Evofem Biosciences Announces Successful Type C Meeting with FDA for STI Prevention Product Candidate

SAN DIEGO, Nov. 30, 2021 /PRNewswire/ -- Evofem Biosciences, Inc. (NASDAQ: EVFM) today reported a successful Type C meeting with the U.S. Food and Drug Administration in which agreement was reached on the preliminary submission strategy for EVO100 for two investigational indications: the prevention of urogenital chlamydia in women and the prevention of urogenital gonorrhea in women. There are currently no FDA-approved prescription products to prevent either of these sexually transmitted infections (STIs).

Chlamydia and gonorrhea are the two most frequently reported bacterial STIs in the United States. More than 1.8 million cases of chlamydia and 600,000 cases of gonorrhea were reported in 2019, representing an increase for the sixth consecutive year.[1] However, because many infections are asymptomatic, reported cases only capture a fraction of the true burden.

Evofem's pivotal Phase 3 clinical trial of EVO100 for prevention of chlamydia and gonorrhea in women, EVOGUARD, is currently enrolling 1,730 women at study sites across the United States.

EVOGUARD builds on the positive results of the Phase 2B/3 AMPREVENCE trial, which 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 *American Journal of Obstetrics and Gynecology* (AJOG).

EVO100 received two Fast Track designations from the FDA for the prevention of chlamydia and prevention of gonorrhea in women. Fast Track is designed to expedite the review of new therapies to treat serious conditions and fill unmet medical needs. EVO100 is also designated a Qualified Infectious Disease Product by the FDA for the prevention of urogenital gonorrhea infection in women, which may provide an additional five years of marketing exclusivity.

The Company expects to report top-line EVOGUARD data in the second half of 2022. Positive outcomes could support submission to the FDA for these potential indications in the first quarter of 2023, with an anticipated PDUFA date in the second half of 2023 due to the expedited review afforded by the Fast Track designations.

"We are pleased that the FDA has recognized the unmet need in preventing these pervasive STIs and look forward to working closely with the Agency to facilitate the review and anticipated approval of what we believe will be the first product approved for the prevention of chlamydia and gonorrhea, as well as hormone-free contraception, in the United States," said Saundra Pelletier, CEO of Evofem Biosciences.

1 US Centers for Disease Control and Prevention – National Overview – Sexually Transmitted Disease Surveillance (2019)

About Evofem Biosciences

Evofem Biosciences, Inc., (NASDAQ: EVFM) is developing and commercializing innovative products and product candidates to address unmet needs in women's sexual and reproductive health, including hormone-free, woman-controlled contraception and protection from certain sexually transmitted infections (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. 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 timing and outcome of the pivotal Phase 3 trial and any submission or approval of EVO100 to the FDA. 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, 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.

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