Evofem Biosciences Announces Orange Book Listing of Two U.S. Patents for Phexxi®

SAN DIEGO, Dec. 11, 2020 /PRNewswire/ -- Evofem Biosciences, Inc., (NASDAQ: EVFM) today announced that two U.S. patents which cover Phexxi® (lactic acid, citric acid and potassium bitartrate) and its labeled indication are now listed in the U.S. Food and Drug Administration (FDA) publication *Approved Drug Products with Therapeutic Equivalence Evaluations,* commonly known as the Orange Book.

Phexxi is the first and only FDA-approved, non-hormonal contraceptive vaginal gel that is designed to be used immediately before or up to an hour before intercourse. It was approved in May 2020 and is now available in the U.S. by prescription. Phexxi works to maintain vaginal pH, which reduces sperm mobility, lowering the chance of sperm reaching the egg.

"The Orange Book listing of these two patents covering Phexxi's composition of matter and its method of use in prevention of pregnancy is an important step in the ongoing development of our patent portfolio, which currently covers Phexxi into 2033," said Evofem Biosciences CEO Saundra Pelletier. "We plan to further expand our intellectual property estate as we continue to develop and iterate our vaginal pH modulator platform for additional unmet medical needs, including the prevention of chlamydia and gonorrhea in women and other potential indications."

The newly listed method of use patent, number 10,568,855 (the '855 patent), covers contraception using the L-Lactic Acid Phexxi formulation. The '855 patent was issued by the U.S. Patent and Trademark Office (USPTO) on February 25, 2020 and is expected to expire in March 2033.

The newly listed patent number 6,706,276 (the '276 patent) is a composition of matter patent covering Phexxi®. Evofem has an exclusive license to this patent, which is held by Rush University. The '276 patent was issued by the USPTO on March 16, 2004, and is expected to expire in March 2026 based on the five-year patent term extension application that was timely filed by the patent owner.

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 evaluating EVO100 in a Phase 3 clinical trial, 'EVOGUARD,' for the prevention of urogenital *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infection in women. For more information, please visit www.evofem.com.

Phexxi® is a registered trademark of Evofem Biosciences, Inc.

About PHEXXI®

Phexxi® (lactic acid, citric acid, and potassium bitartrate) 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.

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.

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 anticipated duration of the newly listed patents and the anticipated five-year term extension for U.S. patent number 6,706,276. 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, including without limitation obtaining the patent term extension for the '276 patent, 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 Current Report on Form 8-K filed with the SEC on June 2, 2020, and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 filed with the SEC on November 9, 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.

Investor Relations Contact
Amy Raskopf
Evofem Biosciences, Inc.
araskopf@evofem.com
Mobile: (917) 673-5775

Media Contact
Ellen Thomas
Evofem Biosciences, Inc.
ethomas@evofem.com
Mobile: (718) 490-3248

SOURCE Evofem Biosciences, Inc.