Evofem Biosciences Announces Presentations on Phexxi and EVO100 at Key Medical Society Meetings

SAN DIEGO, Oct. 7, 2020 /PRNewswire/ -- Evofem Biosciences, Inc., (NASDAQ: EVFM) announced today that new clinical trial data on Phexxi™ (lactic acid, citric acid and potassium bitartrate) and EVO100 are being discussed in oral and poster presentations at major medical society meetings this month.

"We are thrilled to continue to share critical data in nine abstracts at the key women's and reproductive health medical society meetings this fall," said Brandi Howard, PhD, Head of Medical Affairs at Evofem Biosciences. "The data are part of our robust publication strategy and include new insight into the demographics/characteristics of Phexxi users; factors affecting chlamydia and gonorrhea reinfection rates; and exploratory findings related to impact on sex life among women treated with Phexxi and EVO100 in the AMPOWER and AMPREVENCE trials, respectively."

The posters, abstracts and related publications will be made available in the Posters and Publications section of the company's website at www.evofem.com.

Presentation details are as follows:

Society for Family Planning (SFP) Annual Meeting 2020

Dates: October 9-10, 2020

Poster Titles:

- Impact of product adherence and condom use on rates of urogenital re-infection with Chlamydia trachomatis or Neisseria gonorrhoeae in the AMPREVENCE phase 2b/3 clinical trial (Poster # 41)
- Characterization of women according to pregnancy status following treatment with VPR during the AMPOWER study (Poster # 71)

SFP abstracts will be published in the October 2020 issue of Contraception.

Nurse Practitioners in Women's Health (NPWH) 23rd Annual Women's Healthcare Conference

Dates: October 15-18, 2020

Poster Title: A Comparison of Women Who Completed or Discontinued the AMPOWER Study, a Phase 3 Contraceptive Trial for Vaginal pH Regulator (Poster: P-284)

American Society for Reproductive Medicine (ASRM) 2020 Scientific Congress

Oral Presentation

Date: Saturday, October 17, 2020

Time: 11:10 a.m. ET

Title: Sexual Satisfaction with a Vaginal pH Regulator (EVO100): Results from the AMPREVENCE Clinical Trial (Oral: 30)

Poster

Date: Saturday, October 17, 2020

Time: 4:30 – 6:00 p.m. ET

Title: Characterization of Women According to their Sexual Satisfaction After Treatment with the Novel Vaginal pH Regulator (VPR™) During the AMPOWER Study (Poster: P-160)

ASRM abstracts will be published in the October 2020 issue of Fertility and Sterility.

ACOG 2020 Virtual Conference

Dates: October 30-31, 2020

Poster Titles:

- Sexual Satisfaction with Vaginal pH Regulator: Results from the AMPOWER Clinical Trial
- Perfect–Use Pregnancy Rates with Vaginal pH Regulator: Efficacy Results from AMPOWER
- Genitourinary Side Effects with Vaginal pH Regulator: Results from AMPOWER

ACOG abstracts were published in the May 2020 issue of Obstetrics & Gynecology (The Green Journal) (May 2020, Vol 135).

In September, pivotal results from Evofem's Phase 2b AMPREVENCE trial were presented at the 2020 STD Prevention Virtual Conference in a poster titled "**Efficacy and safety of a novel vaginal pH modulator for prevention of chlamydia and gonorrhea**." The biennial conference was organized by the U.S. Centers for Disease Control and Prevention (CDC) and the National Coalition of STD Directors.

About the AMPREVENCE Trial

AMPREVENCE was a double-blinded, placebo-controlled Phase 2b clinical trial that enrolled 860 women who had been treated for chlamydia or gonorrhea in the four months prior to enrolling in the study. Subjects were randomized to receive either EVO100 vaginal gel or placebo vaginal gel. During the four months the women participated in the study, they were asked to apply the product candidate or placebo prior to each act of vaginal sexual intercourse. The primary and secondary endpoints of the study were the reduction in the incidence of urogenital Chlamydia trachomatis and Neisseria gonorrhea, respectively. Fifty centers in the United States participated in this unprecedented trial.

About the AMPOWER Trial

AMPOWER was a single-arm, open-label Phase 3 study designed to evaluate the efficacy and safety of Phexxi™ (lactic acid, citric acid and potassium bitartrate) 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 evaluate the effects of a contraceptive product candidate on the impact of women's sex lives (exploratory endpoint).

IMPORTANT SAFETY INFORMATION

WHAT ARE THE POSSIBLE SIDE EFFECTS OF PHEXXI™ (lactic acid, citric acid, and potassium bitartrate) vaginal gel 1.8%, 1%, 0.4%?

If you have had a history of repeated urinary tract infections or other urinary tract problems, avoid Phexxi™.

The most common side effects were vaginal burning, vaginal itching, vaginal yeast infection, urinary tract infection, vaginal area discomfort, bacterial vaginosis, and vaginal discharge. Women also reported genital discomfort, pain while urinating, and vaginal pain. Some male partners reported genital discomfort.

WHAT ELSE SHOULD I KNOW ABOUT USING PHEXXI™?

Phexxi™ does not protect against any sexually transmitted diseases, including HIV. Avoid using Phexxi™ with a vaginal ring.

Contact your healthcare provider if you are experiencing severe genital irritation or discomfort or urinary tract symptoms. Avoid Phexxi™ if you or your sexual partner is allergic to lactic acid, citric acid, potassium bitartrate, or any of the ingredients in Phexxi™. Stop using Phexxi™ if you develop an allergic reaction.

Please see full Prescribing Information for Phexxi™, including Patient Information.

Please report side effects by contacting Evofem Biosciences® toll-free at 1-833-EVFMBIO or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

WHAT IS PHEXXI™?

Phexxi™ is a prescription vaginal gel used to prevent pregnancy in females who choose to use an on-demand method of birth control. Phexxi™ is only effective when used immediately before (or up to one hour before) each act of vaginal sex. Phexxi™ is not effective when used after vaginal sex.

About Evofem Biosciences

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 hormone-free, prescription vaginal gel approved in the United States for the prevention of pregnancy. The Company is also advancing EVO100 into a **Phase 3 clinical trial** for the prevention of urogenital transmission of both Chlamydia trachomatis and Neisseria gonorrhoeae in women. For more information, please visit **www.evofem.com**.

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 the planned clinical trial of EVO100 for prevention of Chlamydia trachomatis and Neisseria gonorrhoeae in women. 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 filed with the SEC on May 6, 2020 and August 4, 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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