# Evofem Biosciences Announces First Patient Enrolled in Pivotal Phase 3 Trial of EVO100 for Prevention of Chlamydia and Gonorrhea

SAN DIEGO, Oct. 20, 2020 /PRNewswire/ -- Evofem Biosciences, Inc., (NASDAQ: EVFM) today announced enrollment of the first patient in its pivotal Phase 3 clinical trial evaluating the safety and efficacy of EVO100 for the prevention of urogenital chlamydia and gonorrhea in women.

"We are thrilled to initiate the EVOGUARD trial to further evaluate EVO100 for prevention of chlamydia and gonorrhea infection in women, for which there are currently no prescription products available," said Kelly Culwell, MD, Chief Medical Officer for Evofem Biosciences. "Evofem continues to establish itself as a company that can develop and deliver unique products and product candidates to address the true unmet needs of women."

Rates of infection for *Chlamydia trachomatis* and *Neisseria gonorrhea* climbed in 2018 for the fifth consecutive year in the United States.[1] Globally, an estimated 95 million women are likely to contract chlamydia or gonorrhea by 2025.[2]

Gonorrhea is increasingly becoming antibiotic resistant, making it much harder, or sometimes impossible, to treat.[3]

"The dramatic rise and increasing prevalence of chlamydia and gonorrhea, along with the emergence of multi-drug resistant gonorrhea, make the development of a preventative measure such as EVO100 even more critical," Dr. Culwell added.

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 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.

In September 2020, pivotal results from Evofem's double-blinded, placebo-controlled Phase 2b 'AMPREVENCE' trial were presented at the 2020 STD Prevention Virtual Conference in a poster titled "Efficacy and safety of a novel vaginal pH modulator for prevention of chlamydia and gonorrhea."

AMPREVENCE enrolled 860 women who had been treated for chlamydia or gonorrhea in the four months prior to enrolling in the study. Fifty centers in the United States participated in this unprecedented trial.

EVO100 has been granted Fast Track Designation for the prevention of chlamydia in women by the FDA, and is an FDA-designated Qualified Infectious Disease Product (QIDP) for the prevention of gonorrhea in women.

EVOGUARD is funded in part by a recent 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 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.

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