Data on Patient Acceptability and Genitourinary Effects of Evofem Biosciences' Lead Product Candidate, Amphora, and its Role as a Multipurpose Vaginal pH Regulator Presented at 2018 American Society of Reproductive Medicine Annual Congress

SAN DIEGO, Oct. 9, 2018 /PRNewswire/ -- Evofem Biosciences, Inc., (NASDAQ: EVFM) ("Evofem" or the "Company"), a clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health, announced details of two oral presentations of data related to their lead product, Amphora®, a Multipurpose Vaginal pH Regulator (MVP-R) in late-stage development for prevention of pregnancy and prevention of urogenital transmission of chlamydia in women, at the 2018 American Society for Reproductive Medicine (ASRM) Annual Congress earlier today.

"The data presented at ASRM, including patient satisfaction data from the AMP001 Phase 3 trial and important Phase 1 data on Amphora's ability to regulate vaginal pH, support the continuation of our robust clinical development initiatives," said Brandi Howard, PhD, Senior Vice President of Global Clinical Development Medical Affairs of Evofem Biosciences. "These include ongoing development of Amphora for prevention of pregnancy as well as our plans to advance a second MVP-R product candidate to prevent recurrent bacterial vaginosis."

The first presentation focused on data collected during a previously completed Phase 3 trial (AMP001) on the efficacy and safety of Amphora and reported secondary outcomes related to Amphora's acceptability and assessment of genitourinary discomfort compared to nonoxynol-9. Results from the acceptability questionnaire in AMP001 demonstrated that Amphora was the preferred choice of birth control method in women users over the 6-month study period and acceptability remained high after cycle 13. Results from the discomfort questionnaire administered to women and their partners suggested that a lower percentage of women reported mild genitourinary discomfort in the Amphora group after cycle 10 and 13, respectively.

The second presentation at the 2018 ASRM Annual Congress discussed outcomes of a Phase 1 clinical trial (EVO-002) that evaluated Amphora's ability to regulate vaginal pH. The objective of this study was to determine the change and duration of change in vaginal pH following a single dose of Amphora. EVO-002 found that Amphora lowered vaginal pH in subjects regardless of baseline vaginal pH. Furthermore, the sub-analysis found this effect was more pronounced in women with baseline pH levels ≥ 5, which are typically found in women with bacterial vaginosis (BV) or at risk for recurrent BV. These findings support further development of the MVP-R to reduce the recurrence of BV.

"Evofem is passionately committed to improving women's health by developing and commercializing new prescription products designed to let women take control of their reproductive health," said Saundra Pelletier, CEO of Evofem Biosciences. "Alarmingly, 16.5M women say that they do not want to get pregnant but are doing nothing to prevent it from happening, which results in an 85% risk of becoming pregnant in the next 12 months. Based on the outcomes of these studies we believe that Amphora has the potential to be the preferred birth control method for these underserved women and also support the continued development of Amphora to treat the recurrence of BV."

Top-line data are expected by year-end 2018 from the second Phase 3 clinical trial of Amphora (AMP002) for prevention of pregnancy. This MVP-R candidate is expected to be Evofem's first commercial product. Assuming positive results from AMP002, the Company plans to re-submit the Amphora New Drug Application (NDA) in the second quarter of 2019. If approved by the FDA, Evofem expects to commercialize Amphora in early 2020 as the first and only hormone-free, on-demand, woman-controlled MVP-R birth control.

For more information on the AMP-001 or EVO-002 studies, please visit www.clinicaltrials.gov

About Amphora

Amphora® (L-lactic acid, citric acid, and potassium bitartrate) is an investigational non-

Amphora® (L-lactic acid, citric acid, and potassium bitartrate) is an investigational non-hormonal gel designed to regulate vaginal pH within the normal range of 3.5 to 4.5 even in the presence of semen. This maintains an acidic environment which 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.

Top-line data are expected by year-end 2018 from Evofem's single-arm, open-label Phase 3 clinical trial (AMP002) evaluating Amphora for the prevention of pregnancy. AMP002 enrolled approximately 1,400 women aged 18-35 at risk of pregnancy at 112 centers in the United States; enrollment was complete in February 2018. The primary endpoint of this study is pregnancy prevention over seven cycles of use. Assuming positive results, the Company plans to re-submit the Amphora New Drug Application (NDA) in the second quarter of 2019. If approved by the FDA, Evofem expects to commercialize Amphora in early 2020 as the first and only hormone-free, on-demand, woman-controlled MVP-R birth control.

The Company is actively enrolling a double-blinded placebo-controlled Phase 2b clinical trial (AMPREVENCE) of Amphora to prevent urogenital acquisition of *Chlamydia trachomatis* (primary endpoint) and *Neisseria gonorrhea* (secondary endpoint) in women. This study is designed to enroll 844 women at approximately 50 centers in the United States for a four-month interventional period and subsequent one-month follow-up period.

The CDC recently reported that rates of syphilis, gonorrhea and chlamydia have climbed for the fourth consecutive year in the United States. Last year, nearly 2.3 million U.S. cases of these STDs were diagnosed, according to preliminary data, an increase of over 200,000 cases as compared with 2016.[1]

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 is leveraging its proprietary Multipurpose Vaginal pH Regulator (MVP-R) to develop product candidates for multiple indications, including contraception, the prevention of urogenital transmission of chlamydia and gonorrhea in women, and recurrent bacterial vaginosis. For more information regarding Evofem, please visit www.evofem.com.

About the American Society for Reproductive Medicine
The American Society for Reproductive Medicine (ASRM) is a nationally and internationally recognized leader for multidisciplinary information, education, advocacy and standards in the field of reproductive medicine. ASRM is a non-profit organization whose members must demonstrate the high ethical principles of the medical profession, evince an interest in infertility, reproductive medicine and biology, and adhere to the objectives of the Society. For more information regarding ASRM, please visit www.asrm.org

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 are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "could," "would," "intends," "plans," "will," "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 Quarterly Report for the period ended March 31, 2018, as filed with the SEC on Form 10-Q on May 14, 2018, and include but are not limited to the following: objectives, plans and strategies as well as statements, other than historical facts, that address activities, events or developments that the Company intends, expects, projects, believes or anticipates will or may occur in the future; risks and uncertainties associated with market

anticipates will or may occur in the future, risks and uncertainties associated with market conditions; statements about the anticipated results of the Phase 3 clinical trial evaluating Amphora as a contraceptive and the Phase 2b clinical trial of Amphora to prevent urogenital acquisition of *Chlamydia trachomatis* and *Neisseria gonorrhea* in women, and any expected completion dates or general timing for these clinical trials; 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 publications which was obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We have not independently verified market and industry data from any third-party sources.

[1]Centers for Disease Control and Prevention (2018): STD Preliminary Data Accessed August 2018.

Amphora® is a registered trademark of Evofem Biosciences, Inc.

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