PRESS RELEASE
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Dicot Pharma submits an IND application to the FDA

Uppsala, Sweden, May 25, 2026. Dicot Pharma AB announces that the company has submitted an IND application (Investigational New Drug Application) to the US Food and Drug Administration, FDA, ahead of the planned phase 2b study of the drug candidate LIB-01, developed for erectile dysfunction. The study aims to evaluate the efficacy of LIB-01 with repeated dosing and provide a basis for dose selection ahead of phase 3.

Dicot Pharma is developing the drug candidate LIB-01, which has the potential to become a completely new treatment concept for erectile dysfunction. The company has previously announced its intention to initiate a clinical phase 2b study in the second half of 2026. The study is planned to be conducted at several centers in the US and Europe.

Today, Dicot Pharma announces that an IND application has been submitted to the FDA to obtain approval for a study in the US. The FDA now has up to 30 days to raise any questions about the study design. During this period, Dicot Pharma is ready to address potential questions and make necessary adjustments. In parallel, the company is preparing a corresponding application to regulatory authorities in Europe.

The planned phase 2b study builds on the results of Dicot Pharma's phase 2a study, which showed clinically relevant, long-acting treatment effects of LIB-01. The phase 2b study aims to evaluate the effect of LIB-01 after repeated dosing and provide a basis for dose selection for phase 3. The company intends to use an adaptive study design, where the number of participants is at least 200, with the possibility of adjusting the number of patients during the course of the study to optimize the conditions for obtaining the highest possible scientific quality in the data and thus the outcome of the study. All severity levels of erectile dysfunction will be studied and three dose levels of LIB-01 are planned to be included.

"*We have focused on developing a study design that creates the best possible settings for phase 3. The submission of the IND application is an important milestone in our development and the first concrete step into the US market. Our long-term goal is for LIB-01 to become the next generation of drugs with the ability to help millions of men and couples normalize their sexual life,"* says Elin Trampe, CEO of Dicot Pharma.

For further information, please contact:
Elin Trampe, CEO
Phone: +46 72 502 10 10
E-mail: **elin.trampe@dicotpharma.com**

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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 16,750 shareholders. FNCA Sweden AB is appointed Certified Adviser. For more information, please visit **www.dicotpharma.com**.

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