Evofem Biosciences Reports Positive Top-Line Results from Phase 2b Study of Amphora® for Prevention of Chlamydia and Gonorrhea in Women

- AMPREVENCE Study Met Primary and Secondary Endpoints - a 50% Relative Risk Reduction in Chlamydia Infection and a 78% Relative Risk Reduction in Gonorrhea Infection Compared to Placebo -

- Amphora Was Generally Safe and Well Tolerated; Consistent with Previous Findings -

- Company to Host Conference Call on Monday, December 2, 2019 at 8:30 a.m. EST -

SAN DIEGO, Dec. 2, 2019 /PRNewswire/ -- Evofem Biosciences, Inc. (NASDAQ: EVFM), a clinical stage biopharmaceutical company, today announced positive top-line results from AMPREVENCE, a Phase 2b clinical trial evaluating the efficacy and safety of its lead product candidate Amphora® for the prevention of urogenital chlamydia and gonorrhea in women. The study met both its primary and secondary endpoints of reducing the risk of chlamydia and gonorrhea infection, respectively, and demonstrated that Amphora was generally safe and well tolerated.

In this landmark study, the infection rate of chlamydia among women who used Amphora for the four-month study period was 4.9% (n=14/288) compared to 9.8% among those who used placebo for four months (n=28/287) (p=.024), a relative risk reduction of 50% in the primary endpoint.

Among the reported cases of gonorrhea infection, the infection rate was 0.7% in the Amphora arm (n=2/280), compared to 3.2% in the placebo arm (n=9/277) (p=.03), a relative risk reduction of 78% in the secondary endpoint.

Amphora was generally safe and well tolerated in this study population, consistent with previous trial results for use of this investigational drug for pregnancy prevention. The number of adverse events was similar across both arms (7.2% for Amphora and 7.5% for placebo) and no serious treatment-related adverse events were reported.

"In less than one week, we have achieved two major milestones that have the potential to meaningfully impact the sexual and reproductive health of millions of women," said Saundra Pelletier, Evofem Biosciences' Chief Executive Officer. "In addition to resubmitting our New Drug Application to the U.S. FDA for Amphora for prevention of pregnancy, we also now have statistically significant evidence that Amphora can prevent acquisition of chlamydia and gonorrhea among women, two bacterial infections that are increasing at an alarming annual rate in the U.S."

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 B. Todd Chappell, M.D., an AMPREVENCE investigator and an 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 a preventative option for pregnancy that may also help prevent the acquisition of STIs."

"The AMPREVENCE trial demonstrated both robust efficacy and safety, and achieved statistical significance for both its primary and secondary endpoints – a substantial outcome for what we believe is an unprecedented trial with no prior benchmark," said Kelly Culwell, M.D., Evofem Biosciences' Chief Medical Officer. "These data are even more compelling when you consider that there are no approved prescription therapies available to prevent infection with either chlamydia or gonorrhea in women. If confirmed in subsequent trials and approved by the U.S. Food and Drug Administration, Amphora could be the first new female-controlled intervention with the potential to address two significant unmet needs – non-hormonal prevention of pregnancy and prevention of chlamydia and gonorrhea infection."

Top-line results are based on a preliminary analysis of currently available efficacy and safety data. Further analysis is ongoing and final results are subject to change based on a comprehensive review by the Company and the U.S. FDA. The Company expects to submit full results for presentation at an upcoming scientific meeting. These data will also form the basis for an End-of-Phase 2 meeting request with the U.S. FDA.

Conference Call Details

The Evofem management team will host a conference call to discuss the top-line AMPREVENCE results as follows:

Date	Monday, December 2, 2019
Time	8:30 a.m. EST
Dial-in numbers	(866) 503-5561 (U.S. toll-free) or (253) 336-2965
Passcode	1062588
Webcast (live and archived)	www.evofem.com under Investors

The live webcast and related slide presentation can be accessed on the Company's Investor page at https://evofem.investorroom.com/events. Please connect to the Company's website at least 15 minutes prior to the start of the call to download any software that may be required. If participating by phone, please dial in approximately 10 minutes prior to the start of the call.

A telephone replay will be available approximately two hours after the call through Friday, December 6, 2019 at (855) 859-2056 (U.S.) or (404) 537-3406 (International), access code 1062588. The webcast will be archived at https://evofem.investorroom.com/events.

About the AMPREVENCE Trial

AMPREVENCE is 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 Amphora® 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 prevention of acquisition of urogenital *Chlamydia trachomatis* and *Neisseria gonorrhea,* respectively*.* Fifty centers in the United States participated in this unprecedented trial.

About Evofem Biosciences
Evofem Biosciences, Inc., (NASDAQ: EVFM) is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. Evofem Biosciences aims to advance the lives of women by developing innovative solutions, such as woman-controlled contraception and potential protection from certain sexually transmitted infections (STIs). The Company's lead Multipurpose Vaginal pH Regulator (MVP-R™) product candidate, Amphora® (L-lactic acid, citric acid and potassium bitartrate), is in development for multiple potential indications: prevention of pregnancy, prevention of urogenital transmission of *Chlamydia trachomatis* infection (chlamydia) in women and prevention of urogenital transmission of *Neisseria gonorrhoeae* infection (gonorrhea) in women. For more information regarding Evofem, please visit www.evofem.com.

Amphora® is a registered trademark and MVP-R™ is a trademark of Evofem Biosciences, Inc.

Forward-Looking Statements
Statements in this press release about Evofem's future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These statements, include, but are not limited to, statements regarding objectives, plans and strategies that address activities, events or developments that the Company intends, expects, projects, believes or anticipates will or may occur in the future, including, without limitation, statements related to the future potential development of Amphora to prevent urogenital acquisition of *Chlamydia trachomatis* and *Neisseria gonorrhea* in women, and the potential FDA approval of Amphora for prevention of pregnancy. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "could," "would," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of the Company's control. Important factors that could cause actual results, developments, and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in the Company's filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K and subsequent filings, and include but are not limited to the following: the Company's ability to raise the additional funds necessary to commercialize Amphora as a contraceptive and/or to complete the development of Amphora to prevent urogenital acquisition of Chlamydia trachomatis and Neisseria gonorrhea in women; the Company's reliance on third parties to conduct its clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for the Company's products; the impact of potential product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of the Company's common stock, and the

concentration of power in its stock ownership. Forward-looking statements in this press release are made as of the date of this press release, and the Company undertakes no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Evofem's views as of any date subsequent to the date hereof. We have included certain information from government and general publications and research, as well as surveys and studies conducted by third parties. This information has been obtained from sources believed to be reliable, although they do not guaranty the accuracy or completeness of such information. We have not independently verified market and industry data from any third-party sources.

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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