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Arletta Pharma Solutions Announces Positive Results from Phase II Clitoral Doppler Duplex Ultrasound Study of Lybrido™ Combination Targeting Female Sexual Dysfunction

More than 60% average improvement in clitoral blood flow observed with both dose-combinations

- Statistical significance achieved with new high dose-combination despite small sample size
- Results validate dose selection and de-risk pivotal trial in US and Europe clinical development program

Amsterdam, the Netherlands, March 27, 2026 – Arletta Pharma Solutions, a pharmaceutical company specializing in innovative therapies for women diagnosed with Female Sexual Disorders (FSD), today announced highly compelling positive results from its Phase II Clitoral Doppler Duplex Ultrasound (CDU) study evaluating the Lybrido™ combination of testosterone and sildenafil in women with Female Sexual Interest/Arousal Disorder (FSIAD). The study successfully achieved its primary endpoint, demonstrating objective physiological evidence of arousal response to combination therapy and confirming optimal dose selection for the continuation of the clinical program.

This investigator-initiated study, conducted at Chaim Sheba Medical Center and led by Principal Investigator Prof. Cobi Reisman (urologist, sexologist) and Co-Investigator Dr. Anna Padoa (gynecologist), evaluated two dose-combinations of Lybrido™ in premenopausal women diagnosed with acquired generalized FSIAD. The study utilized standardized Clitoral Doppler Duplex Ultrasound to quantify clitoral blood flow parameters, a key biomarker of genital arousal.

Study Highlights and Clinical Relevance

The study results demonstrate compelling objective evidence of Lybrido™'s dual mechanism of action:

- **First-time achievement:** This marks the first time objective biomarker data have been measured with the high dose-combination (Testosterone 1.0 mg + Sildenafil 100 mg) in women with FSIAD, representing a significant milestone in female sexual health research.
- **Robust efficacy signal:** Both dose-combinations showed more than 60% average improvement in Peak Systolic Velocity (PSV), the primary measure of clitoral blood flow.

- **Statistical significance:** The high-dose combination (Testosterone 1.0 mg + Sildenafil 100 mg) achieved statistical significance (p=0.008), demonstrating a clear and consistent physiological arousal response despite the relatively small sample size.
- **Mechanism validation:** Results are entirely consistent with Lybrido™'s known mechanism of action regarding the phosphodiesterase 5 (PDE5) inhibition's enhancement of genital blood flow.
- **Dose confirmation:** The study successfully validates the dose selection for upcoming study/studies, substantially reducing development risk.

Nicole Hijnen, Chief Executive Officer of Arletta Pharma Solutions, said: "These results represent a watershed moment for Arletta Pharma's clinical development program. For the first time, we have objective biomarker evidence demonstrating that our high-dose Lybrido™ formulation produces statistically significant physiological arousal responses in women with FSIAD, even with a small sample size. This study confirms our dose selection and validates our approach. Combined with our expanding patent portfolio and constructive FDA dialogue, we are well-positioned to move forward with our clinical development program."

Prof. Cobi Reisman, MD, PhD, FECSM, ECPS, Principal Investigator, commented: "The CDU study results offer physiological evidence suggesting that combination therapy with sublingual testosterone and oral sildenafil may produce notable improvements in clitoral blood flow, which can serve as an indicator of genital arousal capacity. The fact that statistical significance was reached with the high dose-combination, even with a relatively small sample size, points to a potentially consistent treatment effect. The alignment of these objective findings with previously reported improvements in patient-reported outcomes adds to the growing evidence for this therapeutic approach and its possible role in addressing an important unmet need."

Study Design and Results

The randomized, open-label Phase II dose-response study enrolled 16 premenopausal women with acquired generalized FSIAD. Participants were randomized to receive either the standard dose-combination or the high dose-combination of Testosterone + Sildenafil. The primary outcome measure was change from baseline in Peak Systolic Velocity (PSV) of clitoral blood flow measured by Clitoral Doppler Duplex Ultrasound.

Conclusions: Results Conform to Expectations

The study's conclusions confirm the therapeutic hypothesis and support advancement of the clinical program:

- More than 60% average improvement in clitoral blood flow (PSV) with both dose-combinations
- Statistical significance achieved for the high dose-combination
- Demonstrates objective physiological arousal response to combination therapy
- Consistent with mechanism of action (Testosterone + PDE5 inhibition)
- Confirms dose selection for pivotal program

Earlier studies have already demonstrated that combination therapy is required to achieve the desired therapeutic effect. Previous research by van der Made, Bloemers et al. (2009) established that testosterone enhances the effect of PDE-5 inhibitors on genital blood flow in women with Hypoactive Sexual Desire Disorder (HSDD), with combination therapy showing significantly superior results compared to either component alone ($p<0.03$)[1].

