Evofem Completes Enrollment in EVOGUARD Phase 3 Clinical Trial of EVO100 for Prevention of Chlamydia and Gonorrhea in Women

SAN DIEGO, March 4, 2022 /PRNewswire/ -- Evofem Biosciences, Inc., (Nasdaq: EVFM) announced today that it has completed enrollment in EVOGUARD, the registrational Phase 3 clinical trial evaluating EVO100 (the investigational name for Phexxi® (lactic acid, citric acid, potassium bitartrate)) for two potential new indications: the prevention of chlamydia infection in women and the prevention of urogenital gonorrhea infection in women.

The clinical trial design initially called for an enrollment of 1730 participants. Due to the high level of demand to enter the study, investigators enrolled 1903 participants, providing the potential for a more comprehensive understanding of the trial data and outcomes.

Top-line data from EVOGUARD are expected in the second half of 2022.

"I am seeing a significant increase in the number of chlamydia and gonorrhea infections in my patients," said Dr. Todd Chappell, an investigator for the EVOGUARD trial and practicing obstetrician and gynecologist. "There's a notable need for new, effective and safe ways to prevent these infections, and Phexxi, a potential preventive option against these contagious diseases may offer women a form of protection against these infections."

The CDC estimates that 4.0 million and 1.6 million new cases of chlamydia and gonorrhea, respectively, occurred in 2018 alone.[1] The number of reported cases is lower than the estimated total number because infected people are often unaware of, and do not seek treatment for their infections. Almost 60% of women infected with chlamydia have no symptoms.[2] 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.[3]

Completion of enrollment comes less than a month after the U.S. Food and Drug Administration (FDA) awarded "Qualified Infectious Disease Product" (QIDP) Designation to EVO100 (the investigational name for Phexxi) for the prevention of urogenital chlamydia infection in women. 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.

"Completing enrollment in EVOGUARD marks a major milestone for Evofem and highlights our continuing efforts to evaluate this potential first and only-in-class product in women for the prevention of chlamydia and gonorrhea infections," said Saundra Pelletier, CEO of Evofem Biosciences. "As we speak with women and observe the market environment, we recognize the need to educate the public about these two sexually transmitted infections and are working to seize the opportunity and expand our role in helping women control and protect their sexual health. If approved, Evofem can make an impact beyond preventing unplanned pregnancy, and realize a sizeable new market opportunity."

The FDA previously granted EVO100 Fast Track Designation for the prevention of both chlamydia and gonorrhea, and in 2017 awarded QIDP Designation to EVO100 for the prevention of gonorrhea in women.

Evofem remains grateful to all those taking part in and conducting the EVOGUARD trial, and all other ongoing Evofem-sponsored research.

Sources:

[1] **https://www.cdc.gov/std/infertility/default.htm#infnote1**

[2] 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): e72-e74. doi:10.1097/OLQ.0000000000000858

[3] **https://www.acog.org/en/womens-health/faqs/pelvic-inflammatory-disease**

About Phexxi

Phexxi is an on-demand method of birth control used to prevent pregnancy. Phexxi is not effective when used after sex. For more information about Phexxi, talk to your healthcare provide and see full Product Information at **www.phexxi.com**.

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.

Please report side effects by contacting Evofem Biosciences toll-free at 1-833-EVFMBIO or contact FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Intended for United States residents only.

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 certain sexually transmitted infections (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. Learn more at **phexxi.com** and **evofem.com**.

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

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, statements related to timing and outcome of the confirmatory Phase 3 trial, any submission or approval of Phexxi to or by the FDA for the prevention of chlamydia and gonorrhea, and the size of the market opportunity in preventing chlamydia and gonorrhea. Various factors could cause actual results to differ materially from those discussed or implied in the forward-looking statements, including market and other conditions, 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, 2020, filed with the SEC on March 4, 2021. 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.

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