

## **AMPHORA® (L-lactic Acid, citric acid, and potassium bitartrate) Receives "Qualified Infectious Disease Product" (QIDP) Designation from the FDA**

San Diego, CA - Evofem Biosciences, a biotechnology company focused on the development and commercialization of women's health products, today announced that its drug candidate, AMPHORA, being studied for contraception and treating Sexually Transmitted Infections (STI) has been designated as a "Qualified Infectious Disease Product" (QIDP) by the U.S. Food & Drug Administration (FDA) for two separate indications: the prevention of urogenital gonorrhea infection in women, and to reduce the recurrent episodes of bacterial vaginosis (BV).

QIDP designation is intended to encourage development of new drugs for the treatment of serious or life-threatening infections. The threat level of drug-resistant gonorrhea is characterized as "urgent" in that it has an immediate public health threat that requires urgent and aggressive action. The threat level of vancomycin-resistant BV microorganisms is characterized as "serious" which means these bacteria are a serious concern and require prompt and sustained action to ensure the problem does not grow.

"BV is the most common vaginal infection among women of childbearing age and gonorrhea is the second most commonly reported infectious disease," said Kelly Culwell, MD, Chief Medical Officer for Evofem Biosciences. "According to the Centers for Disease Control (CDC), gonorrhea has developed resistance to nearly all the antibiotics used for treatment, and the recommended treatment for BV is currently only effective in 60% of all cases, with 30-40% recurrence rates."

A drug that receives QIDP designation may qualify for an additional five years of marketing exclusivity and is eligible for the FDA's fast-track program, intended to facilitate development and expedite review of drugs so that an approved product can reach the market expeditiously. Among other benefits the program allows for a priority review, with a goal of within 6 months for FDA to act on the New Drug Application.

"The studies we have conducted to date regarding contraception and vaginal infections suggest that AMPHORA may meet several unmet medical needs in women's health," said Sandra Pelletier, Evofem Biosciences CEO. "These two QIDP designations for AMPHORA are a significant advancement in our efforts to make this drug available to women at risk of infection."

### **About Gonnorrhea**

*Gonorrhoeae* has a major impact on health worldwide, with the highest morbidity and mortality occurring in females. Approximately 820,000 new gonococcal infections occur in the United States each year and it is the second most commonly reported infectious disease. Left untreated, gonorrhea infection can lead to significant health consequences such as pelvic inflammatory disease and infertility.

According to the CDC, the bacteria that causes gonorrhea has developed resistance to nearly all the antibiotics used for treatment: sulfonilamides, penicillin, tetracycline, and fluoroquinolones such as ciprofloxacin. Given the bacteria's ability to adapt and

survive antibiotics, the CDC states that it is critical to encourage research and development of new treatment regimens for gonorrhea.

### **About BV**

BV, a disturbance of vaginal microflora, is notorious for causing severe complications related to the reproductive health of women and left untreated can result in an entire array of serious gynecological and obstetric complications. It is a common cause of adverse vaginal symptoms and is associated with an increased risk of acquisition of sexually transmitted infections, HIV, and with significant adverse pregnancy outcomes such as premature labor and preterm delivery that leads to high prenatal mortality, and long-term neurological consequences in children.

According to the CDC, multiple drug resistant *enterococci* (bacteria associated with BV) have emerged, including those resistant to gentamicin, penicillin, and vancomycin.

### **About Evofem Biosciences**

Evofem Biosciences develops and commercializes innovative products that support and promote women as the primary healthcare consumer. Evofem Biosciences is currently identifying and developing new and novel products that specifically address unmet needs in the areas of sexual and reproductive health, the prevention of acquisition of sexually transmitted infections and products that address or promote general health and wellbeing. Evofem is currently developing AMPHORA as a vaginal contraceptive gel, and for the prevention of certain vaginal infections. For more information on the Company, visit [www.evofem.com](http://www.evofem.com)

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