Evofem Biosciences Receives Fast Track Designation for EVO100 for Prevention of Gonorrhea in Women

- Potential for Expedited NDA Review of EVO100 by FDA -

SAN DIEGO, May 12, 2021 /PRNewswire/ -- Evofem Biosciences, Inc., (NASDAQ: EVFM) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for EVO100 for the prevention of urogenital gonorrhea in women. Fast Track designation is designed to facilitate the development and expedite the review of new therapies to treat serious conditions and fill unmet medical needs.

According to a new report published by the Centers for Disease Control and Prevention, more than 600,000 cases of gonorrhea were reported in 2019, representing an increase for the sixth consecutive year.[1] Currently, there are no FDA-approved prescription products to prevent gonorrhea.

"We are pleased that the FDA has recognized the need for a product such as EVO100 to prevent this common STI, which is increasingly antibiotic-resistant," said Dr. Kelly Culwell, Evofem's Chief Medical Officer. "There are 78 million sexually active woman in the U.S. potentially at risk of contracting sexually transmitted infections, including gonorrhea.[2] Should EVO100 receive FDA approval as a preventive measure, this would be a welcome addition to the physician's armamentarium in the fight against this growing public health concern."

EVO100 previously received Fast Track designation from the FDA for the prevention of chlamydia in women and was also designated as a Qualified Infectious Disease Product (QIDP) by the FDA for the prevention of gonorrhea in women. A drug that receives QIDP designation may qualify for an additional five years of marketing exclusivity.

Evofem's pivotal Phase 3 clinical trial of EVO100 for prevention of chlamydia and gonorrhea in women, EVOGUARD, is currently enrolling 1,730 women in U.S. study sites. The Company expects to complete enrollment by year-end 2021 and to report top-line data in mid-2022. Positive outcomes could support submission of a New Drug Application to the FDA for these potential indications by the end of 2022, with an anticipated PDUFA date in the third quarter of 2023 due to the expedited review afforded by the Fast Track designation.

EVOGUARD builds on the positive, statistically significant results of the Phase 2B/3 AMPREVENCE trial. This double-blinded, placebo-controlled study of EVO100 met its primary and secondary efficacy endpoints, with statistically significant reductions in the risk of chlamydia and gonorrhea infections. The pivotal AMPREVENCE manuscript was published in March 2021 in the highly respected *American Journal of Obstetrics and Gynecology* (AJOG).

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 launched its first FDA-approved commercial product, Phexxi® (lactic acid, citric acid and potassium bitartrate) contraceptive vaginal gel, in the United States in September 2020. For more information, please visit www.evofem.com.

Phexxi® is a trademark of Evofem Biosciences.

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, the progress and prospects of the continued development of EVO100, included any potential timelines or evaluations of enrollment progress, the potential need or demand for EVO100, statements and evaluations regarding or implying potential market acceptance and patient attitudes. 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 the Company's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 4, 2021. 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 and by the Company relating to market size and growth and other data about its industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

References

- Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2019*. Atlanta: U.S. Department of Health and Human Services; 2021. Available at https://www.cdc.gov/std/statistics/2019/default.htm
- Based on US Census Projections, CDC Data Brief 327, available at https://www.cdc.gov/nchs/data/databriefs/db327_tables-508.pdf

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