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(160) THE ALETTA CLINICAL STUDY: DESIGN OF A RANDOMIZED DOUBLE-BLIND PLACEBO-CONTROLLED STUDY INVESTIGATING THE EFFICACY AND SAFETY OF LYBRIDO™ IN PREMENOPAUSAL WOMEN WITH ACQUIRED FSIAD

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Objectives: Low sexual desire is the most common sexual complaint in women. As a result, many women suffer from sexual dissatisfaction and related distress which often negatively interferes with their quality of life. Currently, limited drug treatments are available globally to treat women with Female Sexual Interest & Arousal Disorder (FSIAD). As a result, there is an unmet need, and relevance to develop a drug treatment for women with sexual dysfunction. Lybrido™ (Freya Pharma Solutions, Amsterdam, the Netherlands) is a novel on-demand dual route/dual release fixed dose combination tablet of sublingual testosterone and oral sildenafil. It has shown a promising efficacy and safety profile in Phase 2 and is ready for Phase 3 testing.
Methods: Design: A double-blind, randomized, placebo-controlled, 3-arm, 6-month study to evaluate the efficacy and safety of Lybrido™ in premenopausal women with acquired FSIAD. **Study Population:** European premenopausal women, at least 18 years of age, with a clinical diagnosis of acquired FSIAD. **Interventions:** The study drug is a fixed-dose combination tablet consisting of an inner core containing sildenafil with an outer delayed immediate release coating and an additional outer film coating containing testosterone. Two dose strengths will be evaluated and compared with placebo.
Results: Outcome Measures: Primary endpoint: change from baseline to Week 24 Female Sexual Function Index Desire Domain (FSFI-D) (Items 1 and 2). Secondary efficacy endpoints: Female Sexual Distress Scale-Desire/Arousal/Orgasm (FSDS-DAO) score; Elements of Desire Questionnaire (EDQ) 'event-based'; FSFI Arousal Domain (FSFI-A); FSFI total score; FSDS-DOA total score; Sexual Satisfaction of an Event Questionnaire (SSEQ), reported within 24 hours; Patient Global Impression of Improvement (PGI-I) Scale; Patient Global Impression of

Severity (PGI-S) Scale; and total number of sexual events. Safety outcomes: frequency of (serious) adverse events.

Conclusions: Study Planning: First Patient In: Q2 2023; Interim Analysis: Q4 2023; Last Patient Out: Q2 2024.

Conflicts of Interest: Study supported by Freya Pharma Solution.