DICOT

Good safety and improved erectile function reported from Dicot’s phase 1 study

Press release: Uppsala, April 23, 2024. Dicot's completed phase 1 clinical study demonstrates that the company's drug candidate LIB-01 has a very good safety profile, which was the primary objective of the study. In addition to this, the company can deduce an efficacy signal from the study where participants reported an improved erectile function, in some cases beyond 28 days post first dose.

The primary objective of Dicot's phase 1 study has been to investigate the safety profile in humans for LIB-01, the company’s drug candidate for treatment of erectile dysfunction. In January, Dicot reported good results from the first part where participants received single dosing (a so-called SAD study). Dicot has now locked the database for the final part of the study where the participants were given repeated dosing (a so-called MAD study).

Based on today's readout of data, the company can now announce that LIB-01 demonstrated a very good safety profile. No serious adverse effects occurred and there were no dropouts due to adverse events. Only occasional and mild adverse effects were reported in participants receiving LIB-01.

Dicot can also see an efficacy signal from the MAD part, in which 24 otherwise healthy men with erectile dysfunction participated and were dosed for three days. An improvement in erectile function has been reported, which was captured by subjective self-report questionnaires and supported by objective measurements using a RigiScan® device. Participants also reported that the improved erectile function lasted for a long time, in some cases the effect remained at the end of the study, i.e., 28 days post first dose.

Later in the second quarter, Dicot will be able to provide an in-depth summary of results where the above results will be presented in more detail.

The exploratory efficacy measurements will provide important data for the design of the company's planned phase 2a study. The efficacy signal that Dicot has noted must be confirmed in a clinical phase 2a study to provide a definitive "proof-of-concept", i.e. a statistically significant result from a larger group of participants. The study is planned to start in the second half of 2024.

”*I am very impressed with Dicot’s Phase 1 study results. The safety data of LIB-01 look very good, which is crucial for a drug for erectile dysfunction (ED). And the fact that the effect in some cases lasted at least four weeks after a 3-day treatment is unique and has never been reported for an ED drug*”, comments Professor François Giuliano, urologist and specialist in male sexual dysfunction, past-president of the European Society of Sexual Medicine.

“*It has been 26 years since a new class of oral ED therapy was approved. LIB-01 appears to have the potential to positioning as a new first-line oral treatment. These results point to excellent safety and early indications of prolonged effect on restoring erectile function*”, comments Harin Padma-Nathan, MD, past-Professor of Urology, University of Southern California, Principal Investigator for Viagra and Cialis.

"*Our goal has always been to develop a completely new generation of potency drugs with a long duration of action and without any disturbing side effects. These results clearly demonstrate that we are moving towards that goal, which would make a big difference for affected men and couples. This is a very big day for Dicot*", comments Dicot CEO Elin Trampe.

This disclosure contains information that Dicot AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on April 23, 2024, at 18.10 CET.

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About Dicot AB

Dicot is developing the drug candidate LIB-01, 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 current available drugs. Today, over 500 million men suffer from these sexual dysfunctions and the market is valued at USD 8 billion. Dicot's strategy is to develop LIB-01 under own auspices until phase 2a studies and thereafter in partnership with larger, established pharmaceutical companies, finance and develop LIB-01 further to a registered pharmaceutical on the world market.

Dicot is listed on Spotlight Stock Market and has approximately 5,500 shareholders. For more information, please visit www.dicot.se.