



## Evofem Signs SOLOSEC License Agreement for Middle East with Pharma 1

— Pharma 1 Targets Mid-2025 Regulatory Submission in UAE for SOLOSEC to Treat Bacterial Vaginosis and Trichomoniasis —

SAN DIEGO, May 21, 2025 /PRNewswire/ -- Women's health innovator **Evofem Biosciences, Inc.** (OTCPK: EVFM) and private Emirati health care company **Pharma 1 Drug Store LLC** have signed a License and Supply Agreement for the Middle East rights to **SOLOSEC® (secnidazole) 2 g oral granules**, Evofem's FDA-approved single-dose oral treatment for two common sexual health conditions.

Consideration to Evofem for the exclusive commercial rights to SOLOSEC in the Territory includes an upfront payment, payments on achievement of certain regulatory milestones, and sales-based milestone payments. Once approved, Evofem will supply SOLOSEC to Pharma 1 for sale in the Territory at cost-plus.

"SOLOSEC offers a convenient 'one-and-done' oral treatment for two common sexual health conditions, bacterial vaginosis (BV) and trichomoniasis, which affect millions of people in the member states of the Gulf Cooperation Council (GCC)," said Abdulwahab Atfah, CEO of Pharma 1 Drug Store. "We are pleased to secure exclusive commercial rights to SOLOSEC in the Territory and eager to file for regulatory approval of SOLOSEC in the United Arab Emirates (UAE) this summer."

"In addition to its strong brand identity, SOLOSEC is manufactured in the United States, which holds considerable value in markets where trust in quality, regulatory rigor, and prescriber confidence are key differentiators," added Mr. Atfah.

"We applaud Pharma 1's focus on sexual health, particularly in women, and are excited to expand our strong relationship beyond PHEXXI to now include SOLOSEC," said Evofem CEO Sandra Pelletier. "We are confident that Pharma 1 is the right partner to effectively launch and commercialize SOLOSEC in the UAE and surrounding region."

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<sup>1</sup>. 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.<sup>3</sup> 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).<sup>2</sup> Trichomoniasis was more common in intermediate- and high-risk populations (17.2% and 10.3%, respectively) and among symptomatic women (13.9%).

Under the terms of the agreement, Pharma 1 will have the exclusive commercialization rights for PHEXXI in the Middle East, including the UAE, Kuwait, Saudi Arabia, Qatar and certain other countries in the region. Pharma 1 will be responsible for obtaining and maintaining any regulatory approvals required to market and sell SOLOSEC, and will handle all aspects of distribution, sales and marketing, pharmacovigilance and all other commercial functions in these countries.

### About Bacterial Vaginosis

Bacterial vaginosis (BV), the most common cause of vaginal discharge in reproductive-age women<sup>1</sup>, 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.<sup>4</sup> A study published in the New England Journal of Medicine in 2025 provided evidence that BV is in fact an STI.<sup>5</sup>

### 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.<sup>3</sup> 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.<sup>6</sup> 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.<sup>2</sup>

### About SOLOSEC

**SOLOSEC® (secnidazole) 2 g oral granules** is a single dose oral 5-nitroimidazole drug. It is FDA-approved for the treatment of two sexual health diseases: Bacterial vaginosis (BV), a common vaginal infection, in females 12 years of age and older, and *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.

### About Evofem Biosciences

**Evofem Biosciences, Inc.** is commercializing two FDA-approved products to address unmet needs in women's sexual and reproductive health: PHEXXI and SOLOSEC. 2024 was its fourth consecutive year of net sales growth.

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

Peebles K, Vellozo J, Balkus JE, McClelland RS, Barnabas RV. High Global Burden and Costs of Bacterial Vaginosis: A Systematic Review and Meta-Analysis. Sex Transm Dis. 2019 May;46(5):304-311. doi: 10.1097/OLQ.0000000000000972. PMID: 30624309.

Harfouche M, Gherbi WS, Alareeki A, Alaama AS, Hermez JG, Smolak A, Abu-Raddad LJ. Epidemiology of Trichomonas vaginalis infection in the Middle East and North Africa: systematic review, meta-analyses, and meta-regressions. EBioMedicine. 2024 Aug;106:105250. doi: 10.1016/j.ebiom.2024.105250. Epub 2024 Jul 17. PMID: 39024899; PMCID: PMC11286989.

World Health Organization. Trichomoniasis Fact Sheet. 2024 November 25. Accessed 2025 May 15 via <https://www.who.int/news-room/fact-sheets/detail/trichomoniasis#:~:text=Key%20facts,%2C%2082.6%20million%20in%20males>.

Muzny CA, Balkus J, Mitchell C, et al. Diagnosis and management of bacterial vaginosis: summary of evidence reviewed for the 2021 Centers for Disease Control and Prevention sexually transmitted infections treatment guidelines. Clin Infect Dis. 2022;74:Suppl\_2:S144-S151.

Vodstrcil L, Plummer E, Fairley C, Hocking, Law M, Petoumenos M, Bateson D et al. Male-Partner Treatment to Prevent Recurrence of Bacterial Vaginosis. N Engl J Med. 2025; 392:947-957. DOI: 10.1056/NEJMoa2405404.

U.S. Center for Disease Control. Sexually Transmitted Diseases: About Trichomoniasis. Accessed 2025 May 15 via

<https://www.cdc.gov/trichomoniasis/about/index.html#:~:text=About%2070%25%20of%20people%20with,develop%20symptoms%20until%20much%20later>

### 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 planned filing for regulatory approval of SOLOSEC in the UAE. 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, and any subsequent Form 10-Q 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.

### Contact

Amy Raskopf  
Evofem Biosciences, Inc.  
[araskopf@evofem.com](mailto:araskopf@evofem.com)  
(917) 673-5775

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