

Evoform Biosciences Completes Enrollment of Phase 3 Contraceptive Trial of Amphora Ahead of Schedule

Trial Data Expected First Quarter 2019

SAN DIEGO, Feb. 15, 2018 /[PRNewswire](#)/ -- Evoform Biosciences, Inc., (NASDAQ: EVFM) ("Evoform" or the "Company"), a biotechnology company developing innovative products to fill women's unmet healthcare needs, announced early completion of enrollment in its Phase 3 clinical trial evaluating Amphora[®] (L-lactic acid, citric acid, and potassium bitartrate) vaginal gel for the prevention of pregnancy. Trial data is expected in the first quarter of 2019.

This single-arm, open-label, multicenter, Phase 3 clinical trial enrolled over 1,350 women aged 18-35 at risk of pregnancy at over 100 centers in the United States. The primary endpoint of the study is the contraceptive efficacy of Amphora over seven cycles of use.

"The tremendous efforts of our investigators and women's enthusiasm towards the study enabled us to meet our target enrollment much faster than anticipated," said Brandi Howard, PhD, Evoform's VP of Global Clinical Development and Medical Affairs. "We believe this strong demand may be attributed to the non-hormonal attributes of Amphora which underscores the need for a new birth control option. We would like to thank our investigators and patients who are participating in this clinical trial, and look forward to reporting study outcomes in the first quarter of 2019."

Amphora is concurrently being evaluated in a double-blinded placebo-controlled Phase 2b/3 trial of Amphora for the prevention of urogenital chlamydia and gonorrhea in women. This sexually transmitted infection (STI) trial, which announced first patient enrollment on January 23, 2018, is designed to enroll approximately 850 women at up to 20 centers in the United States. Patients will be on-study for a four-month interventional period and subsequent one-month follow-up period.

"We believe it is time for women to have an on-demand method of contraception with no hormones," said Sandra Pelletier, Evoform Biosciences' CEO. "These differentiating attributes, combined with the potential to prevent two common and vexing STIs, position Amphora to fill a serious and substantial unmet need in women's health."

For more information on ongoing clinical trials of Amphora, visit www.clinicaltrials.gov.

About Amphora

Amphora is a non-hormonal, surfactant-free bioadhesive vaginal gel designed for on-demand use as needed or desired by a woman. This investigational new drug is being developed as an on-demand, non-hormonal vaginal contraceptive and for the prevention of certain sexually transmitted infections (STIs). A Phase 3 clinical trial of Amphora for the prevention of pregnancy and a Phase 2b/3 clinical trial of Amphora for the prevention of urogenital chlamydia and gonorrhea in women are underway. Amphora is designated as a Qualified Infectious Disease Product (QIDP) by the U.S. Food & Drug Administration for the prevention of urogenital gonorrhea infection in women. The Company's second multipurpose prevention technology (MPT) vaginal gel candidate has QIDP designation for the reduction of recurrence of bacterial vaginosis. These QIDP designations may enable Evoform Biosciences to more rapidly evaluate and make these drugs available to women at risk of these infections.

About Evofem Biosciences

Evofem Biosciences, Inc., (NASDAQ: EVFM) is a biotechnology company that develops and anticipates commercializing innovative products to address unmet needs in women's sexual and reproductive health. For more information regarding Evofem, visit www.evofem.com.

Forward-Looking Statements

Statements in this press release about Evofem's future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements about the results of the Phase 3 contraceptive clinical trial and any expected completion date for this clinical trial as well as statements about the results of the Phase 2b/3 STI clinical trial and any expected completion date for this clinical trial.

Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whether Evofem will be able to raise the additional funding necessary to complete its clinical trials, including the Phase 3 contraceptive clinical trial of Amphora and the Phase 2b/3 STI clinical trial; whether Evofem's product candidates will advance through the clinical trial process on a timely basis, according to presently contemplated schedules or at all; whether Evofem's product candidates will receive approval from regulatory agencies on a timely basis or at all; whether, if product candidates obtain approval, they will be successfully distributed and marketed and other factors discussed in the "Risk Factors-Risks Related to Evofem" section of a registration statement on Form S-4 initially filed with the Securities and Exchange Commission (the SEC) by Evofem Biosciences, Inc. (formerly known as Neothetics, Inc.) on November 15, 2017, a copy of which is available on the Evofem website. In addition, the forward-looking statements included in this press release represent Evofem's views as of the date hereof. Evofem anticipates that subsequent events and developments will cause its views to change. However, while Evofem may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Evofem's views as of any date subsequent to the date hereof.

Evofem Biosciences' Contact

Amy Raskopf
Investor Relations
araskopf@evofem.com
858-550-1900 x167

SOURCE Evofem Biosciences, Inc.
