

Dicot Pharma submits CTA for phase 2b study in EU

Uppsala, Sweden, August 17, 2026. Dicot Pharma AB announces that the company has submitted a Clinical Trial Application (CTA) in EU for the phase 2b study of the drug candidate LIB-01, to be conducted in the United States and Europe. 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. As previously announced, in June 2026 the company received clearance from the FDA to initiate the first part of the phase 2b study in the United States, with study initiation planned for the second half of 2026. As the study is planned to be conducted in both the United States and Europe, the corresponding application to initiate the study has now been submitted in the EU. A decision is expected in the fourth quarter of 2026.

The phase 2b study is designed to evaluate the efficacy of LIB-01 with repeated dosing and generate data to support dose selection for phase 3. The company plans to use an adaptive study design enrolling at least 200 participants, including patients with all degrees of erectile dysfunction severity.

“We are making solid progress with the preparations for the phase 2b study and remain on track with our plans. Submitting the application in the EU marks an important milestone, and we look forward to advancing the study in both the United States and Europe,” 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

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 17,450 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.