

## **KARO BIO REPORTS POSITIVE RESULTS FOR KB3305 IN DIABETES PATIENTS**

**Karo Bio's compound KB3305, a liver selective antagonist for the glucocorticoid receptor, shows clinically relevant and statistically significant effects on plasma glucose levels in type 2 diabetes patients.**

Karo Bio has concluded a clinical phase I program with the anti-diabetes compound KB3305. The program consists of three parts. The first part, where KB3305 was successfully given as increasing single doses to healthy volunteers, was reported in a press release on April 17, 2008.

Karo Bio has now completed the second and third parts which involved repeated dosing to healthy volunteers and repeated dosing in a group of type 2 diabetes patients, respectively.

In the second part of the phase I program, 24 healthy volunteers were treated with KB3305 at doses up to 450 mg per day for a period of five days. Tolerability and safety were satisfactory, and no serious adverse events were recorded. The pharmacokinetic profile of the compound was robust and predictable.

In the third part of the program, 14 patients with type 2 diabetes were treated with up to 450 mg KB3305 per day over a period of 14 days. A control group was given the corresponding placebo. The allocation to each treatment group was randomized and blinded. Since KB3305 is a first in class compound, the purpose of this study was to establish *proof of principle*, i.e. to investigate if KB3305 has clinically relevant effects on fasting plasma glucose levels in diabetes patients.

The results show a pronounced, clinically relevant, and statistically significant lowering of fasting plasma glucose levels (compared to baseline as well as against placebo) and also a statistically significant improvement in glucose tolerance tests. The side-effect profile was acceptable, and no serious adverse events were recorded.

Before initiation of phase II clinical trials, Karo Bio will evaluate all existing data and make a decision regarding the need for further optimization of the pharmaceutical formulation.

“KB3305 is a first in class compound, and with these results Karo Bio confirms its capability to develop innovative and efficacious treatment principles. The clinical results are consistent and pronounced, and offer an excellent basis for further clinical development”, says Per Olof Wallström, President of Karo Bio.

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**About KB3305 and type 2 diabetes**

*200 million people in the world suffer from type 2 diabetes and the incidence is increasing rapidly. By 2025 the number of people with type 2 diabetes is expected to be around 300 million. There are several oral medications on the market for diabetes treatment, but in spite of this, 60% of the patients do not reach the target levels for bloodglucose. Therefore, there is a great need for improved pharmaceuticals with new mechanisms of action. None of the existing treatments directly target the increased glucose production which is driven by the glucocorticoid hormonecortisol in the liver. KB3305 is a promising first in class liver selective glucocorticoid antagonist that has shown excellent efficacy and safety in several preclinical models for type 2 diabetes. KB3305 represents a novel treatment concept that was developed in collaboration with Professor Suad Efendić at the Karolinska Institute.*

**About Karo Bio**

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

*The company has a project portfolio with innovative molecules that primarily target cardiovascular, metabolic and inflammatory diseases as well as women's health. In these areas, there are significant market opportunities and a need for pharmaceuticals with new mechanisms of action. Karo Bio develops compounds aimed at treatment of broad patient populations up to clinical proof of concept before out-licensing. In therapeutic niche areas, Karo Bio has capacity to bring selected compounds into late stage clinical development and, potentially, to the market. 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 NASDAQ OMX Stockholm since 1998 (Reuters: KARO.ST).*

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