Evofem Files IND for Evaluation of Prevention of Recurrence of Bacterial Vaginosis

SAN DIEGO – March 31, 2016 — Evofem, a biotechnology company focused on the development and commercialization of women's health products, announced today that it filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) requesting clearance to begin human clinical trials for its lead product in development, a proprietary vaginal gel, to be evaluated for the prevention of recurrence of bacterial vaginosis (BV).

BV is an infection caused by an imbalance of bacteria in the vagina and is the most common vaginal infection in women ages 15-44. (Centers for Disease Control, 2014). Because the etiology and pathogenesis of BV are not completely understood, treatment for BV is not always effective, resulting in high recurrence rates (Sobel, 2009). Recurrent BV is generally defined as three or more episodes of BV per year, and one study found that 6-month recurrence rates were as high as 80 percent (Marrazzo J, 2010). Given the treatment challenges and the fact that BV is the most common vaginal infection for women of reproductive age, the condition causes considerable frustration for both patients and providers (Swidsinski A, 2008).

Current research suggests Evofem's proprietary vaginal gel works through a novel mechanism of action with potential efficacy in helping restore and maintain the proper balance of beneficial bacteria. The study Evofem will conduct is a randomized, placebo controlled study in a group of 100 women and will provide information on dose and dosing frequency for a subsequent Phase II prevention trial. The Company expects to initiate the study by May 2016 with planned completion within six months. The Company had previously announced a Pre-IND meeting to discuss BV with FDA in December 2015. Prior to that, a New Drug Application for Amphora® as a non-hormonal, vaginal gel contraceptive was submitted to the FDA in July of 2015 and accepted by FDA in September.

"Our team is working diligently to develop innovative treatments to meet the unmet medical needs of women," said Saundra Pelletier, Chief Executive Officer of Evofem. "This is a key milestone in the life cycle management of Amphora. Millions of women suffer from the recurrence of BV and Amphora has the potential to be an important new treatment option."

About Evofem

Evofem Holdings, Inc. seeks to address a growing global contraceptive market, while delivering effective, woman-controlled products with global distribution. Evofem has two lead product candidates: Amphora®, a vaginal contraceptive gel, and the Nestorone® Ring, a one-year contraceptive vaginal ring, both of which have completed Phase III clinical studies. For more information on the Company, visit www.evofem.com.

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