



FDA Orange Book Lists New U.S. Patent for SOLOSEC, Evofem Biosciences' "One and Done" Oral Treatment for Bacterial Vaginosis and Trichomoniasis

-- Evofem now holds eleven Orange Book - listed patents covering SOLOSEC into late 2041 --

SAN DIEGO, Aug. 19, 2025 /PRNewswire/ -- **Evofem Biosciences, Inc.** (OTCID: EVFM) today announced that a newly-issued U.S. patent which covers **SOLOSEC® (secnidazole) 2 g oral granules** and one of its labeled indications is now listed in the U.S. Food and Drug Administration (FDA) publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

"The Orange Book listing of this patent covering SOLOSEC's method, pharmaceutical composition, and use in trichomoniasis is an important step in further strengthening our patent portfolio," said Evofem Biosciences CEO Sandra Pelletier. "The patent itself extends SOLOSEC's intellectual property and market exclusivity into December 2041, which significantly benefits prescribers, patients, and our investors with a longer opportunity to build the SOLOSEC brand – the first and only single-dose oral treatment FDA-approved to treat BV as well as trichomoniasis – in the U.S."

The newly listed U.S. Patent No. 12,280,037 (the '037 patent) covers "method and pharmaceutical composition for treating or preventing trichomoniasis and uses thereof". The '037 patent was issued by the U.S. Patent and Trademark Office (USPTO) on April 22, 2025 and is expected to expire in December 2041. It is directed to treatment of *Trichomonas vaginalis* infections (trichomoniasis) with SOLOSEC, with broad claims centered on pharmacokinetics and formulation features of Evofem's single-dose oral antimicrobial agent.

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.¹ 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.

Patient recruitment is underway in an [investigator-led, NIH-funded Phase 4 clinical trial](#) evaluating the effectiveness and cost-effectiveness of SOLOSEC (single-dose, one time) versus metronidazole (twice daily for seven days) for the treatment of *T. vaginalis* in men and women. Study investigators hypothesize that the rate of repeat infections with *T. vaginalis* will be 1.75 lower in the SOLOSEC arm versus the multi-dose oral metronidazole arm and that single-dose SOLOSEC will have higher initial cost but will be more cost effective compared to multi-dose metronidazole, largely due to lower breakthrough rates of infection.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.

Evofem filed a preliminary proxy on July 24, 2025 regarding its planned Special Meeting of Stockholders at which stockholders of record may vote on a proposal to approve the transactions contemplated under the A&R Merger Agreement between the Company, Aditxt, Inc. (NASDAQ: ADTX) and Adifem, Inc., a wholly owned subsidiary of Aditxt. Under the A&R Merger Agreement, Adifem will merge with and into the Company, with Evofem surviving as a wholly owned subsidiary of Aditxt. A definitive proxy filing is expected in a few weeks.

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

Sources

Kreisel KM et al. [Sexually Transmitted Infections Among US Women and Men: Prevalence and Incidence Estimates, 2018](#). Sex Transm Dis. 2021 Apr 1;48(4):208-214. doi: 10.1097/OLQ.0000000000001355. PMID: 33492089; PMCID: PMC10245608.

National Institute of Allergy & Infectious Diseases (NIAID) of the National Institutes of Health. Award number R01AI183266: [Refining Trichomonas vaginalis treatment in women and men.](#)

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 anticipated timing of the definitive proxy filing regarding the planned Special Meeting of Stockholders. The closing of the transactions with Evofem, Aditxt and Adifem, Inc., contemplated by the A&R Merger Agreement are subject to several conditions including, but not limited to, 1) approval of the transactions by a majority of the combined voting power of Evofem's E-1 and Common Stock, voting together as a single class, at a meeting where quorum is present, and 2) Aditxt raising sufficient capital to fund its closing obligations, notably a cash payment of approximately \$15 million required to satisfy Evofem's senior secured noteholder. Should Aditxt fail to secure these funds, Evofem's senior secured noteholder is expected to seek to prevent the closing of the merger. No assurance can be provided that all of the conditions to closing will be obtained or satisfied or that the transaction will ultimately close. 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.

No Offer or Solicitation

This release shall not constitute a solicitation of a proxy, consent, or authorization with respect to any securities or in respect of the proposed transactions under the A&R Merger Agreement. This release shall also not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval, nor shall there be any sale of any securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such other jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act, or an exemption therefrom.

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