Evofem Reports Top-Line Results from Phase 3 EVOGUARD Clinical Trial Evaluating EVO100 for Prevention of Chlamydia and Gonorrhea Infection in Women

SAN DIEGO, Oct. 11, 2022 /PRNewswire/ -- Evofem Biosciences, Inc. (OTCQB: EVFM) announced today that the recently completed Phase 3 EVOGUARD clinical trial evaluating EVO100 for the prevention of chlamydia and gonorrhea infection in women did not achieve its endpoints.

The product safety profile was consistent with what has been observed in prior clinical trials, and only two women (0.1%) in the study discontinued due to adverse events.

"We are disappointed that EVO100 did not achieve the desired outcome in this STI clinical trial, despite the data observed in our prior study," said Saundra Pelletier, Chief Executive Officer of Evofem. "The impact of the public health response to the COVID pandemic included universal recommendations for social distancing, individual and household quarantines, and clinic visits for health emergencies only. We believe changes in clinical site operations, subject behavior and actions including deviations from following the clinical study protocol requirements related to STI acquisition, detection, and prevention contributed to this outcome," added Pelletier.

"As clinical study lead for the Phase 2b/3 AMPREVENCE STI trial and the Phase 3 EVOGUARD trial, I believe the study environment changed significantly from the AMPREVENCE trial to the EVOGUARD trial, specifically subject risk behaviors as well as site and CRO turnover. In a non-COVID environment, I believe the results would have likely been different, and that infection rates would have been higher in the placebo arm, as was seen in AMPREVENCE," said Dr. Brandi Howard.

"As the lead statistician on both the Company's EVOGUARD trial and the earlier Phase 2b/3 STI study, I am surprised by these study results and I believe COVID impacted the observed infection rates," said Clint Dart, VP, Biostatistics and Programming at Premier Research.

"Prevention trials are challenging in their own right, even absent a pandemic environment," noted Lisa Rarick, MD, FACOG, a practicing ObGyn, former FDA division director and Evofem board member. "I believe STI prevention is important to prove, but we must not lose sight of the fact that Phexxi is an FDA-approved product that is the first and only non-hormonal, on-demand, prescription contraceptive that empowers women to control their fertility, always, whenever they want to."

As previously reported, Evofem has experienced strong growth in net sales of Phexxi® (lactic acid, citric acid and potassium bitartrate), as well as market access expansion, as payers and pharmacy benefit managers (PBMs) continue to add Phexxi to their formularies, allowing women to fill their prescriptions immediately.

At this time, the Company will focus on continuing to meet the unmet contraceptive need of millions of women with Phexxi but will discontinue further investment in the development of this STI clinical program due to financial resources.

About the EVOGUARD Trial

The EVOGUARD trial was a Phase 3, double-blind, placebo-controlled efficacy trial of Phexxi vaginal gel for the prevention of urogenital Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) infection. A total of 1903 women, ages ≥18, who had a documented urogenital CT or GC infection or an undocumented self-reported CT or GC infection with risk factors, at any time over the 17 weeks preceding the enrollment visit, or positive at screening visit were enrolled. Enrolled subjects were randomized 1:1 to receive either EVO100, 5g or placebo, 5g, supplied in a pre-filled, single-dose applicator, immediately before or up to one hour prior to coitus for the duration of the 16-week intervention period. The primary efficacy endpoint is the proportion of subjects in the modified Intent to Treat (mITT) population defined as all randomized subjects who were negative for CT and GC at enrollment and were provided with study product who successfully completed the 16 weeks without any chlamydia or gonorrhea infection as measured by nucleic acid amplification test; usage of prohibited antibiotics; or an invalid chlamydia or gonorrhea nucleic acid amplification test at 16 weeks.

About Evofem Biosciences

Evofem Biosciences, Inc., is developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. 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 the evaluations, interpretations and judgments regarding the top-line results, whether and to what extent COVID-19 impacted those results, whether and to what extent the top-line results are predictive of final results, and evaluations and judgments relating to Phexxi, recent revenue growth and market access. 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.

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