

Rise in Prevalence of STDs Reported by CDC Supports Continued Development of Novel Solutions, Like Evofem's Product in Development, Amphora®, for the Prevention of Chlamydia

SAN DIEGO, Aug. 29, 2018 /[PRNewswire](#)/ -- Evofem Biosciences, Inc., (NASDAQ: EVFM) ("Evofem" 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, believes that new data recently released by the Centers for Disease Control and Prevention (CDC) on the increasing rates of sexually transmitted diseases (STDs) in the United States support the continued need for and clinical development of Amphora® (L-lactic acid, citric acid, and potassium bitartrate) vaginal gel for the prevention of *Chlamydia trachomatis* and *Neisseria gonorrhea* in women.

The CDC reported this week at the National STD Prevention Conference in Washington 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

Amphora is being studied as an on-demand vaginal contraceptive and for the prevention of certain STDs. Evofem is conducting a Phase 2b double-blinded placebo-controlled efficacy trial ([AMPREVENCE](#)) to evaluate Amphora for the prevention of urogenital acquisition of *Chlamydia trachomatis* (primary endpoint) and *Neisseria gonorrhea* (secondary endpoint) in women. This clinical trial is actively enrolling 844 women at up to 50 centers in the United States for a four-month interventional period and subsequent one-month follow-up period.

Earlier this year, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for Amphora for the prevention of urogenital chlamydia in women. Fast Track designation is designed to facilitate the development and expedite the review of new therapies to treat serious conditions and fill unmet medical needs.

"As the prevalence of sexually transmitted diseases continues to rise, there is an increasing need for preventive measures. We believe the AMPREVENCE trial will provide data in support of Amphora's use to prevent these infections in women," said Kelly Culwell, MD, Chief Medical Officer of Evofem Biosciences. "With the growing epidemic of STDs, and chlamydia in particular, we have the potential to address a significant unmet medical need with a preventative therapeutic."

The Company expects to report top-line data by year-end 2018 from its confirmatory Phase 3 clinical trial of Amphora for contraception. Assuming positive results, Evofem expects to re-submit the Amphora New Drug Application (NDA) in the first half of 2019 which, if approved by the FDA, would position the Company to commercialize Amphora as the first and only hormone-free, on-demand contraceptive drug in early 2020.

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 Multi-purpose Prevention Technology vaginal gel 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.

¹Centers for Disease Control and Prevention (2018): STD Preliminary Data Accessed August 2018.

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