Potential US Phase II Study to Complement Clinical Development Program

In parallel with the planned pivotal study in Europe, Arletta Pharma is evaluating the initiation of a smaller Phase II study in the United States, focusing on the highest Lybrido™ dose-combination identified in the CDU study (1.0 mg Testosterone / 100 mg Sildenafil). Depending on timing and resources, these two studies may be initiated sequentially or in overlapping fashion, with the US Phase II trial designed to further characterize the efficacy and safety profile of the high-dose regimen in the target population of women suffering from FSIAD. Together, the pivotal program and the potential US Phase II study are intended to maximize the clinical and strategic value of Lybrido™'s development, supporting optimal value creation for patients and stakeholders.

About Female Sexual Interest/Arousal Disorder (FSIAD)

Among female sexual disorders (FSD), low sexual desire and arousal consistently represent the most common issues affecting women, often leading to clinically significant distress, dissatisfaction in intimate relationships, and profoundly impacting emotional well-being and quality of life.

Female Sexual Interest/Arousal Disorder (FSIAD), as defined in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), is characterized by persistent reductions in both sexual interest and/or arousal. FSIAD is diagnosed when symptoms persist for a minimum of six months and cause clinically significant distress.

FSIAD represents the clustering of Hypoactive Sexual Desire Disorder and Female Sexual Arousal Disorder, which are listed in the World Health Organization's International Classification of Diseases, 11th Revision (ICD-11) under Code HA00/HA01.0. An estimated 8% of adult women meet diagnostic criteria for FSIAD, representing approximately 250 million women worldwide, an enormous unmet medical need.

About Lybrido™

Lybrido™ is an investigational on-demand, dual-action therapy designed to address both the psychological and physiological components of Female Sexual Interest/Arousal Disorder (FSIAD) and Hypoactive Sexual Desire Disorder (HSDD). The treatment consists of a novel dual-route, dual-release, fixed dose-combination tablet with a testosterone coating for sublingual administration and an inner-core component containing the PDE5 inhibitor sildenafil.

Lybrido™'s proprietary delayed-immediate-release formulation ensures that peak plasma concentration of sildenafil coincides with the window of increased sexual motivation induced by sublingually administered testosterone. This synchronized dual mechanism enables increased genital arousal through enhanced responsivity to sexual stimuli, with effects lasting 3 to 6 hours after intake. The on-demand administration provides women with control over their treatment.

To date, Lybrido™ has been investigated in 20 Phase I and Phase IIa trials, plus large-scale Phase IIb trials conducted across 17 US research sites, establishing a substantial safety and efficacy database. The therapy addresses both central sexual motivation (desire) and peripheral genital arousal, representing a differentiated mechanism of action compared to currently available treatments.

About Arletta Pharma Solutions

Arletta Pharma Solutions is a pharmaceutical company, previously known as Freya Pharma Solutions, focused on developing effective pharmaceutical therapies for FSIAD/HSDD, building upon more than fifteen years of rigorous scientific research. The company's core asset under development is Lybrido™, designed to address FSIAD/HSDD through an innovative on-demand dual-action mechanism that targets both psychological and physiological components of female sexual dysfunction.

Based in Amsterdam, The Netherlands, Arletta Pharma Solutions aims to offer patients a convenient, personalized on-demand solution for this recognized unmet medical need affecting millions of women worldwide. The company's name, derived from a rare butterfly species, symbolizes transformation, beauty, and freedom, concepts that resonate deeply with women's healthcare and the company's mission to empower women to take control of their sexual health.

References

[1] van der Made F, Bloemers J, et al. (2009). The influence of testosterone combined with a PDE5-inhibitor on cognitive, affective, and physiological sexual functioning in women suffering from sexual dysfunction. *Journal of Sexual Medicine*, 6(3), 429-439. https://doi.org/10.1111/j.1743-6109.2008.01142.x

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This press release contains forward-looking statements regarding Arletta Pharma Solutions' clinical development plans, regulatory strategy, and commercial potential. Actual results may differ materially from those projected. Lybrido™ is an investigational product that has not been approved by any regulatory authority.