Press release

DICOT

Dicot initiates toxicology studies before applying for clinical trials

Press release: Uppsala, January 29, 2021. Potency agent drug developer Dicot launches a toxicology program for the drug candidate LIB-01. The program runs until the autumn and will form the basis for an application for clinical trials on humans.

In accordance with Dicot's development plan, the company will move on to toxicological studies that are expected to be completed in the autumn of 2021. It is toxicology that determines the extent of possible side effects in the body. The studies aim at evaluating the extent to which the active substance in the drug candidate LIB-01 (formerly Libiguin) is toxic to the user. Since all chemicals are considered to have a certain toxic effect if the dose is high enough, the study also establishes the maximum dose that can be used in future studies.

Dicot's toxicological program consists of one study in rodents and one in non-rodents, which is a requirement of the medical products agencies. Rat and dog are the most common animal models in this type of study.

The program began in December with a fourteen-day study - a so-called dose range finding study - in rats. Analysis of the results is currently underway. It will be followed by the same type of study in dogs, thereafter by experiments in both animal models with dosing for 28 days. The studies are carried out in collaboration with certified Clinical Research Organizations (CRO) with extensive experience of regulatory studies and accredited to perform these according to the standard Good Laboratory Practice.

Studies of a drug candidate's toxicity constitute a necessary and important part of the authorities' assessment prior to clinical trials and will form the basis for Dicot's application to perform clinical trials in healthy volunteers.

"*In early preclinical studies, we have noted that side effects appear to be very limited. My hope is that the results from our toxicological program will provide answers that confirm this* ", Göran Beijer, CEO of Dicot, comments.

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About Dicot AB
Dicot is developing the drug candidate LIB-01 (formerly Libiguin), which will be a potency agent to better treat erectile dysfunction and premature ejaculation. The ambition is to create a drug with significantly longer effect and far fewer side effects, compared to those on the market. Today, at least 500 million men suffer from these sexual dysfunctions and the market is valued at SEK 50 billion.

Research and development is conducted under own auspices up to phase 1 studies. Thereafter, Dicot's intention is to form strategic alliances, or alternatively carry out a trade sale, with larger, established pharmaceutical companies to be able to introduce LIB-01 on the world market.

Dicot is listed on Spotlight Stock Market and has approximately 1,800 shareholders. For more information, please visit: www.dicot.se