



## Evofem Strengthens SOLOSEC Intellectual Property with New U.S. Patent from USPTO

-- Allowed Patent Extends SOLOSEC IP to 2040 with Broad Claims that are Orange Book-listable --

SAN DIEGO, Feb. 13, 2025 /PRNewswire/ -- **Evofem Biosciences, Inc.** (OTCQB: EVFM) today announced that the United States Patent and Trademark Office (USPTO) issued to the Company a Notice of Allowance for patent application 17/028,838, entitled "Method and Pharmaceutical Composition for Treating or Preventing Trichomoniasis and Uses Thereof." This Notice of Allowance is expected to result in the issuance of a U.S. patent once administrative processes are completed.

"This new U.S. patent extends SOLOSEC's IP protection by a full five years, from 2035 to 2040," said Sandra Pelletier, Chief Executive Officer of Evofem. "This extension, for the treatment of trichomoniasis, significantly benefits prescribers, patients, and our investors with a longer opportunity to build the SOLOSEC brand with its single-dose regimen."

The allowed patent application is directed to treatment of *Trichomonas vaginalis* infections (trichomoniasis) with **SOLOSEC® (secnidazole) 2 g oral granules**, with broad claims centered on pharmacokinetics and formulation features of Evofem's single-dose oral antimicrobial agent. Evofem expects the resulting patent will be Orange Book-listable.

Trichomoniasis is the most common non-viral sexually transmitted infection in the world. There are an estimated 6.9 million new infections with *T. vaginalis* in the U.S. each year.<sup>1</sup> Undiagnosed infections and lack of compliance with multi-day treatment regimens are critical contributing factors. All sexual partners of people infected with trichomoniasis should be treated with the same dose and at the same time to prevent reinfection. SOLOSEC® is designed to be easy to take; one oral dose contains a complete course of treatment.

SOLOSEC is the first and only single-dose oral antibiotic FDA-approved to treat bacterial vaginosis (BV) in females 12

years of age and older as well as trichomoniasis in people 12 years of age and older. Evofem acquired global rights to the product in July 2024 and relaunched SOLOSEC in the U.S. in November 2024 with its women's health-focused commercial team.

## About Trichomoniasis

Trichomoniasis (or "Trich") is a sexually transmitted infection (STI) caused by infection with *Trichomonas vaginalis*, a protozoan parasite. It is the most common nonviral STI globally. Up to 70% of people infected with Trich are unaware that they are infected and may unwittingly pass the parasite to sexual partners. 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, HIV acquisition, and, among women with HIV infection, pelvic inflammatory disease (PID). Pregnant women who have Trich may 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 Evofem Biosciences

**Evofem** is commercializing innovative products to address unmet needs in women's sexual and reproductive health. The Company's first FDA-approved product, **PHEXXI® (lactic acid, citric acid, and potassium bitartrate)**, is a 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.

In July 2024 Evofem broadened its commercial offering with the acquisition of **SOLOSEC® (secnidazole) 2g oral granules**, 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.

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

## 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. 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, 2023 filed with the SEC on March 27, 2024, Quarterly Report on Form 10-Q for the three months ended September 30, 2024 filed with the SEC on November 14, 2024, 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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## Sources

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Mayo Clinic. Diseases & Conditions: Trichomoniasis. 17 May 2022. Accessed 5 Nov 2024 at

<https://www.mayoclinic.org/diseases-conditions/trichomoniasis/symptoms-causes/syc-20378609>.

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