

BREXAFEMME® (ibrexafungerp tablets) Added to Major National Formulary, Providing Access for Millions More Commercially Insured Patients

A novel first-in-class, one-day oral antifungal treatment, BREXAFEMME is now covered for more than 45% of commercially insured patients in the U.S.

JERSEY CITY, N.J., Dec. 20, 2021 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: [SCYX](#)), a biotechnology company pioneering innovative medicines to overcome and prevent difficult-to-treat and drug-resistant fungal infections, today announced that BREXAFEMME® (ibrexafungerp tablets) has been added to a major national formulary, bringing total coverage for this innovative product to more than 45% of commercially insured patients in the U.S., according to the MMIT database, commonly used to track insurance coverage.

“We are extremely pleased to achieve such a significant level of reimbursement coverage, representing nearly half of commercially insured patients, so early in the launch of BREXAFEMME,” said Christine Coyne, Chief Commercial Officer of SCYNEXIS. “This formulary coverage allows appropriate patients to more easily access BREXAFEMME and reinforces recognition by payers of the unmet need that BREXAFEMME is filling for patients with VVC.”

BREXAFEMME is a novel first-in-class fungicidal triterpenoid antifungal, designed to kill the yeast causing the infection, including azole-resistant strains. It was approved by the U.S. Food and Drug Administration (FDA) in June 2021 as a treatment for vulvovaginal candidiasis (VVC), commonly referred to as vaginal yeast infection. The one-day oral medication represents the first new antifungal class approved by the FDA in more than 20 years.¹

About Vulvovaginal Candidiasis (VVC)

Vulvovaginal Candidiasis (VVC), commonly known as a vaginal yeast infection due to *Candida*, is the second most common cause of vaginitis. Although frequently caused by *Candida albicans*, infections caused by fluconazole-resistant and non-*albicans Candida* strains, such as *Candida glabrata*, have been reported to be on the rise.² VVC can be associated with significant discomfort (pain, itching, burning), reduced sexual pleasure and activity, psychological distress (stress, depression, anxiety), embarrassment, reduced physical activity, and loss of productivity. An estimated 70-75% of women worldwide will have at least one episode of VVC in their lifetime, and 40-50% of

those will experience multiple episodes.³

About BREXAFEMME® (ibrexafungerp tablets)

BREXAFEMME is a novel oral antifungal approved for the treatment of vulvovaginal candidiasis (VVC), also known as vaginal yeast infection. Its mechanism of action, glucan synthase inhibition, is fungicidal against *Candida* species, meaning it kills fungal cells.⁴ The New Drug Application (NDA) for BREXAFEMME was approved by the U.S. Food and Drug Administration (FDA) on June 1, 2021. The NDA was supported by positive results from two Phase 3, randomized, double-blind, placebo-controlled, multi-center studies (VANISH-303 and VANISH-306), in which oral ibrexafungerp demonstrated efficacy and a favorable tolerability profile in women with VVC. BREXAFEMME represents the first approved drug in a new antifungal class in over 20 years and is the first and only treatment for vaginal yeast infections which is both oral and non-azole.

INDICATION

BREXAFEMME is a triterpenoid antifungal indicated for the treatment of adult and postmenarchal pediatric females with vulvovaginal candidiasis (VVC).

DOSAGE AND ADMINISTRATION

The recommended dosage of BREXAFEMME is 300 mg (two tablets of 150 mg) twice a day for one day, for a total treatment dosage of 600 mg. BREXAFEMME may be taken with or without food.

IMPORTANT SAFETY INFORMATION

- BREXAFEMME is contraindicated during pregnancy and in patients with a history of hypersensitivity to ibrexafungerp
- BREXAFEMME administration during pregnancy may cause fetal harm based on animal studies. Prior to initiating treatment, verify pregnancy status in females of reproductive potential and advise them to use effective contraception during treatment
- When administering BREXAFEMME with strong CYP3A inhibitors, the dose of BREXAFEMME should be reduced to 150 mg twice a day for one day. Administration of BREXAFEMME with strong CYP3A inducers should be avoided
- Most common adverse reactions observed in clinical trials (incidence $\geq 2\%$) were diarrhea, nausea, abdominal pain, dizziness, and vomiting

To report SUSPECTED ADVERSE REACTIONS, contact SCYNEXIS, Inc. at 1-888-982-SCYX (1-888-982-7299) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information, visit www.brexafemme.com. Please click [here](#) for Prescribing Information.

About SCYNEXIS

SCYNEXIS, Inc. (NASDAQ: SCYX) is a biotechnology company pioneering innovative medicines to help millions of patients worldwide overcome and prevent difficult-to-treat infections that are becoming increasingly drug-resistant. SCYNEXIS scientists are

developing the company's lead asset, ibrexafungerp (formerly known as SCY-078), as a broad-spectrum, systemic antifungal for multiple fungal indications in both the community and hospital settings. SCYNEXIS has initiated the launch of its first commercial product in the U.S., [BREXAFEMME® \(ibrexafungerp tablets\)](#), which was approved by the U.S. Food and Drug Administration (FDA) on June 1, 2021. In addition, late-stage clinical investigation of ibrexafungerp for the prevention of recurrent vulvovaginal candidiasis (rVVC) and the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. For more information, visit www.scynexis.com.

Forward-Looking Statements

Statements contained in this press release regarding expected future events or results are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to statements regarding: ease of access to BREXAFEMME and recognition by payers of the unmet need that BREXAFEMME is filling. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, but are not limited, to: BREXAFEMME may not be accepted by physicians and patients at the rate SCYNEXIS expects; and SCYNEXIS' reliance on third parties to commercialize its products. These and other risks are described more fully in SCYNEXIS' filings with the Securities and Exchange Commission, including without limitation, its most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, including in each case under the caption "Risk Factors," and in other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. SCYNEXIS undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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¹ Nosanchuk JD. Current status and future of antifungal therapy for systemic mycoses. Recent Pat *Antiinfect Drug Discov*. 2006 Jan;1(1):75-84. doi: 10.2174/157489106775244109. PMID: 18221136. <https://pubmed.ncbi.nlm.nih.gov/18221136/> Accessed September 7, 2021.

² Berkow EL, Lockhart SR. Fluconazole resistance in *Candida* species: a current

perspective. *Infect Drug Resist.* 2017;10:237-245. Published 2017 Jul 31. doi:10.2147/IDR.S118892. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546770/> Accessed September 7, 2021.

³ Zeng X, Zhang Y, Zhang T, Xue Y, Xu H, An R. Risk Factors of Vulvovaginal Candidiasis among Women of Reproductive Age in Xi'an: A Cross-Sectional Study. *Biomed Res Int.* 2018;2018:9703754. Published 2018 Jun 7. doi:10.1155/2018/9703754. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6011108/> Accessed September 7, 2021.

⁴ BREXAFEMME® U.S. prescribing information. June 2021.



Source: Scynexis