Evofem Biosciences Announces Peer-Reviewed Publication of the Pivotal Phase 3 AMPOWER Study Results For Phexxi™ (lactic acid, citric acid and potassium bitartrate) in Contraception

SAN DIEGO, July 15, 2020 /PRNewswire/ -- Evofem Biosciences, Inc. (NASDAQ: EVFM), a commercial-stage biopharmaceutical company, today announced that Contraception, an international, peer-reviewed, reproductive health journal, published the primary efficacy and safety results from the Phase 3 AMPOWER study evaluating Phexxi™ (lactic acid, citric acid and potassium bitartrate) for the prevention of pregnancy. The results were published "online first" this week in Contraception: X (https://bit.ly/38HLFBh) and will appear in a future print edition of the journal.

Phexxi is the first non-hormonal, on-demand, vaginal pH regulator contraceptive designed to maintain vaginal pH within the normal range of 3.5 to 4.5 – an acidic environment that is inhospitable to sperm. It was approved by the U.S. Food and Drug Administration (FDA) on May 22, 2020 for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception based on the results of the Phase 3 AMPOWER study.

"The publication of these pivotal data in such an important, peer-reviewed journal underscores the rigor of the AMPOWER clinical trial and the importance of our novel approach to addressing women's contraceptive needs," said Saundra Pelletier, Evofem Biosciences' Chief Executive Officer. "Through the ongoing presentation and publication of new data, we are ensuring that clinicians have the most comprehensive information available about Phexxi, the first and only non-hormonal prescription contraceptive gel that puts women in full control of their sexual and reproductive health. We look forward to the commercial launch of Phexxi in early September and the opportunity to provide an innovative option to the more than 17 million women in the U.S. who are fed up with hormonal contraception."

The final data analysis demonstrated a cumulative pregnancy rate of 13.7% over seven cycles of use (95% CI 10.0,

17.5). The incidence of serious adverse events (SAEs) was low (1.1%), and none of the SAEs were considered definitely related to treatment with Phexxi. Most adverse events (AEs) were mild to moderate in severity, and fewer than 2% of treated subjects discontinued prematurely due to an AE.

The study also measured self-reported satisfaction ratings related to Phexxi use. At baseline, less than half (46.5%) of the 1,325 respondents were "satisfied" or "very satisfied" with their existing contraceptive method. This number nearly doubled during the trial, with greater than 80% of women reported being "satisfied" or "very satisfied" with the use of Phexxi.

About AMPOWER

AMPOWER was a single-arm, open-label Phase 3 study designed to evaluate the efficacy and safety of Phexxi in preventing pregnancy. The study enrolled 1,384 women aged 18-35 years across 112 centers in the United States. AMPOWER is the only large-scale, Phase 3 contraceptive clinical trial to explore the effects of a contraceptive product candidate on the impact of women's sex lives.

Three new data sets from the AMPOWER trial were accepted for presentation at the 2020 American College of Obstetricians and Gynecologists (ACOG) Annual Meeting in April and published in Obstetrics & Gynecology (The Green Journal). Among the key findings:

- Perfect-use failure rates over seven cycles of Phexxi ranged from 6.67% to 9.99% .
- Data collected as part of an exploratory endpoint at baseline and at study visits 3, 4 and 5 (after at least one cycle of Phexxi use), demonstrated that 45% of women reported their sex life was 'a little' or 'a lot' better compared to just 17% at baseline.
- Rates of genitourinary (GU) symptoms associated with the use of Phexxi decreased from baseline with each consecutive cycle (up to 7 cycles) from 20% to 1.4% in women with existing GU infections and 11.2% to 0.3% in the general study population.

Additional data have been accepted and will be presented at two major medical meetings this fall, including the Society of Family Planning's Virtual Annual Meeting (Oct. 9-10) and the Nurse Practitioners in Women's Health (NPWH) 23rd Annual Premier Women's Healthcare Virtual Conference (Oct. 15-18).

For more information, please visit the "Posters and Publications" page on the Evofem website (**https://bit.ly/2Cx3neM**).

About Phexxi™ (lactic acid, citric acid and potassium bitartrate) Vaginal Gel

Phexxi is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

Limitations of Use

Phexxi is not effective for the prevention of pregnancy when administered after intercourse.

Warnings and Precautions

Few cases (0.36%) reported adverse reactions of cystitis, pyelonephritis and other upper urinary tract infection (UTI) have been reported in Phexxi clinical studies. Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of Phexxi in females of reproductive potential with history of recurrent urinary tract infection or urinary tract abnormalities.

Adverse Reactions

Most common adverse reactions (≥2%) were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain.

Patients should be counseled on the following:

- To contact and consult with their healthcare provider for severe or prolonged genital irritation or experiencing urinary tract symptoms.
- To discontinue Phexxi if they develop a local hypersensitivity reaction.
- That Phexxi does not protect against HIV infection (AIDS) or other sexually transmitted infections.

Please see full Prescribing Information for Phexxi. To report suspected adverse reactions, contact Evofem at toll-free phone 1-833-EVFMBIO or you may contact FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

About Evofem Biosciences, Inc.

Evofem Biosciences, Inc., (NASDAQ: EVFM) is a commercial-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health, including hormone-free, woman-controlled contraception and protection from certain sexually transmitted infections (STIs). The Company's first commercial product, Phexxi™ (lactic acid, citric acid and potassium bitartrate), is the first and only vaginal pH regulator approved in the United States for the prevention of pregnancy. The Company is also advancing EVO100 into Phase 3 clinical trials for the prevention of urogenital transmission of both Chlamydia trachomatis infection (chlamydia) and Neisseria gonorrhoeae infection (gonorrhea) in women.

Forward-Looking Statements

This press release includes "forward-looking statements," within the meaning of the safe harbor for forward-looking statements provided by Section 21E of the Securities Exchange Act of 1934, as amended; and the Private Securities Litigation Reform Act of 1995, including, without limitation, statements related to Evofem's expectations. Various

factors could cause actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Important factors that could cause actual results to differ materially from those discussed or implied in the forward-looking statements, or that could impair the value of Evofem Biosciences' assets and business are disclosed in Evofem's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 12, 2020, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 filed with the SEC on May 6, 2020 and its Current Report on Form 8-K filed with the SEC on June 2, 2020. All forward-looking statements are expressly qualified in their entirety by such factors. Evofem does not undertake any duty to update any forward-looking statement except as required by law.

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