

Evoform Biosciences to Present Data on Methodology and Current Status of Two Ongoing Clinical Studies of Amphora at the 2018 International Federation of Gynecology and Obstetrics (FIGO) World Congress

SAN DIEGO, Oct. 3, 2018 /[PRNewswire](#)/ -- Evoform Biosciences, Inc., (NASDAQ: EVFM) ("Evoform" 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, will present an update on the methodology and status of two ongoing late stage clinical trials of its lead product candidate, Amphora®. This first-in-class Multipurpose Vaginal pH Regulator (MVP-R) is being studied for prevention of both pregnancy and certain sexually transmitted infections (STIs).

Data will be presented at the 2018 International Federation of Gynecology and Obstetrics (FIGO) World Congress in Rio De Janeiro from AMP002, a Phase 3 clinical trial assessing the efficacy and safety of Amphora for the prevention of pregnancy, and AMPREVENCE, a Phase 2b clinical trial assessing the efficacy and safety of Amphora for the prevention of urogenital *Chlamydia trachomatis* (CT) infection.

Presentation details are as follows:

- **Abstract title:** *Amphora Gel, A Multipurpose Prevention Product*
- **Date:** October 15, 2018
- **Presenter:** Dr. Kelly Culwell, MD, MPH
- **Location:** Rio De Janeiro, Brazil

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 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 Evoform'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 the 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, Evoform expects to commercialize Amphora in early 2020 as the first and only hormone-free, on-demand, woman-controlled MVP-R for 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.

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," "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 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.

¹Centers 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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