



Notable Data on Evofem's SOLOSEC in Recurrent Bacterial Vaginosis (BV) Released at ACOG Annual Meeting

-- BV Market Projected to Reach \$1.0 Billion in the U.S. by 2033 --

-- BV Affects 21 Million U.S. Women; As many as 50% Experience Recurrent BV Within Six Months of Treatment --

SAN DIEGO, June 11, 2025 /PRNewswire/ -- Women's health innovator **Evofem Biosciences, Inc.** (OTCPK: EVFM) today announced that a study of **SOLOSEC® (secnidazole) 2 g oral granules** for recurrent bacterial vaginosis (BV) presented at the 2025 American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting supports further development of SOLOSEC for the management of recurrent BV, a potential new indication.

In a focused clinical study of 24 women with recurrent BV, once-weekly dosing with secnidazole oral granules (SOLOSEC) demonstrated efficacy matching or potentially surpassing outcomes of current CDC-recommended suppressive treatments. These promising results underscore SOLOSEC's potential to redefine the standard of care for recurrent BV – offering a simpler treatment option for long-term symptom control.

Chemen M. Neal, MD, associate clinical professor at the Indiana University School of Medicine and lead investigator of the study, notes, "These study results demonstrate that 2 g oral secnidazole granules, dosed once-weekly, effectively suppressed recurrence of BV with recurrence rates equivalent to and possibly better than published study outcomes of current CDC-recommended suppressive treatments. We also believe there may be improved adherence by women managing their recurrent BV with the once-weekly oral dosing versus other, more complicated treatment regimens."

BV is the most common cause of vaginal discharge in reproductive-age women, affecting approximately 29% of U.S. women, or roughly 21 million individuals.^{1,2} Beyond discharge, BV symptoms include odor and irritation. These

symptoms can lead to embarrassment, social withdrawal, and diminished interest in relationships and physical activity. The many consequential negative outcomes associated with BV include an increased risk of adverse birth outcomes, acquisition of human immunodeficiency virus and other STIs, and pelvic inflammatory disease.³

These dynamics are driving significant commercial interest in more effective and manageable therapies. StrategyHorizon Insights projects the market for BV treatments in the U.S. will reach \$1.0 billion by 2033, propelled by increasing BV incidence, greater public health awareness, and improvements in diagnostic approaches.

Importantly, up to 50% of women who are treated for BV will experience a recurrence within six months, and nearly half will experience recurrence within one year of treatment. This high rate of symptomatic recurrence poses a substantial burden on the patients and the healthcare system alike.

A [recent article in the journal 'Contemporary OB/GYN'](#) notes that 'traditional treatment protocols for recurrent BV are burdensome, involving daily oral antibiotics followed by twice-weekly doses, or the use of intravaginal gels that can cause discomfort. Some regimens even combine oral and intravaginal treatments, making adherence particularly challenging,' and that 'many patients struggle with such complex regimens, especially over the extended periods needed for suppressive therapy.'

Once-weekly dosing of SOLOSEC represents a potential alternative to existing treatment regimens for recurrent BV. This approach involves a single oral dose each week, which may simplify administration and support treatment adherence. While SOLOSEC is currently approved for the treatment of BV in women aged 12 and older, its use in recurrent BV remains an investigational indication.

Dr. Neal presented the study, entitled '[Once Weekly Secnidazole Granules for the Treatment of Recurrent Bacterial Vaginosis](#),' at the ACOG Annual Meeting as an ePoster. She plans to submit the study for publication in a peer-reviewed journal.

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 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.
- **SOLOSEC® (secnidazole) 2 g 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.

Evoform's commercial team relaunched SOLOSEC in November 2024, and promotes the product alongside PHEXXI to OB/GYNs in the U.S. The Company is entering global markets through strategic partnerships, including a license agreement with emerging Emirati company Pharma 1 Drug Store LLC under which PHEXXI and SOLOSEC are expected to launch in the UAE in 2026.

As previously announced, Evoform entered into a definitive agreement to be acquired by Aditxt, Inc. (Nasdaq: ADTX). Through the proposed acquisition of Evoform under the July 2024 Amended and Restated Merger Agreement between Evoform, Aditxt and Adifem, Inc., as amended (the "A&R Merger Agreement"), Aditxt aims to add a dedicated women's health program to its social innovation platform accelerating promising health innovations. The companies are working toward a targeted close in the second half of 2025.

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

Sources

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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.

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 potential further evaluation of SOLOSEC for the investigational indication and potential outcomes thereof. The closing of the transaction with Evofem, Aditxt and Adifem, Inc., under the A&R Merger Agreement, as amended, is subject to several conditions including, but not limited to, 1) approval of the transaction 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 obligations at closing. These obligations include cash payments of approximately \$17 million for Evofem, which includes 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 with Evofem. 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, 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.

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