Evofem Biosciences Completes Phase 3 Clinical Trial of Amphora for Prevention of Pregnancy

-- Company Remains on Track for AMPOWER Top-line Results in Late 2018 --

SAN DIEGO, Nov. 8, 2018 /PRNewswire/ -- Evofem Biosciences, Inc., (NASDAQ: EVFM) ("Evofem" or the "Company") today announced the last patient has completed her last visit in AMPOWER, the second Phase 3 clinical trial of Amphora® (L-lactic acid, citric acid and potassium bitartrate), its lead Multipurpose Vaginal pH Regulator (MVP-R) product candidate, for the prevention of pregnancy.

Amphora is an investigational, first-in-class MVP-R designed to give a woman control over some of the most intimate issues of her life and health. This non-hormonal, non-systemic vaginal gel is being developed for woman-controlled birth control as well as prevention of certain sexually transmitted infections (STIs).

"We have long recognized the need for well-studied birth control options that will address the needs of women who do not wish to become pregnant but will not or cannot use hormonal birth control methods," said Bassem Maximos, MD, MPH, FACOG, a practicing obstetrician/gynecologist and principal investigator for AMPOWER. "An FDA-approved hormone-free birth control product that is both on-demand and woman-controlled would represent a new and important option in the gynecologist's arsenal, unlike anything that is available today."

"Widespread demand for participation in this important Phase 3 clinical trial allowed us to successfully enroll approximately 1,400 women, the last of whom has just completed her final study visit. Achieving this critical milestone brings us another step closer to moving forward with data analyses, keeping us on track for top-line AMPOWER data by the end of this year," said Brandi Howard, PhD, Evofem's Senior Vice President of Global Clinical Development & Medical Affairs.

"Assuming positive results, Evofem will re-submit the Amphora New Drug Application in the second quarter of 2019," said Saundra Pelletier, Chief Executive Officer of Evofem Biosciences. "Subject to FDA approval, we expect to commercialize Amphora in January 2020 as the first and only non-hormonal, woman-controlled prescription birth control method in the U.S."

"We would like to thank our investigators and site coordinators, as well as the patients who participated in this important study, which will provide critical insight on the potential of Amphora as a non-hormonal birth control method," Dr. Howard continued. "This first-in-class product has the potential to be a paradigm-shifting new option for millions of women in the U.S., including the 16.5 million women who do not wish to become pregnant and currently use no form of birth control.[1]"

Women who do not use any contraceptive method but who are not trying to become pregnant have an 85% risk of experiencing an unintended pregnancy within one year.[1]

Pelletier continued, "Most women don't have sex every day, yet the majority of available options require a daily dose of hormones. It is time that women have access to a product designed for them, that empowers them with a safe and effective non-hormonal birth control

option, that they use only when needed."

About Amphora
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. 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.

Evofem expects top-line data in December 2018 from AMPOWER, its Phase 3 clinical trial evaluating Amphora for the prevention of pregnancy. This single-arm, open-label trial enrolled approximately 1,400 women aged 18-35 who are at risk of pregnancy at 112 U.S. centers. The primary endpoint of the study is pregnancy prevention over seven cycles of use.

The Company is actively enrolling AMPREVENCE, a double-blinded placebo-controlled Phase 2b clinical trial 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 chlamydia, the most frequently reported bacterial sexually transmitted disease (STD) in the U.S., and gonorrhea 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.[2] There are currently no FDA-approved products for either of these STDs.

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 prevention of pregnancy, prevention of urogenital transmission of chlamydia and gonorrhea in women and the prevention of recurrent bacterial vaginosis. For more information regarding Evofem, please visit www.evofem.com.

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; statements about the anticipated results of the Phase 3 clinical trial evaluating Amphora for birth control 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. These statements are often characterized by terminology such as "believes," "hope" "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 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: 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 publications and general publications and research, 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.

[1]NHS Data Brief #173, December 2014, "Current Contraceptive Status Among Women Aged 15-44" (Based on National Survey of Family Growth data)

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

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