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Arletta Pharma Solutions Receives FDA Response Supporting the Clinical Development Program of Lybrido™ for Female Sexual Interest/Arousal Disorder in the US

FDA endorses key elements of the proposed Phase 2 dose-ranging study and openness to a single pivotal Phase 3 study to support a future NDA

Amsterdam, the Netherlands, 16 July 2026 — Arletta Pharma Solutions, a clinical-stage biopharmaceutical company dedicated to developing innovative therapies for women diagnosed with Female Sexual Disorders (FSD), today announced that the United States (US) Food and Drug Administration (FDA) has provided a response to the Company's Type C meeting request regarding the US clinical development program of Lybrido™, its lead investigational therapy for Female Sexual Interest/Arousal Disorder (FSIAD) and Hypoactive Sexual Desire Disorder (HSDD). In its response, the FDA endorsed core elements of Arletta's proposed Phase 2 MONARCH study and expressed openness to a streamlined path toward a future New Drug Application (NDA), providing the Company with a clear and constructive framework to advance Lybrido™ in the United States.

In its written response, the FDA confirmed that the proposed doses and treatment duration for the planned Phase 2 dose-ranging MONARCH study (FPS203) *appear reasonable*, and that a single primary endpoint focused on sexual desire is *acceptable*. The Agency also expressed openness to Arletta Pharma's strategy of relying on a single pivotal Phase 3 study in the United States to support a future New Drug Application (NDA), in combination with confirmatory evidence from the Company's broader development program.

As is customary at this stage of development, the FDA also identified a number of areas where refinements to the program are requested, including elements of the study design, statistical approach, and safety characterization. Arletta Pharma considers these observations constructive and consistent with the Company's expectations, and will address them adequately in the finalization of the US development plan in close dialogue with the Agency.

The FDA's response follows a comprehensive Type C meeting package submitted by Arletta and reflects continued engagement between the Company and the Agency's Division of Urology, Obstetrics, and Gynecology. The response provides a clear framework for advancing Lybrido™ through Phase 2 and toward pivotal development in the United States.

The positive tone of the feedback also comes at a time when the FDA has shown increasing openness toward the use of hormone therapy and testosterone in women, an evolution that supports Arletta Pharma's dual-action approach. Combined with the recently reported positive Phase II Clitoral Doppler Duplex Ultrasound (CDU) results for Lybrido™, the company believes it is well positioned to advance its US program with confidence.

> *"The FDA's feedback represents a significant validation of our development strategy and an important step forward for Arletta Pharma. The Agency's endorsement of key aspects of our proposed Phase 2 MONARCH study, combined with its openness to a streamlined path to NDA submission based on a single pivotal Phase 3 trial, provides a clear framework for our U.S. development program. Alongside the encouraging Phase II CDU results and the evolving regulatory landscape supporting testosterone-based therapies for women, we believe we are well positioned to advance this promising treatment option for women with FSD. We remain committed to working closely with the FDA and look forward to continuing our constructive engagement as we move toward the next phase of development."*
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> **— Steve van Os, Chief Medical Officer, Arletta Pharma Solutions**

The Company is currently finalizing preparations for the said Phase 2 study.

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 is designed so that the peak plasma concentration of sildenafil coincides with the window of increased sexual motivation induced by sublingually administered testosterone, with effects lasting 3 to 6 hours after intake. To date, Lybrido™ has been investigated in 20 Phase 1 and Phase 2a trials, plus large-scale Phase 2b studies conducted across 17 US research sites, establishing a substantial safety and efficacy database.

About Arletta Pharma Solutions

Arletta Pharma Solutions (formerly Freya Pharma Solutions) is a clinical-stage biopharmaceutical company focused on developing effective pharmaceutical therapies for women diagnosed with Female Sexual Disorders (FSD), building upon more than fifteen years of rigorous scientific research. The Company's core asset is Lybrido™, an innovative on-demand dual-action therapy for FSIAD and HSDD. Arletta is based in Amsterdam, the Netherlands, and is advancing Lybrido's late-stage development on parallel tracks in Europe and the United States.

Forward-looking statements

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

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