Evofem, Inc. Submits New Drug Application to U.S. FDA for Amphora™ as a Contraceptive

San Diego, CA – Evofem, Inc. announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for approval of Amphora as a contraceptive vaginal gel for women. The submission is based on the results of 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.

“Evofem is committed to our mission of empowering women by providing new innovations in women’s health and more ways for women to manage their fertility,” said Saundra Pelletier, Chief Executive Officer of Evofem, Inc. “Based on the results of the phase III trial, we believe Amphora can become an important and exciting new product for women and address a large unmet need in the market because it is woman-controlled, pericoital and hormone-free.”

About Amphora

Amphora is a non-hormonal vaginal gel. In addition to submission 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 which acts against both semen 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 care, contraception, and the prevention of sexually transmitted infections. Evofem, Inc. is committed to delivering effective, woman-controlled, rapidly reversible forms of contraception to women globally.

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