Evofem's SOLOSEC Submitted for Marketing Approval in United Arab Emirates

— First ex-U.S. Regulatory Filing for SOLOSEC® —

— Pharma 1 Targets 1H 2026 Launch in UAE for SOLOSEC® to Treat Bacterial Vaginosis and Trichomoniasis, leveraging its commercial infrastructure and expertise in women's health —

SAN DIEGO, Oct. 1, 2025 /PRNewswire/ -- Women's health innovator **Evofem Biosciences, Inc.** (Evofem, or the Company) (OTCID: EVFM) announced today that its licensee for the Middle East and North Africa (MENA), private Emirati health care company **Pharma 1**, has filed an application with the United Arab Emirates (UAE) Ministry of Health and Prevention (MOHAP) seeking approval to commercialize **SOLOSEC® (secnidazole) 2 g oral granules**, Evofem's FDA-approved single-dose oral treatment for two common sexual health conditions.

"Bacterial vaginosis (BV) and trichomoniasis affect millions of people in the member states of the Gulf Cooperation Council (GCC). SOLOSEC treats both of these sexual health conditions with just one oral dose. With the submission complete, we are developing our commercial strategy and look forward to launching this important product in the UAE as quickly as possible following approval," said Abdulwahab Atfah, CEO of Pharma 1 Drug Store. "We expect SOLOSEC will be extremely well received in the medical community, among women with BV, and by men and women afflicted with trichomoniasis seeking a convenient, single-dose oral treatment."

"This filing is an important milestone towards the commercialization of SOLOSEC outside the U.S. and to further expand and diversify our revenue stream," said Saundra Pelletier, CEO of Evofem. "We look forward to receiving Pharma 1's initial order shortly after approval to support the launch in the UAE."

Pharma 1 holds the exclusive commercialization rights for SOLOSEC® and PHEXXI® (lactic acid, citric acid and potassium bitartrate) in the Middle East, including the UAE, Kuwait, Saudi Arabia, Qatar and certain other countries in the licensed Territory. In addition to obtaining and maintaining any regulatory approvals required to market and sell the products, Pharma 1 will handle all aspects of distribution, sales and marketing, pharmacovigilance, and all other commercial functions in these countries.

Since its inception in 2019, Pharma 1 has continued to successfully execute its mission of offering practical solutions to fulfill health care needs based on scientific studies and accurate surveys. The company's success reflects its substantial expertise, scientific approach, and agility to adapt to the very dynamic and growing market in the GCC.

SOLOSEC®, a single dose oral 5-nitroimidazole drug, is FDA-approved and indicated for the treatment of two sexual health diseases:

Bacterial vaginosis (BV), a common vaginal infection, in females 12 years of age and older

Trichomonas vaginalis, a common sexually transmitted infection (STI), in people 12 years of age and older
SOLOSEC® provides a complete course of therapy in just one dose.

Studies in the Middle East and North Africa (MENA) region have reported BV prevalence ranging from 25% to 41%. A systematic review and meta-analysis of global BV prevalence among reproductive-aged women in the general population found that one in four women in MENA have BV[1]. In the UAE alone, this represents between 1.0 million and 1.7 million women.

Despite the availability of anti-infectives approved to treat Trichomonas vaginalis, the parasite that causes trichomoniasis, in 2020 the WHO estimated 156.3 million new cases of **trichomoniasis** worldwide: 73.7 million in females and 82.6 million in males.[3] Undiagnosed infections and lack of compliance with multi-day treatment regimens are critical contributing factors.

A meta-analysis of evidence sourced from 263 international, regional, and national databases found that MENA has a substantial trichomoniasis prevalence, with approximately 4.7% of women in the general population affected by this sexually transmitted infection (STI).[2] Trichomoniasis was more common in intermediate- and high-risk populations (17.2% and 10.3%, respectively) and among symptomatic women (13.9%).

About Bacterial Vaginosis

Bacterial vaginosis (BV), the most common cause of vaginal discharge in reproductive-age women[1], is associated with multiple consequential adverse outcomes including an increased risk of adverse birth outcomes, acquisition of human immunodeficiency virus and other STIs, pelvic inflammatory disease, and a high incidence of symptomatic recurrence.[4] A study published in the New England Journal of Medicine in 2025 provided evidence that BV is in fact an STI.[5]

About Trichomoniasis

Trichomoniasis (or "Trich") is an STI caused by infection with Trichomonas vaginalis, a protozoan parasite. It is the most common nonviral STI globally, affecting an estimated 156 million men and women worldwide. [3] The CDC notes that up to 70% of people infected with Trich are unaware that they are infected and may unwittingly pass the parasite to sexual partners.[6] Untreated infections might last from months to years.

In women, Trich can cause a foul-smelling vaginal discharge, genital itching, and pain with urination or sex. Trich is also associated with an increased risk for cervical cancer, infertility, HIV acquisition, and, among women with HIV infection, pelvic inflammatory disease (PID). Pregnant women who have Trich might be at higher risk of delivering their babies prematurely.

Men who have Trich typically have no symptoms, however when men do have symptoms these may include itching or irritation inside the penis, burning with urination or after ejaculation and discharge from the penis.[2]

About Evofem Biosciences

Evofem is commercializing innovative products to address unmet needs in women's sexual and reproductive health. The Company generates revenue from the sale of two FDA-approved products.

PHEXXI® (lactic acid, citric acid, and potassium bitartrate), is the first and only hormone-free, on-demand prescription contraceptive vaginal gel. It comes in a box of 12 pre-filled applicators and is applied 0-60 minutes before each act of sex. Visit **phexxi.com** to learn more and for important safety information.

SOLOSEC® (secnidazole) 2g oral granules is an FDA-approved oral antibiotic for the treatment of two sexual health diseases: bacterial vaginosis (BV), a common vaginal infection, in females 12 years of age and older, and trichomoniasis, a common sexually transmitted infection (STI), in people 12 years of age and older. SOLOSEC provides a complete course of therapy in just one dose. Visit **solosec.com** to learn more and for important safety information.

PHEXXI® and SOLOSEC® are registered trademarks of Evofem Biosciences, Inc.

About Pharma 1

Pharma 1 Drug Store is an Emirati company dedicated to providing practical solutions, backed by scientific studies and accurate surveys, that cater to the ever-evolving healthcare needs of people in the GCC and support development of a healthier community. Pharma 1 are agents to a growing number of pharmaceutical companies, with a variety of commercial products and medications in process with the Ministry of Health and Prevention. Learn more at https://pharma1ds.com/.

Sources

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Forward-Looking Statements

This press release includes "forward-looking statements," within the meaning of the safe harbor for forward-looking statements provided by Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. Words such as, but not limited to, "anticipate," "aim," "believe," "contemplate," "continue," "could," "design," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "seek," "should," "suggest," "strategy," "target," "will," "would," and similar expressions or phrases, or the negative of those expressions or phrases, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements include but are not limited to expected timing of the review by MOHAP of the SOLOSEC® dossier and outcome thereof. You are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Important factors that could cause actual results to differ materially from those discussed or implied in the forward-looking statements are disclosed in the Company's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 24, 2025, amended on March 28, 2025, Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, filed with the SEC on August 14, 2025, and any subsequent filings. All forward-looking statements are expressly qualified in their entirety by such factors. The Company does not undertake any duty to

update any forward-looking statement except as required by law.

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