can be achieved without affecting the heart, bone, muscle and thyroid function.

The study demonstrated that a pronounced and clinically relevant lowering of LDL cholesterol can be obtained while preserving the thyroid homeostasis outside the liver and biomarkers for heart, bone, muscle and other organs were kept at normal levels. The mild increase in liver enzymes that was picked up in the previous 2-week phase I trial, was observed in this study as well, however, it seems to be a transient and benign effect. In addition to the positive result regarding efficacy and safety it was also shown that the enteric coating of KB2115 was effective in protecting the compound from chemical modification in the stomach.Thereby, a safety concern for longer exposure in man is removed.

The specific results from the KB2115 phase II study will be presented at upcoming international conferences during the year. The phase II program for KB2115 will continue with additional studies both in combination with statins, as well as in defined patient groups, to prepare for the phase III program.

“This is a break through for Karo Bio” says Per Olof Wallström, President of Karo Bio. “The major concerns around KB2115 have been adequately addressed and successfully resolved. The results are impressive and clear, KB2115 induces a significant lowering of LDL and the compound appears to be safe in a longer study. We strongly believe that KB2115 will be beneficial in the future treatment of dyslipidemia and that the compound may well be a candidate for use in a broader patient population”.

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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. Karo Bio has three clinical and four preclinical projects.

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 dislipidemia. 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 Stockholm Stock Exchange since 1998 (Reuters: KARO.ST).

This press release is also available online at: www.karobio.com and www.waymaker.net.