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Freya Pharma Solutions Announces Launch of Phase II Clinical Dose-Response Study testing its Lybrido™ Concept Targeting Female Sexual Dysfunction

- Study evaluates Lybrido™'s Dual-Action therapy for Female Sexual Dysfunction
- Innovative clitoral blood flow measurement technique aims to objectively quantify treatment efficacy of two dose-combinations
- ALETTA Pivotal Study prepared for Late 2025 launch in Europe amid significant unmet medical need

Amsterdam, the Netherlands, 4 August 2025 - Freya Pharma Solutions, a pharmaceutical company specializing in innovative therapies for women diagnosed with Female Sexual Disorders (FSD), today announced the initation of a Phase II clinical study evaluating its Lybrido™ concept. The study will investigate two dose-combinations of testosterone and sildenafil, assessing their effects on female sexual response through physiological measurements of genital blood flow parameters.

This investigator-initiated clinical study, designed and led by Princial Investigator **Prof. Cobi Reisman**, (urologist, sexologist), and Co-Investigator **Dr. Anna Padoa** (gynecologist), will be conducted at the Chaim Sheba Medical Center. The study aims to assess objective physiological measurements of arousal response in premenopausal women diagnosed with acquired generalized Female Sexual Interest/Arousal Disorder (FSIAD) following treatment with combined sublingual testosterone and oral sildenafil therapy. Clitoral blood flow parameters – a key biomarker of genital arousal - will be quantified using standardized Clitoral Doppler Duplex Ultrasound imaging.

Prof. Cobi Reisman, MD, PhD, FCESM,ECPS said:

> *"Combination therapy of sublingual testosterone and oral sildenafil is reported as a potentially effective and safe treatment option for premenopausal women with FSIAD. We are very interested in this promising treatment modality, and aim to better understand the mechanisms behind the clinical observations reported sofar. Sexual function is frequently measured with validated and standardized questionnaires to determine the subjective sexual response, whereas objective measures warrant physical measurement. In this regard, clitoral vascularization is reported as a relevant physiological indicator of the female genital arousal response. In our study we will use Clitoral Doppler Duplex Ultrasound which is a promising technique to assess clitoral blood flow in women."*

Dr. Jan van der Mooren, Chief Medical Officer at Freya Pharma Solutions commented:

> *"The combination of sublingual testosterone and oral sildenafil being studied by Prof. Reisman and Dr. Padoa closely mirrors the mechanism of action of Lybrido™, our investigational product*

for women diagnosed with FSIAD. This research aligns with Freya Pharma's commitment to advancing science in this field, and we're proud to support a study that could deepen our understanding of Lybrido™'s therapeutic potential. Concurrently, Freya Pharma Solutions is finalizing preparations for the ALETTA clinical study - a pivotal clinical study as part of Lybrido™'s European clinical development program. Enrollment is slated to begin in late 2025 across 20 European research sites in five countries."

About Female Sexual Disorders

Among female sexual disorders (FSD), representing a significant health concern, low sexual desire consistently is reported as the most common issue affecting women. This widespread challenge often leads to clinically significant distress, dissatisfaction in intimate relationships, profoundly impacting emotional well-being and social connections.

In the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), Female Sexual Interest/Arousal Disorder (FSIAD) combines persistent reductions in both sexual interest and/or arousal, requiring symptoms to persist for six months, while causing clinically significant distress. Clinicians diagnose FSIAD through specific symptom thresholds and further categorize it by severity (mild, moderate, or severe) and subtype: lifelong versus acquired, and generalized versus situational presentations. FSIAD is the clustering of Hypoactive Sexual Desire Disorder and Female Sexual Arousal Disorder; listed in the World Health Organization's International Classification of Diseases, 11th Revision (ICD-11) under Code 17 HA00/HA01.0 Hypoactive Sexual Desire Dysfunction and Female Sexual Arousal Dysfunction (https://icd.who.int/).

About Lybrido™

A total of 20 phase I and phase IIa trials, and large-scale phase IIb trials in 17 research sites in the US have been conducted to date. These trials have investigated the efficacy and safety of two novel on-demand pharmacological treatments that have been designed to treat FSIAD, Lybrido™ and Lybridos™. Lybrido™ increases central sexual motivation and physiological sexual responses, such as swelling of genitals and lubrication. The therapy can be taken 'on-demand' and helps to increase central sexual motivation from 3 to 6 hours after intake. This treatment consists of a novel (dual-route, dual-release, fixed-dose) combination tablet, consisting of a testosterone coating for sublingual administration and an inner-core component containing the phosphodiesterase type 5 (PDE 5) inhibitor, sildenafil. The inner-core component is coated with a delayed-immediate-release matrix to ensure that the peak plasma concentration of the PDE 5 inhibitor coincides with the window of increased sexual motivation induced by the sublingually administered testosterone. Thus, this combination enables an increase in genital arousal through an increase in responsivity to sexual stimuli.

About Freya Pharma Solutions

Freya Pharma Solutions is a pharmaceutical company, focused on developing effective pharmaceutical therapies for FSIAD/HSDD, building upon fifteen years of solid research. The company's core asset under development is Lybrido™, designed to address FSIAD/HSDD. Based in Amsterdam, The Netherlands, Freya Pharma Solutions aims to offer patients a convenient, personalized 'on-demand' solution for this recognized unmet medical need.

For further information please contact:

Freya Pharma Solutions, Amsterdam
Marcel Wijma, Chief Business Officer
marcel@freyapharmasolutions.com

For media
LifeSpring Life Sciences Communication, Amsterdam
Leon Melens
T: +31 6 538 16 427
E: lmelens@lifespring.nl