

# Evofem Biosciences Announces Last Patient Enrolled for AMPREVENCE, the Phase 2b Sexually Transmitted Infections Trial of Amphora

Top-line Data Expected in the Fourth Quarter of 2019

SAN DIEGO, April 23, 2019 /[PRNewswire](#)/ -- Evofem Biosciences, Inc. (NASDAQ: EVFM) ("Evofem"), a clinical stage biopharmaceutical company, today announced the completion of patient enrollment in AMPREVENCE, the Phase 2b clinical trial evaluating its lead product candidate Amphora<sup>®</sup>, a Multipurpose Vaginal pH Regulator<sup>™</sup> (MVP-R), for the prevention of chlamydia and gonorrhea in women.

According to the CDC, chlamydia is the most frequently reported sexually transmitted bacterial infection in the U.S. Rates of both gonorrhea and chlamydia climbed for the fourth consecutive year, with over 2.2 million cases reported in 2017.<sup>1</sup>

"We are eager to gain further insight into the ability of Amphora to prevent chlamydia and gonorrhea, and expect to report top-line AMPREVENCE data by the end of this year," said Sandra Pelletier, CEO of Evofem Biosciences.

AMPREVENCE, a double-blinded, placebo-controlled Phase 2b trial, enrolled approximately 850 women who had been treated for chlamydia or gonorrhea in the preceding four months. Subjects have been randomized to either Amphora or placebo vaginal gel treatment arms where they were asked to apply the study drug before engaging in sexual intercourse for four months. The primary and secondary endpoints of the study are the prevention of acquisition of urogenital *Chlamydia trachomatis* and *Neisseria gonorrhea*, respectively. Over 50 United States centers are participating 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. 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 is leveraging its proprietary Multipurpose Vaginal pH Regulator<sup>™</sup> (MVP-R) platform to develop Amphora<sup>®</sup> (L-lactic acid, citric acid and potassium bitartrate) for birth control and prevention of urogenital acquisition of certain STIs.

Amphora is 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. For more information, please visit [www.evofem.com](http://www.evofem.com).

Amphora<sup>®</sup> is a registered trademark and Multipurpose Vaginal pH Regulator<sup>™</sup> 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 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 the Evofem Biosciences' assets and business are disclosed in the risk factors contained in its Annual Report on Form 10-K filed with the Securities and Exchange Commission 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

<sup>1</sup> Centers for Disease Control and Prevention (2018): [2017 STD Surveillance Report](#), accessed April 18, 2019.

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