Evofem Biosciences Resubmits New Drug Application to U.S. FDA for Amphora® for the Prevention of Pregnancy

- Submission Supported by Phase 3 AMPOWER Data -

- FDA Decision Anticipated Within Six Months -

SAN DIEGO, Nov. 26, 2019 /PRNewswire/ -- Evofem Biosciences, Inc. (NASDAQ: EVFM), a clinical-stage biopharmaceutical company, today announced that it has resubmitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Amphora®, a Multipurpose Vaginal pH Regulator (MVP-R™), for the prevention of pregnancy.

"Today's submission represents a significant step forward for Evofem and for the millions of women who are dissatisfied with their current contraceptive options and are eagerly awaiting a new alternative," said Saundra Pelletier, Evofem Biosciences' Chief Executive Officer. "We have submitted a comprehensive and compelling package that we believe addresses the Agency's outstanding questions, and we look forward to the potential opportunity to provide millions of women with an innovative new hormone-free, on-demand, prescription contraceptive option that gives them control over their sexual and reproductive health."

The Amphora NDA resubmission includes full results from the Phase 3 AMPOWER study, a confirmatory single-arm, open-label Phase 3 trial evaluating the safety and efficacy of Amphora in approximately 1,400 healthy women aged 18-35 years. The trial was designed with guidance and input from the FDA to address questions raised in the Complete Response Letter received by Evofem in April 2016.

According to the FDA's classification, this application will be considered a Class 2 resubmission. Under the Prescription Drug User Fee Act (PDUFA), FDA review of a Class 2 resubmission is expected to be completed within a six-month period beginning on the date the resubmission is received.

About Amphora
Amphora® (L-lactic acid, citric acid and potassium bitartrate) is an investigational Multipurpose Vaginal pH Regulator (MVP-R™) designed to regulate vaginal pH within the normal range of 3.5 to 4.5, even in the presence of semen, which normally raises the vaginal pH to 7.0 – 8.0. This maintains an acidic environment that is inhospitable to sperm, as well as certain viral and bacterial pathogens associated with sexually transmitted infections, but it is integral to the survival of healthy bacteria in the vagina.

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®, 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; and statements about the anticipated timing and outcome of the re-submission of the NDA for 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.

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