PRESS RELEASE
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Dicot Pharma receives FDA clearance to initiate the first part of the Phase 2b study with LIB-01 in the U.S.

Uppsala, Sweden, June 25, 2026. Dicot Pharma AB announces that the company has received clearance from the U.S. Food and Drug Administration (FDA) to initiate the first part (Part I) of the Phase 2b study with its drug candidate LIB-01. Part I will establish the highest dose to be evaluated in the study's efficacy portion (Part II). To initiate Part II of the study in the U.S., additional toxicology data are required. Therefore, Dicot Pharma will bring forward an already planned preclinical study. An application to commence the study in Europe will be submitted to the relevant regulatory authorities in the third quarter. The study is expected to start in the second half of 2026, in line with the previously communicated timeline. LIB-01 is being developed to become an entirely new treatment concept for erectile dysfunction.

Dicot Pharma announced in May that it had submitted an Investigational New Drug Application (IND) to the FDA for the planned Phase 2b study of its drug candidate, LIB-01. The company can today announce that the FDA has reviewed the quality of all documentation in the application and has granted clearance to initiate the first part of the study (Part I) in the U.S., thereby activating the IND.

The placebo-controlled, randomized Phase 2b study with LIB-01 builds on the results of Dicot Pharma's Phase 2a study, which demonstrated clinically relevant and long-lasting treatment effects, and aims to provide guiding data for dose selection ahead of Phase 3. All severity levels of erectile dysfunction will be studied, and three dose levels of LIB-01 are planned to be included: 25 mg and 50 mg, which demonstrated proof of concept in Phase 2a, as well as a higher dose. Higher doses have already demonstrated a favorable safety and tolerability profile following single-dose administration in a previous Phase 1 study but need to be qualified for repeated dosing, which will be addressed in Part I of the Phase 2b study.

The FDA has raised no questions regarding the extensive preclinical and clinical safety documentation for LIB-01 submitted by Dicot Pharma in its IND application, but requests data from a 3-month preclinical toxicology study before granting clearance to initiate Part II of the Phase 2b study in the U.S. The company is therefore bringing forward this already planned study.

Preparations for an application to initiate the Phase 2b study in Europe are underway, and Dicot Pharma plans to submit it in the third quarter of 2026.

"It is an important milestone and a mark of quality for our development work that the FDA, following its review of our IND application, has granted clearance to initiate the first step of the Phase 2b study of LIB-01. We are now continuing our work to apply for study initiation in Europe," says Elin Trampe, CEO of Dicot Pharma.

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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.