

# Evofem Announces Completion of Last Subject Last Visit (LSLV) in Registrational Phase 3 "EVOGUARD" Trial Evaluating Phexxi® for the Prevention of Chlamydia and Gonorrhea in Women

***-- Top-line readout of data expected in October 2022 --***

***-- U.S. regulatory submission planned for the first half of 2023 --***

***-- Phexxi may become the first-ever woman-controlled prophylactic for the prevention of chlamydia and gonorrhea --***

SAN DIEGO, Aug. 1, 2022 /[PRNewswire](#)/ -- **Evofem Biosciences, Inc., (Nasdaq: EVFM)** today announced that the last subject has completed her last visit in *EVOGUARD*, the Company's registrational Phase 3 trial evaluating the efficacy and safety of [Phexxi®](#) (lactic acid, citric acid, potassium bitartrate) for the prevention of chlamydia and gonorrhea infection in women. There are no prescription pharmaceuticals approved to prevent these sexually transmitted infections (STIs).

Top-line data from *EVOGUARD* is expected in October 2022. Evofem expects positive outcomes would enable the Company to submit regulatory applications in the first half of 2023 to the U.S. Food and Drug Administration (FDA) to expand Phexxi's approved indications to include prevention of urogenital chlamydia and gonorrhea in women. Phexxi is currently approved in the U.S. for the prevention of pregnancy.

"This is a major milestone for Evofem and brings us closer to our goal of providing women a safe and effective, woman-controlled prophylactic measure against chlamydia and gonorrhea, the two most commonly reported sexually transmitted infections in the U.S.," said Sandra Pelletier, Chief Executive Officer of Evofem. "We believe these potential new indications represent significant upside for shareholders, above and beyond the multi-billion-dollar birth control market which we continue to increasingly penetrate with Phexxi for hormone-free contraception."

20% of people in the U.S. had an STI on any given day in 2018, according to [a 2021 study in the journal \*Sexually Transmitted Diseases\*](#). The CDC estimates that 4.0 million and 1.6 million new cases of chlamydia and gonorrhea, respectively, occurred that year.<sup>1</sup> Infected people are often unaware of, and do not seek treatment for their infections. Almost 60% of women infected with chlamydia have no symptoms.<sup>2</sup>

[Chlamydia](#) is the most frequently reported bacterial infection in the U.S. and can infect both men and women. It can cause serious, permanent damage to a woman's reproductive system and make it difficult or impossible for a woman to become pregnant later in life.

Chlamydia and gonorrhea have been reported to be responsible for one-third to half of pelvic inflammatory disease (PID) cases. PID can cause serious, long-term problems including infertility, ectopic pregnancy, and chronic pelvic pain.

*EVOGUARD* builds on the positive, statistically significant outcomes of *AMPREVENCE*, the randomized, double-blind placebo-controlled Phase 2b/3 study evaluating Phexxi for the prevention of chlamydia and gonorrhea. *AMPREVENCE* met its primary and secondary

endpoints and showed that the product was generally safe and well-tolerated.

The FDA has granted Fast Track designation and "Qualified Infectious Disease Product" (QIDP) designation to Evofem's product candidate for the prevention of both chlamydia and gonorrhea in women.

The Fast Track program facilitates the expedited development and review of new drugs or biologics that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The purpose is to get important new drugs to the patient earlier.

QIDP designation is intended to encourage development of new products for the treatment of serious or life-threatening infections. A drug or product in development that receives this designation qualifies for an additional five years of marketing exclusivity following FDA approval for that indication.

Evofem is grateful to the study investigators and coordinators at the more than 100 participating study centers across the U.S., as well as the 1,903 women who participated in this landmark study.

### **About Evofem Biosciences**

Evofem Biosciences, Inc., (Nasdaq: EVFM) is developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health, including hormone-free, woman-controlled contraception and protection from chlamydia and gonorrhea. The Company's first FDA-approved product, Phexxi® (lactic acid, citric acid and potassium bitartrate), is a hormone-free, on-demand prescription contraceptive vaginal gel. It comes in a box of 12 pre-filled applicators and is applied 0-60 minutes before each act of sex. The Company expects to report top-line data this fall from its registrational Phase 3 *EVOGUARD* clinical trial evaluating Phexxi for two potential new indications – prevention of chlamydia and prevention of gonorrhea in women. Learn more at [phexxi.com](http://phexxi.com) and [evofem.com](http://evofem.com).

*Phexxi® is a registered trademark of Evofem Biosciences, Inc.*

### **About Phexxi**

Phexxi is an on-demand method of birth control used to prevent pregnancy. Phexxi is not effective when used after sex.

### **Important Safety Information**

- Rare cases (0.36%) of bladder and kidney infections have been reported. If you have a history of urinary tract problems that keep coming back, you should not use Phexxi.
- Contact your healthcare provider if you are experiencing genitourinary side effects such as vaginal burning, itching, discharge, genital discomfort (including in male partners), yeast infection, urinary tract infection, or bacterial vaginosis.
- Phexxi does not protect against sexually transmitted infections, including HIV.

For more information about Phexxi, talk to your healthcare provider and see full Product Information at [www.phexxi.com](http://www.phexxi.com). Please report side effects by contacting Evofem Biosciences toll-free at 1-833-EVFM BIO or contact FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Intended for United States residents only.

### **Forward-Looking Statements**

This press release includes "forward-looking statements," within the meaning of the safe harbor for forward-looking statements provided by Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, including, without limitation, the expansion of Phexxi's label, any FDA approvals of new indications and the resulting effect on stockholder value, evaluations and judgments regarding Evofem, its products, its product candidates and their development, and demand for Evofem's products and product candidates. Various factors could cause actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this press release. Each of these forward- looking statements involves risks and uncertainties. Important factors that could cause actual results to differ materially from those discussed or implied in the forward-looking statements, or that could impair the value of Evofem Biosciences' assets and business are disclosed in the Company's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 10, 2022 and its Quarterly Report on Form 10-Q filed with the SEC on May 10, 2022. All forward-looking statements are expressly qualified in their entirety by such factors. The Company does not undertake any duty to update any forward-looking statement except as required by law.

#### **Sources:**

- <https://www.cdc.gov/std/infertility/default.htm#infnote1>
- Patel, Chirag G et al. "The Proportion of Young Women Tested for Chlamydia Who Had Urogenital Symptoms in Physician Offices." *Sexually Transmitted Diseases* vol. 45,9 (2018)

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