



U.S. FDA Approves Evofem Biosciences' Phexxi™ (lactic acid, citric acid and potassium bitartrate), the First and Only Non-Hormonal Prescription Gel for the Prevention of Pregnancy

SAN DIEGO, May 22, 2020 /PRNewswire/ -- Evofem Biosciences, Inc. (NASDAQ: EVFM) today announced that the U.S. Food and Drug Administration (FDA) has approved Phexxi™ (lactic acid, citric acid and potassium bitartrate) vaginal gel for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

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.

"There have been a limited number of advances in birth control over the last two decades; Phexxi represents an important step forward in women's health," said Michael A. Thomas, M.D., Chair of the Department of Obstetrics and Gynecology at the University of Cincinnati College of Medicine. "Many of my patients have cycled through numerous contraceptive options and still have not found the right fit for their sexual and reproductive needs. Phexxi offers women freedom from hormones and control over how they choose to prevent pregnancy. I look forward to offering this new on-demand option to my patients."

The Company expects to launch Phexxi in early September alongside the Phexxi Concierge Experience, a comprehensive patient and healthcare provider telemedicine support system. This robust offering of services is designed to provide physicians with on-demand educational support, and speed and simplify women's access to Phexxi. Through this offering, women would be able to secure a prescription, determine their insurance coverage and/or out-of-pocket costs, receive counseling support and refill reminders, and fill their prescription through their local neighborhood pharmacy or an online pharmacy that is expected to deliver Phexxi right to their door.

"The FDA approval of Phexxi means women now have access to a non-hormonal contraceptive option that they

control, on their terms, to be used ONLY when they need it," said Sandra Pelletier, Evofem Biosciences' Chief Executive Officer. "Empowerment results from innovation and we are proud and excited to deliver new innovation to women in a category ready for change."

As the first vaginal pH regulator with a unique mechanism of action, the Company is working to have Phexxi covered under the Affordable Care Act (ACA). The ACA mandates that private health plans provide coverage with no out-of-pocket costs for one treatment per class in each of the classes identified by the FDA for women in its Birth Control Guide.

Evofem is committed to ensuring access to Phexxi for all women seeking non-hormonal contraception, including for women who are not covered by government or private health plans, and will provide a financial assistance program to enable access for eligible women.

"During my 15-year career at the FDA, I participated in the review and approval of many sexual and reproductive health products, and I believe that Phexxi serves a true unmet need in contraception," said Lisa Rarick, M.D., former FDA Division Director and Evofem board member. "Phexxi offers women protection and control—on their terms, and at their discretion—without the use of hormones. I am proud to be a part of this team and this moment in history."

Conference Call Details

Evofem Biosciences will host a conference call and audio webcast to discuss the FDA approval of Phexxi as follows:

Date	Tuesday, May 26, 2020
Time	8:30 a.m. EDT (5:30 a.m. PDT)
Dial-in numbers	(866) 503-5561 (U.S. toll-free) or (253) 336-2965
Passcode	4638796
Webcast	www.evofem.com under "Investors" or click here

Please connect to the Company's website at least 15 minutes prior to the start of the call to download any software that may be required. If participating by phone, please dial in approximately 10 minutes prior to the start of the call.

A telephone replay will be available approximately two hours after the call through Sunday May 30, 2020, at (855)

859-2056 (U.S.) or (404) 537-3406, access code 4638796. The live and archived webcast can be accessed at <https://evofem.investorroom.com/events>.

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%) of 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 ($\geq 2\%$) 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 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 or other sexually transmitted infections.

To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFM BIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Full Prescribing Information for Phexxi is available at Phexxi.com.

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. 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's first commercial product, Phexxi™ (lactic acid, citric acid and potassium bitartrate), is approved in the United States for the prevention of pregnancy. The Company is advancing EVO100 for the prevention of urogenital transmission of both *Chlamydia trachomatis* infection (chlamydia) and *Neisseria gonorrhoeae* infection (gonorrhea) in women. For more information regarding Evofem, please visit www.evofem.com.

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 Evofem Biosciences' expectations regarding the success and timing of commercial launch and availability of Phexxi, the availability and success of our telehealth support system and our ability to obtain coverage under the ACA. 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, and Quarterly Report on 10-Q for the first quarter of 2020 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.

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