Evofem Biosciences Completes Phase 2b 'AMPREVENCE' Trial of Amphora for Prevention of Chlamydia and Gonorrhea in Women

SAN DIEGO, Aug. 26, 2019 /PRNewswire/ -- Evofem Biosciences, Inc., (NASDAQ: EVFM) ("Evofem" or the "Company") today announced the last patient has completed her last visit in AMPREVENCE, the Phase 2b clinical trial evaluating the Company's lead product candidate Amphora®, a Multipurpose Vaginal pH Regulator (MVP-R™), for the prevention of acquisition of chlamydia and gonorrhea in women (as primary and secondary endpoints, respectively).

According to the CDC, rates of infection with Chlamydia trachomatis and Neisseria gonorrhea climbed in 2017 for the fourth consecutive year in the United States. Nearly 2.3 million domestic cases of these sexually transmitted infections (STIs) were diagnosed in 2017 with chlamydia accounting for 1.7 million of these cases, making it the most frequently reported bacterial STI[1]. Further, gonorrhea is increasingly becoming antibiotic resistant, making it much harder, or sometimes impossible, to treat[2].

"It is hard to believe that with the extensive advances in modern medicine, we continue to see a rise in the annual reported number of chlamydia infections," said Saundra Pelletier, Chief Executive Officer at Evofem Biosciences. "Assuming positive top-line results in November of this year, we look forward to the continued clinical development of Amphora for the prevention of acquisition of chlamydia in mid-2020. If successful, Amphora could be the first new innovation to address this growing STI, reducing the negative fertility impacts associated with chlamydia."

"We are grateful to our investigators and site coordinators as well as the 860 women who participated in this landmark study. AMPREVENCE will provide critical insight on the potential of Amphora for prevention of these bacterial infections," added Brandi Howard, PhD, Evofem's Head of Medical Affairs.

AMPREVENCE, a double-blind, placebo-controlled, Phase 2b trial, enrolled 860 women who had been treated for chlamydia or gonorrhea in the four months preceding enrollment in the study. Subjects were randomized to either Amphora or placebo vaginal gel treatment arms. During the four months the women participated in the study, they

were asked to apply the product candidate prior to each act of vaginal sexual intercourse. The primary and secondary endpoints of the study are the prevention of acquisition of urogenital Chlamydia trachomatis and Neisseria gonorrhea, respectively. Fifty U.S. centers participated in this unprecedented trial.

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 has the potential to maintain an acidic environment that is inhospitable to sperm as well as certain viral and bacterial pathogens associated with STIs 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 STIs. 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 November of 2019. For more information, please visit **www.evofem.com**.

Amphora® is a registered trademark and MVP-R™ is a trademark of Evofem Biosciences, Inc.

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 the timing of the planned Amphora re-submission of the Amphora NDA for prevention of pregnancy, potential FDA approval of Amphora, and the potential commercial launch of Amphora, the anticipated results of the Phase 2b clinical trial of Amphora to prevent urogenital acquisition of Chlamydia trachomatis and Neisseria gonorrhea in women, and any expected completion date or general timing for this clinical trial. 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, 2018 filed with the Securities and Exchange Commission on March 1, 2019 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.

References

[1] Centers for Disease Control and Prevention (2018): **2017 STD Surveillance Report**.

[2] Centers for Disease Control and Prevention (2018): **Antibiotic-Resistant Gonorrhea Basic Information**.

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