

# Evoform Biosciences Announces First Patient Enrolled in Phase 2b/3 STI Trial of Amphora® and Expects Phase 3 Contraceptive Clinical Trial Data First Quarter 2019

STI Trial Investigates Amphora for Prevention of Urogenital Chlamydia Trachomatis Infection in Women

SAN DIEGO, Jan. 23, 2018 /PRNewswire/ -- Evoform Biosciences, Inc., (NASDAQ: EVFM), a clinical-stage specialty biopharmaceutical company focused on the development and commercialization of women's healthcare products, today announced enrollment of the first patient in a Phase 2b/3 clinical trial evaluating Amphora and its ability to prevent urogenital chlamydia and gonorrhea in women. Amphora is an investigational compound being studied for the prevention of certain reproductive tract infections and as an on-demand, non-hormonal vaginal contraceptive.

"We are excited to initiate this trial and expect that it will provide data in support of Amphora's use to prevent sexually transmitted infections, or STIs, in women when administered within one hour prior to sex," said Kelly Culwell, MD, Chief Medical Officer for Evoform Biosciences. "This STI study, along with Evoform's AMPOWER contraceptive efficacy trial, represents a significant step toward the development of a multipurpose prevention product."

AMPREVENCE, a Phase 2b/3 double-blinded placebo-controlled efficacy trial of Amphora for the prevention of acquisition of urogenital *Chlamydia trachomatis* infection in women, is intended to demonstrate Amphora's ability to prevent urogenital acquisition of *Chlamydia trachomatis* (primary endpoint) and *Neisseria gonorrhea* (secondary endpoint). Approximately 850 women at up to 20 centers in the United States are expected to be enrolled for a four-month interventional period and subsequent one-month follow-up period.

"In 2016, we saw the highest ever number of recorded cases of chlamydia and gonorrhea in the U.S. and of the two million recorded cases of sexually transmitted diseases in the U.S., 1.6 million were chlamydia. With this dramatic rise of STIs, along with the emergence of multi-drug resistant gonorrhea, the development of a preventative measure such as Amphora is even more critical," said Sandra Pelletier, Evoform Biosciences' CEO. "We believe that Amphora, as both a contraceptive and as a method of prevention of the acquisition of STIs, will fill a serious unmet need in women's health."

Evoform's current Phase 3 clinical trial evaluating Amphora for the prevention of pregnancy is expected to be fully enrolled in late February of 2018 with data reported in the first quarter of 2019. AMPOWER is a single-arm, open-label, multicenter study in women aged 18-35 years and is evaluating the contraceptive efficacy and safety of Amphora Contraceptive Vaginal Gel. The trial is expected to enroll approximately 1,350 women at risk of pregnancy at over 100 centers in the United States. The primary endpoint is the contraceptive efficacy of Amphora over seven cycles of use.

## About Amphora

Amphora is an on-demand non-hormonal, woman controlled, surfactant-free investigational new drug being developed as a vaginal contraceptive and for the prevention of certain sexually transmitted infections and is currently being evaluated in the AMPOWER Phase 3

clinical trial for the prevention of pregnancy. Amphora is also designated as a Qualified Infectious Disease Product (QIDP) by the U.S. Food & Drug Administration for two separate indications: the prevention of urogenital gonorrhea infection in women, and for the reduction of reoccurrence of bacterial vaginosis. These two QIDP designations could potentially offer a significant advancement in Evofem Biosciences' efforts to make this drug available to women at risk of infection.

## **About Evofem Biosciences**

Evofem Biosciences (Evofem) develops and anticipates commercializing innovative products that support and promote women as the primary healthcare consumer. Evofem is currently identifying and developing new and novel products to specifically address unmet needs in the areas of women's sexual and reproductive health, the prevention of acquisition of sexually transmitted infections and products that address or promote general health and wellbeing. For more information regarding Evofem, visit [www.evofem.com](http://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 AMPOWER study and any expected completion date for the AMPOWER study as well as statements about the results of the AMPREVENCE study and any expected completion date for the AMPREVENCE study.

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 AMPREVENCE clinical trial; whether Evofem's product candidates will advance through the clinical trial process on a timely basis, 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 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.

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