U.S. FDA Acknowledges Receipt of Evofem Biosciences' New Drug Application Resubmission for Amphora® for the Prevention of Pregnancy

- Assigns PDUFA Goal Date of May 25, 2020 -

SAN DIEGO, Dec. 18, 2019 /PRNewswire/ -- Evofem Biosciences, Inc. (NASDAQ: EVFM), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) acknowledged receipt of the New Drug Application (NDA) resubmission for Amphora®, a Multipurpose Vaginal pH Regulator (MVP-R™), for the prevention of pregnancy. Deemed a Class 2 resubmission by the FDA, the agency has assigned a six-month review period and a Prescription Drug User Fee Act (PDUFA) goal date of May 25, 2020.

"Today's acknowledgement brings us one step closer to delivering the first true contraceptive innovation in decades," said Saundra Pelletier, Evofem Biosciences' Chief Executive Officer. "We look forward to continuing to work closely with the FDA during the review process and to the potential to offer women a new, non-hormonal prescription contraceptive option that puts them in control of their sexual health."

The Amphora NDA resubmission includes full results from the Phase 3 AMPOWER study, a confirmatory single-arm, open-label Phase 3 trial that evaluated the efficacy and safety of Amphora in approximately 1,400 healthy women ages 18 to 35 years.

The Company is also evaluating the potential use of Amphora for the prevention of urogenital chlamydia and gonorrhea in women. Top-line results from the Phase 2b AMPREVENCE trial, reported in December 2019, demonstrated that the study met both its primary and secondary endpoints, with a 50% relative risk reduction in chlamydia infection and a 78% relative risk reduction in gonorrhea infection compared to placebo.

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 to 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 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, including, without limitation, 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 most recent Annual Report on Form 10-K and subsequent filings, and include but are not limited to the following: whether the FDA approves Amphora as a contraceptive; 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 gonorrhoeae* 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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