

## FIRST PATIENT INCLUDED IN PHASE III STUDY

STOCKHOLM, 4 October 2011 - The first patient has now been included in Karo Bio's phase III trial (the AKKA study) with eprotirome. A total of 630 patients with the hereditary condition HeFH will be studied for safety, and to confirm the beneficial effects on LDL-cholesterol that has been shown previously.

"The recruitment of the first patient to the Phase III study is an important milestone for Karo Bio. Strong Phase II data, collaborations with key opinion leaders and prominent specialist clinicians, provide excellent conditions. We look forward to carrying out the study as it is an important step towards the commercialization of eprotirome. It is our hope that a future product will help many people who, despite treatment, today suffer from high levels of cholesterol," says Per Bengtsson acting President of Karo Bio.

A total of 630 patients with the hereditary condition Heterozygous Familial Hypercholesterolemia (HeFH) will be included in the study. The purpose of the study is to determine safety and efficacy of eprotirome in long-term treatment of HeFH patients. The main study parameter of efficacy is reduction of LDL-cholesterol in the blood.

Patients with HeFH have difficulties metabolizing cholesterol. Cholesterol accumulates in blood vessels, and these patients have very high cholesterol levels, resulting in 11 times higher mortality in coronary heart disease. At least one in 500 people has the condition and current treatment options are inadequate. Around 70 per cent of patients fail to reach established treatment goals.

Karo Bio's study is led by Professor John J.P. Kastelein at Amsterdam Medical Center. Professor Kastelein has extensive experience in organizing and managing clinical trials in the cholesterol field and has paid particular interest to HeFH. The committee overseeing the study is supervised by one of the leading clinicians within cholesterol research in the US, Professor Steven E. Nissen at the Cleveland Clinic.

Karo Bio has in three clinical phase II trials, each with three months of treatment, showed that eprotirome effectively reduces LDL cholesterol and several other important risk factors for cardiovascular disease. Eprotirome's effects in these studies were shown to be additive and complementary to those with other lipid-lowering medications.

An interim analysis, which will assess preliminary efficacy of eprotirome, is planned for during the second quarter of 2012. This analysis, together with the ongoing monitoring of safety data, will provide further information regarding both safety and efficacy of eprotirome.

Karo Bio's goal is to complete the study so that a registration application may be submitted in the EU during 2014.

## For further information, please contact:

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## **About Karo Bio**

Karo Bio is a pharmaceutical company focused on the research and development of innovative drugs for large medical needs. The company runs a number of drug development projects within the indication areas cardiovascular and metabolic diseases, neuropsychiatry, inflammation, autoimmune diseases, cancer and women's health. An important foundation for the company's activities is its unique knowledge of nuclear receptors as target proteins for the development of novel pharmaceuticals, as well as related mechanisms of action. Karo Bio is based in Huddinge, Sweden, has around 70 employees and is listed on NASDAQ OMX Stockholm.

This information is such that Karo Bio is required to disclose under the Swedish Securities Market Act. The information was disclosed on October 4<sup>th</sup>, 2011, 13:30 CET.

This press release is also available online at <a href="www.karobio.se">www.newsroom.cision.com</a>