Evofem Biosciences to Present Data at the 2020 STD Prevention Virtual Conference from Phase 2b Trial of EVO100 for Prevention of Chlamydia and Gonorrhea in Women

- Company plans to initiate Phase 3 STI trial by the end of 2020 -

SAN DIEGO, Sept. 14, 2020 /PRNewswire/ -- Evofem Biosciences, Inc. (NASDAQ: EVFM) today announced pivotal results from the Phase 2b AMPREVENCE trial in a poster presentation from the 2020 STD Prevention Virtual Conference, which will take place online September 14 through 24.

AMPREVENCE evaluated the safety and efficacy of the Company's investigational product candidate EVO100 for the prevention of urogenital chlamydia and gonorrhea in women. The Phase 2b study met its primary and secondary endpoints, with women receiving EVO100 experiencing a relative risk reduction for chlamydia and gonorrhea infection of 50% and 78%, respectively, compared to women receiving placebo. EVO100 was generally safe and well tolerated by women participating in the study.

Positive, statistically significant data from the AMPREVENCE study along with a recent data review from the FDA has positioned Evofem to begin a Phase 3 clinical trial of EVO100 for prevention of chlamydia and gonorrhea in women in the fourth quarter of 2020.

"EVO100 has the potential to impact the health of millions of women by reducing infection rates of chlamydia and gonorrhea," said Kelly Culwell, M.D., Evofem Biosciences' Chief Medical Officer. "We recently had a productive Type C meeting with the FDA that confirmed a very clear path forward in our clinical development and we look forward to initiating our Phase 3 clinical trial before the end of the year."

According to the U.S. Centers for Disease Control and Prevention (CDC), rates of infection for *Chlamydia trachomatis* and *Neisseria gonorrhea* climbed in 2018 for the fifth consecutive year in the United States. Nearly 2.4 million domestic cases of these sexually transmitted infections (STIs) were diagnosed in 2018, with 1.8 million newly reported chlamydia cases and approximately 580,000 newly reported gonorrhea cases.[1] The CDC also reported that gonorrhea is increasingly becoming antibiotic resistant, making it much harder, or sometimes impossible, to treat.[2]

"Chlamydia and gonorrhea are both urgent public health issues with significant consequences, and the emergence of drug-resistant gonorrhea demonstrates that treatment alone is not going to curb this growing epidemic," said poster author B. Todd Chappell, M.D., an AMPREVENCE investigator and obstetrician/gynecologist practicing at Adams Patterson Gynecology & Obstetrics in Memphis, Tennessee. "I am very encouraged by the results of the AMPREVENCE trial and the notion that, in the future, we may be able to provide women with an innovative option to help prevent the acquisition of STIs."

2020 STD Prevention Virtual Conference poster details are as follows:

- Title: Efficacy and Safety of a Novel Vaginal Ph Modulator for Prevention of Chlamydia and Gonorrhea
- Authors: B. Todd Chappell, M.D.; Scott Mollan, MS, MBA; Kelly Culwell, MD, MPH; Brandon Howard, PhD
- Poster Topic: Novel Methodologies & Techniques

- The poster is available for download on the conference website

About the AMPREVENCE Trial
AMPREVENCE was a double-blinded, placebo-controlled Phase 2b clinical trial that enrolled 860 women who had been treated for chlamydia or gonorrhea in the four months prior to enrolling in the study. Subjects were randomized to receive either EVO100 vaginal gel or placebo vaginal gel. During the four months the women participated in the study, they were asked to apply the product candidate or placebo prior to each act of vaginal sexual intercourse. The primary and secondary endpoints of the study were the reduction in the incidence of urogenital *Chlamydia trachomatis* and *Neisseria gonorrhea*, respectively. Fifty centers in the United States participated in this unprecedented trial.

About Evofem Biosciences, Inc.
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 also advancing EVO100 into a Phase 3 clinical trial for the prevention of urogenital transmission of both *Chlamydia trachomatis* and *Neisseria gonorrhoeae* 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 Evofem's expectations regarding the success of the commercial launch of Phexxi, the success of the Phexxi Concierge Experience, our ability to obtain coverage under the ACA and the copay assistance program. 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] Centers for Disease Control and Prevention (2018): Antibiotic-Resistant Gonorrhea Basic Information.

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