Evofem, Inc. Announces FDA Acceptance of New Drug Application for Amphora™ as a Contraceptive

San Diego, CA — Evofem, Inc. today announced that a New Drug Application for Amphora has been accepted for filing by the United States Food and Drug Administration (FDA). The NDA requests FDA approval for Amphora as a non-hormonal, vaginal gel contraceptive.

“We are delighted that the FDA has accepted this filing for Amphora,” said Evofem CEO Saundra Pelletier. “We believe that the data from our phase III trial with over 3,000 patients demonstrates that Amphora has the potential to be an important hormone-free contraceptive option for women.”

The application is supported by a large, multicenter, open-label, randomized, phase III trial that examined the repeated use of Amphora gel compared to a vaginal gel containing Nonoxynol-9 as the primary method of contraception over seven cycles of use. The FDA has also conditionally accepted the company’s proposed trade name of Amphora, a decision that would be finalized upon approval of the NDA.

About Amphora

Amphora is a non-hormonal vaginal gel. In addition to the regulatory filing for approval as a contraceptive, Amphora is being investigated for microbicidal properties to develop a potential multipurpose prevention technology. Amphora works by restoring the vaginal pH levels to those consistent with a healthy vaginal environment. A healthy vaginal environment acts against both sperm, as well as, viral and bacterial pathogens.

About Evofem, Inc.

Evofem, Inc. is a privately held biotechnology company that discovers, develops and commercializes prescription and over-the-counter products in the areas of feminine health and hygiene and for the prevention of sexually transmitted infections. Evofem, Inc. is committed to delivering effective, woman-controlled products and to distributing our products globally.

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