Dicot Pharma has successfully completed a pre-IND meeting with FDA

Uppsala, Sweden, July 2, 2024. Dicot Pharma AB today announced that the company has held a pre-IND meeting with the US Food and Drug Administration (FDA) and received positive feedback on the development program for the drug candidate LIB-01. This is considered a validation of the quality of the program and is an important step towards an application to include US study centers in future clinical studies and to ensure that the current development plan meets the regulatory requirements for future market approval in the US.

Dicot Pharma has recently had its first formal interaction with the US Food and Drug Administration (FDA) via a pre-IND meeting where the agency gave its feedback in writing. An early interaction with FDA is considered valuable to reach a consensus on the structure and objectives of a development program and ultimately secure market approval in the United States. A pre-IND meeting precedes the opening of an Investigational New Drug (IND) application in the United States, which is required to be able to include US study centers in future clinical studies.

The main purpose of the meeting was to obtain the Agency's views on the overall development program for LIB-01 in general and the upcoming Phase 2a study in particular. Based on the submitted background material, the FDA provided its views on study design, preclinical development, chemistry, manufacturing, and quality controls. In essence, the company considers that the agency's feedback was positive and helps to ensure that the development program meets the regulatory requirements for the US market.

"*The FDA's response shows that we are on the right track in our efforts to create a best-in-class drug in erectile dysfunction. It is also a quality mark for our development work that adds weight in discussions with potential pharmaceutical partners*", comments Elin Trampe, CEO of Dicot Pharma AB.

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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's strategy is to develop LIB-01 under own auspices until phase 2a study

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 5,700 shareholders. For more information, please visit www.dicotpharma.com.