# Evofem Announces Issuance of U.S. Patent Covering Phexxi® Composition of Matter

-- Issuance of U.S. Patent No. 11,439,610 Further Strengthens Evofem's Intellectual Patent Portfolio --

-- Newly Issued Patent Expected to Provide Protection for Phexxi into At Least 2033 --

SAN DIEGO, Sept. 23, 2022 /PRNewswire/ -- Evofem Biosciences (OTCPK: EVFM) today announced that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent No. 11,439,610, which covers the composition of matter of Phexxi® (lactic acid, citric acid, potassium bitartrate).

Phexxi is the first and only FDA-approved hormone-free, woman-controlled contraceptive gel that women use on demand. It works by maintaining vaginal pH in the optimal range of 3.5 to 4.5, which is inhospitable to sperm, as well as certain bacterial and viral pathogens including chlamydia and gonorrhea. Since Phexxi's initial launch in 2020, more than 100,000 women have been prescribed Phexxi by nearly 21,000 health care providers.

"We are extremely pleased with the continued development of the Phexxi patent portfolio, which comprises more than 40 patents. This newly issued patent expands the breadth and depth of our Phexxi intellectual property portfolio, adding composition of matter protection to our Orange Book-listed method of use patents and the further protection afforded by the QIDP designation granted by the FDA for the prevention of chlamydia and gonorrhea in women," said Saundra Pelletier, Chief Executive Officer of Evofem.

Top-line data from EVOGUARD, Evofem's registrational Phase 3 clinical trial evaluating Phexxi for these two potential new indications, are expected in mid-October. Preliminary CDC data for 2021 show that infections with chlamydia and gonorrhea continued to increase during the second year of the COVID-19 pandemic, with no signs of slowing.

At a medical conference this week, Leandro Mena, director of the CDC's Division of STD Prevention, said, "It is imperative that we... work to rebuild, innovate, and expand [STD] prevention in the U.S."

Positive outcomes of the EVOGUARD trial would enable regulatory submissions and potential approval of Phexxi for prevention of chlamydia and gonorrhea in 2023. There are currently no FDA-approved drug products to prevent these infections.  Mena notes that a decrease in condom usage, particularly among young people, is fueling the rising rates.

Over 1.6 million cases of chlamydia were reported in 2021. Chlamydia usually has no signs or symptoms, and most cases are identified through preventive care visits. Therefore, CDC notes it is likely chlamydia was disproportionately affected by reduced screening during the Covid-19 pandemic, resulting in undiagnosed infections.

That same year reported cases of gonorrhea increased for the eighth consecutive year to 700,000.

In 2020, about 50% of all gonorrhea infections were estimated to be resistant to at least one antibiotic.

The newly issued patent, entitled, "Compositions and Methods for Enhancing the Efficacy of Contraceptive Microbicides," is expected to provide protection into at least 2033. Evofem now has the sole right in the United States to make, have made, market, and sell for any commercial purpose the composition of matter that comprises Phexxi.

## About Phexxi

Phexxi is an on-demand method of birth control used to prevent pregnancy. Phexxi is not effective when used after sex.  For more information about Phexxi, talk to your healthcare provider and see full Product Information at **www.phexxi.com**.

## Important Safety Information

- Rare cases (0.36%) of bladder and kidney infections have been reported. If you have a history of urinary tract problems that keep coming back, you should not use Phexxi.
- Contact your healthcare provider if you are experiencing genitourinary side effects such as vaginal burning, itching, discharge, genital discomfort (including in male partners), yeast infection, urinary tract infection, or bacterial vaginosis.
- Phexxi does not protect against sexually transmitted infections, including HIV.

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**.

Intended for United States residents only.

## About Evofem Biosciences

Evofem Biosciences, Inc. is 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 chlamydia and gonorrhea. The Company's first FDA-approved product, Phexxi® (lactic acid, citric acid and potassium bitartrate), is a hormone-free, on-demand prescription contraceptive vaginal gel. It comes in a box of 12 pre-filled applicators and is applied 0-60 minutes before each act of sex. The Company expects to report top-line data in October 2022 from its registrational Phase 3 EVOGUARD clinical trial evaluating Phexxi for two potential new indications – prevention of chlamydia and prevention of gonorrhea in women. Learn more at **phexxi.com** and **evofem.com**.

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

## 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 anticipated impact the potential results of the Company's registrational Phase 3 trial and related implications on women's health and related markets. Various factors could cause actual results to differ materially from those discussed or implied in the forward-looking statements, including market and other conditions, 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 the Company's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 10, 2022, its Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 12, 2022. and subsequent filings. All forward-looking statements are expressly qualified in their entirety by such factors. The Company does not undertake any duty to update any forward-looking statement except as required by law. This press release contains estimates and other statistical data made by independent parties. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

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