

## Dicot Pharma Announces Positive Results from its Phase 2a Study

Uppsala, Sweden October 23, 2025. Today, Dicot Pharma announces positive topline results from its phase 2a study of LIB-01 for the treatment of erectile dysfunction. The outcomes demonstrated clinically meaningful improvements in erectile function at week 4, following a single 3-day oral treatment with LIB-01. Furthermore, the effect was sustained at week 8 and showed statistical significance in one of the pre-specified subgroups. Treatment with LIB-01 remained well tolerated. Based on the results, Dicot Pharma will now proceed with the development of LIB-01 according to plan with initiation of a phase 2b study during 2026.

Dicot Pharma's phase 2a study (NCT06703840) aimed to investigate the efficacy and safety of the drug candidate LIB-01 for treatment of erectile dysfunction (ED). The double-blind, placebo-controlled study included 156 men, ages 26 to 65, with mild to moderate ED, classified as 11–25 on the regulatory and clinically relevant International Index of Erectile Function - Erectile Function domain score (IIEF-EF). The trial evaluated LIB-01 at three different doses, 10 mg, 25 mg, and 50 mg. Participants were assessed at four and eight weeks to evaluate the effect of LIB-01.

The primary objective of the phase 2a study was to evaluate the change in erectile function by IIEF-EF domain assessment at week 4 following an initial three-day oral dosing versus placebo. A pre-specified subgroup analysis for the primary endpoint based on ED severity (baseline IIEF-EF score 11-17 [moderate ED] and 18-25 [mild or mild to moderate ED]) was included.

There was no relevant difference in baseline characteristics between the different treatment arms and placebo.

The pre-defined pooled subgroup of the 25 mg + 50 mg doses at 8-weeks showed a **statistically significant improvement versus placebo** (p=0.03), which will help form the basis for the design of the planned phase 2b clinical trial.

### *Results overview at week 4*

- **An improvement in erectile function was seen in all LIB-01 treatment groups**, with the 50 mg group demonstrating a 4-point shift from baseline (p=0.0002 vs baseline, p=0.34 vs placebo). This represents a **clinically meaningful improvement** (a minimum 2-points shift from baseline for this severity group).

- In the subgroup analyses, a strong effect was seen in patients with more pronounced ED (IIEF-EF 11-17 at baseline). **A clinically meaningful improvement** was seen in the two higher dose groups, with the 50 mg group demonstrating a shift from baseline of 8.5 (p=0.008 vs baseline, p=0.11 vs placebo), which is considerably greater than the minimum 5-point shift required for this severity group. Additionally, 31% of patients were **complete responders** (meaning these patients reached an IIEF-EF score >25), compared to 0% in the placebo group (p=0.04 vs placebo). A **clear dose-response relationship** could also be seen in this severity group.
- In patients with less pronounced ED (IIEF-EF 18-25 at baseline), **a clinically meaningful improvement was seen in the two higher dose groups** with shifts from baseline of 4 points, which is greater than the required minimum 2-point shift for this severity group.

#### *Results overview at week 8*

- The effect of LIB-01 was sustained over the entire study period of eight weeks in the two higher dose groups, where **a clinically meaningful improvement remained regardless of the severity of ED**. At week 8, patients with more severe ED demonstrated a shift from baseline of 7.5 points for the 50 mg group (p=0.03 vs baseline, p=0.06 vs placebo). Pooling of the 25 mg and 50 mg groups demonstrated a **statistically significant improvement vs placebo** (p=0.03) of 6.5 points from baseline.

**LIB-01 was well tolerated at all dose levels.** Adverse events (AEs) were few, mainly mild, transient, and occurred during the initial days following LIB-01 administration. The most common AE was gastrointestinal (GI) upset, which was mild and self-limited.

#### *Conclusion*

LIB-01 at 25 mg and 50 mg showed clinically meaningful improvements in erectile function, as measured by the EF domain of the IIEF, at 4 weeks following a single 3-day oral treatment. This was consistent in the full study population, as well as the subgroups. Notably, the magnitude of improvement and the dose-response relationship seen in the group with moderate ED demonstrated a clear pharmacological effect of LIB-01. Moreover, the pro-erectile effect of LIB-01 showed a maximum during the first four weeks and was sustained over the entire study period of eight weeks, whereas the pronounced placebo effect tapers off. Taken together, these results point towards a monthly dosing interval of LIB-01 going forward. Treatment with LIB-01 was well tolerated at all dose levels.

Dicot Pharma will now proceed with the development of LIB-01 according to plan with initiation of a phase 2b study during 2026.

*“At a time when the medical community is awaiting therapeutic innovations for erectile dysfunction, these phase 2a study results are highly encouraging, particularly demonstrating a clear dose-response relationship, a sustained duration of action, and a favorable safety profile. Equally reassuring for the continued development of LIB-01 is the remarkable consistency of the data observed from the preclinical stage through phase 1, now reinforced by these latest results,”* comments Professor Francois Giuliano, Medical Expert in the phase 2a trial and international medical expert in the field of sexual dysfunctions.

*“Looking at the potential implications and impact of LIB-01, there is now even greater evidence that this molecule may dramatically change first-line therapy with the possibility of infrequent dosing, long duration of efficacy and normalization of erectile function, thus obviating the need for on-demand or daily dosing therapy,”* comments Dr Harin Padma-Nathan, international medical expert in erectile dysfunction, Principal Investigator for Viagra and Cialis.

*“We are very satisfied with these results, and I wish to thank everyone who has been involved. The outcome clearly demonstrates LIB-01’s unique long-term effect with the potential to help millions of affected men and couples normalizing their sex life. We are now well positioned to take the next step in the journey to further develop and optimize LIB-01 into a new first-in-class treatment for ED,”* comments Dicot Pharma’s CEO Elin Trampe.

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**About Dicot Pharma AB**

Dicot Pharma 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 Pharma's business model involves evaluating industrial and financial partnerships during clinical development to bring LIB-01 to commercialization on the world market.

Dicot Pharma is listed on Nasdaq First North and has approximately 16,300 shareholders. FNCA Sweden AB is appointed Certified Adviser. For more information, please visit [www.dicotpharma.com](http://www.dicotpharma.com).

*This is a translation from the Swedish original. In case of differences between versions, the Swedish version prevails.*

*This information is information that Dicot Pharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-10-23 07:15 CEST.*