Evofem Biosciences Provides Update on Pivotal Phase 3 Trial of EVO100 for Prevention of Chlamydia and Gonorrhea

High Level of Interest from Clinical Sites Seeking to Participate in EVOGUARD Trial

EVOGUARD Met Enrollment Targets in October and November

SAN DIEGO, Dec. 17, 2020 /PRNewswire/ -- Evofem Biosciences, Inc., (NASDAQ: EVFM) today announced that its pivotal Phase 3 trial, 'EVOGUARD,' of EVO100 for the prevention of chlamydia and gonorrhea remains firmly on schedule. EVOGUARD was initiated and the first patient was enrolled in October 2020, and study enrollment targets were met in both October and November 2020 despite the ongoing COVID-19 pandemic.

"Inbound interest has been exceptionally high from women and study centers alike, with more than double the number of planned sites requesting to participate in this important clinical trial," said Kelly Culwell, MD, Chief Medical Officer of Evofem Biosciences. "Approximately one-third of participating study centers will be up and running by year-end 2020. We will activate all remaining sites in 2021, and expect to complete enrollment of this 1,730-patient trial by year-end 2021."

Despite the CDC recommendation for condom use to prevent sexually transmitted infections (STIs), rates of infection with *Chlamydia trachomatis* and *Neisseria gonorrhea* climbed in 2018 for the fifth consecutive year in the United States.[1] A large number of cases are not reported because most people with chlamydia are asymptomatic and do not seek testing.

"Any sexually active person can be infected with chlamydia or gonorrhea, and despite current preventive measures, such as condoms, the number of reported cases of these STIs continues to rise," said Valerie Sorkin-Wells, M.D., FACOG, of the Arizona Wellness Center for Women and a Principal Investigator in the EVOGUARD clinical trial. "If the results of the ongoing EVOGUARD trial confirm the statistically significant AMPREVENCE trial results, EVO100 could be an important new method to prevent the transmission of chlamydia and gonorrhea in women."

EVO100 is an investigational vaginal gel designed to modulate vaginal pH in the normal acidic range. It was previously evaluated in a double-blinded, placebo-controlled Phase 2b trial, AMPREVENCE, conducted in 860 women at 50 U.S. study centers. This landmark study met its primary and secondary efficacy endpoints, with statistically significant reductions in chlamydia and gonorrhea infection rates in women receiving EVO100 versus placebo. There was a 50% reduction of risk in chlamydia infection and 78% reduction of risk in gonorrhea infection following 16 weeks of EVO100 use compared with placebo, and EVO100 was generally well tolerated with most side effects being mild to moderate. These positive and statistically significant outcomes were presented at the Virtual 2020 STD Prevention Conference in September 2020.

Chlamydia is the most frequently reported bacterial sexually transmitted infection in the United States[2]. It can cause cervicitis in women and urethritis and proctitis in both men and women, and chlamydial infections in women can lead to serious consequences including pelvic inflammatory disease (PID), tubal factor infertility, ectopic pregnancy, and chronic pelvic pain.

Gonorrhea, the second most frequently reported infectious disease in the United States, is increasingly becoming antibiotic resistant, making it much harder, or sometimes impossible, to treat.[3]

The California Department of Public Health has received increasing reports of disseminated gonococcal infections (DGI), an uncommon but severe complication of untreated gonorrhea[4]. DGI occurs when *Neisseria gonorrhoeae* invades the bloodstream and spreads to distant sites in the body, leading to clinical manifestations such as septic arthritis, polyarthralgia, tenosynovitis, petechial/pustular skin lesions, bacteremia, or, on rare occasions, endocarditis or meningitis.

EVO100 has been granted Fast Track Designation for the prevention of chlamydia in women by the FDA. The vaginal pH modulator is also an FDA-designated Qualified Infectious Disease Product (QIDP) for the prevention of gonorrhea in women. Under QIDP guidelines, EVO100 is eligible for certain incentives, including priority review associated with a New Drug Application (NDA) submission and a five-year extension of market exclusivity upon FDA approval for this indication.

About EVOGUARD
EVOGUARD is a double-blind, placebo-controlled Phase 3 clinical trial designed to evaluate the safety and efficacy of EVO100 for the prevention of urogenital *Chlamydia trachomatis* and *Neisseria gonorrhea* infection in women. The study will enroll 1,730 women who have had a urogenital chlamydia or gonorrhea infection at any time over the 16 weeks preceding the Enrollment Visit along with one or more risk factors for infection. Participating women will be randomized at 90 study centers in the United States to receive either EVO100 vaginal gel or placebo, and will remain in the study until completion of 16 weeks of study medication or observation or testing positive for chlamydia or gonorrhea infection. For more information, please visit www.evoguardstudy.com/ct/.

EVOGUARD is funded in part by a strategic investment in Evofem by Adjuvant Capital, LLC.

About Evofem Biosciences
Evofem Biosciences, Inc., (NASDAQ: EVFM) is a commercial-stage biopharmaceutical company committed to 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 (STIs). The Company's first commercial product, Phexxi® (lactic acid, citric acid and potassium bitartrate), is the first and only hormone-free, prescription vaginal gel approved in the United States for the prevention of pregnancy. The Company is evaluating EVO100 in a Phase 3 clinical trial, 'EVOGUARD,' for the prevention of urogenital *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infection in women. For more information, please visit www.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 the ongoing EVOGUARD clinical trial of EVO100 for prevention of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infection in women. 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 Evofem's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 12, 2020, its Quarterly Report on Form 10-Q for the quarter ended March 31 filed with the SEC on May 6, 2020 and August 4, 2020, and its Current Report on Form 8-K filed with the SEC on June 2, 2020. All forward-looking statements are expressly qualified in their entirety by such factors. Evofem does not undertake any duty to update any forward-looking statement except as required by law.

References

[1] Centers for Disease Control and Prevention (2019): 2018 STD Surveillance Report.

[2] Chlamydia, gonorrhea, trichomonas and syphilis: global prevalence and incidence estimates. June 6, 2019.

[3] Centers for Disease Control and Prevention (2018): Antibiotic-Resistant Gonorrhea Basic Information.

[4] California Department of Public Health Dear Colleague Letter - Increasing Reports of Disseminated Gonococcal Infection in CA. November 5, 2020.

Investor Relations Contact
Amy Raskopf
Evofem Biosciences, Inc.
araskopf@evofem.com
Mobile: (917) 673-5775

Media Contact
Ellen Thomas
Evofem Biosciences, Inc.
ethomas@evofem.com
Mobile: (718) 490-3248

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