FDA Awards QIDP Designation for Prevention of Chlamydia to Evofem Biosciences

-- Adds Five Years of Market Exclusivity on Approval --

SAN DIEGO, Feb. 9, 2022 /PRNewswire/ -- Evofem Biosciences, Inc., (NASDAQ: EVFM) announced today that the U.S. Food and Drug Administration (FDA) has awarded "Qualified Infectious Disease Product" (QIDP) Designation to EVO100 (the investigational name for Phexxi® (lactic acid, citric acid and potassium bitartrate)) for the prevention of urogenital chlamydia infection in women, a potential new indication in late stage clinical development. Chlamydia is the most frequently reported bacterial infection in the United States.

Top-line data from *EVOGUARD,* the confirmatory Phase 3 trial of Phexxi for the prevention of chlamydia and gonorrhea, are expected in the third quarter of 2022. Positive outcomes could support submission to the FDA for these potential new indications in the first quarter of 2023.

"The unmet need for STI prevention for millions of women is significant when you consider that there are no FDA-approved products available to prevent infection with either chlamydia or gonorrhea," said Saundra Pelletier, CEO of Evofem Biosciences. "Every sexually active woman, no matter what form of contraception she is using, is potentially at risk to contract one of these STIs, which we believe represents a large potential new market opportunity for Evofem."

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 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]

QIDP designation is intended to encourage development of new drugs 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.

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

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 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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