Evofem Biosciences Reports Additional Data from Phase 3 'AMPOWER' Study of Amphora® for Hormone-Free Birth Control

SAN DIEGO, Aug. 5, 2019 /PRNewswire/ -- Evofem Biosciences, Inc. (NASDAQ: EVFM) (Evofem), a clinical-stage biopharmaceutical company, today reported additional data from its Phase 3 'AMPOWER' clinical trial of Amphora® for the prevention of pregnancy. These findings reveal that the use of Amphora, a first-in-class investigational Multipurpose Vaginal pH Regulator (MVP-R™), may improve sexual satisfaction and have a positive impact on women's sex lives. The analysis also confirmed certain previously reported safety and efficacy data.

AMPOWER is the first clinical study to explore the effects of a contraceptive product candidate on sexual satisfaction.

As part of a sexual satisfaction exploratory endpoint, study participants were asked to answer survey questions (*unvalidated instrument*) aimed at assessing the impact of their most recent contraceptive method on their sex life at two time points: upon entry into the study (baseline; n=1330) and after using Amphora for one month (n=1118). At baseline, just 17% of study participants reported their most recent contraception made their sex life 'a little' or 'a lot' better than before. However, after at least one cycle of Amphora use, 45% of women reported their sex life was 'a little' or 'a lot' better.

"For the first time, we are investigating not only the clinical benefits of a birth control method but also listening to women's needs throughout their reproductive and sexual health journey," said Saundra Pelletier, CEO of Evofem Biosciences. "These data, although preliminary, suggest that use of Amphora increased the number of women reporting an improved sex life compared with the contraceptive methods they used before entering the AMPOWER study. If approved, we look forward to launching Amphora in 2020 as the first MVP-R for hormone-free birth control."

In addition, our third party data and statistics analyst has completed its comprehensive review of the complete data set for our AMPOWER trial, which confirms the favorable safety profile of this first-in-class MVP-R product candidate. During AMPOWER, 1330 women used Amphora and contributed 7561 cycles of safety data. The incidence of serious adverse events (SAEs) was low (1.1%), and none of the SAEs were considered definitely related to treatment with Amphora. Most adverse events (AEs) were mild to moderate in severity, and fewer than 2% of treated subjects discontinued prematurely due to an AE. Pregnancy outcome and infant assessments did not reveal any adverse pregnancy outcomes from participation in the study.

Further, using the Kaplan-Meier statistical method, our third party data and statistics analyst has also confirmed that the cumulative pregnancy rate was 13.7% over seven cycles of use (95% CI 9.9, 17.4), which corresponds to an 86.3% efficacy rate for typical use and exceeds the pre-determined primary end point of the AMPOWER trial. While conducting final data analysis, our third party biostaticians identified an inconsistency in the programming logic of their initial top-line assessment for women who correctly used Amphora as directed (sometimes referred to as perfect use). The recalculated cumulative pregnancy rate for women who used Amphora according to the research protocol was 6.7% over seven cycles of use [(95% CI 4.6, 8.7)], which corresponds to a 93.3% efficacy rate. Perfect use is not considered an endpoint of interest for FDA approval.

Additional data related to efficacy, safety and patient satisfaction in the AMPOWER trial will be presented at three clinical and medical society conferences in October 2019. Further data related to the AMPOWER study's exploratory endpoint evaluating the impact of Amphora on sexual satisfaction is targeted for presentation in 2020.

About AMPOWER
The Phase 3 'AMPOWER' clinical trial assessed the effectiveness and safety of the investigational product Amphora in preventing pregnancy over seven menstrual cycles of use in approximately 1,330 women at 112 centers in the United States. Evofem's lead candidate Amphora met the pre-specified primary endpoint of this trial, had a favorable safety profile, and was well tolerated.

About Evofem Biosciences
Evofem Biosciences, Inc., is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. The Company is leveraging its proprietary Multipurpose Vaginal pH Regulator (MVP-R™) platform to develop its first product candidate, Amphora® (L-lactic acid, citric acid and potassium bitartrate). Amphora is an investigational MVP-R 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 plans to resubmit the Amphora New Drug Application (NDA) for prevention of pregnancy and vaginal lubrication in the fourth quarter of 2019. If approved, the Company plans to launch Amphora in 2020 as the first-in-class MVP-R for hormone-free, woman-controlled birth control.

This investigational MVP-R is also in development for prevention of certain sexually transmitted infections. Evofem expects to report top-line data from AMPREVENCE, the ongoing Phase 2b trial of Amphora to prevent urogenital acquisition of *Chlamydia trachomatis* (primary endpoint) and *Neisseria gonorrhea* (secondary endpoint) in women, in the fourth quarter of 2019.

For more information, please visit www.evofem.com.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements related to anticipated presentations at upcoming medical society meetings, the timing of the planned Amphora NDA re-submission for prevention of pregnancy, potential FDA approval of Amphora, and the potential commercial launch of Amphora. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from those, express or implied, in these forward-looking statements. Important factors that could impair the value of Evofem Biosciences' assets and business are disclosed in the risk factors contained in its Annual Report on Form 10-K for the year ended December 31, 2108 filed with the Securities and Exchange Commission on March 1, 2109 and subsequent filings. All forward-looking statements are expressly qualified in their entirety by such factors. Evofem Biosciences does not undertake any duty to update any forward-looking statement except as

required by law.

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