

## **SCYNEXIS Announces U.S. Availability of BREXAFEMME® (ibrexafungerp tablets), the First New Antifungal Class of Therapy Approved by the U.S. FDA for Vaginal Yeast Infections in More Than 20 Years**

- *First and only oral non-azole treatment option approved for vaginal yeast infections is now available in pharmacies including cloud-based pharmacy*
- *New treatment is fungicidal against Candida species, disrupting the fungal cell wall and killing the fungi causing the infection, rather than only inhibiting its growth*

JERSEY CITY, N.J., Sept. 22, 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 the U.S. availability of BREXAFEMME® (ibrexafungerp tablets), the first and only oral non-azole prescription medication approved by the U.S. Food and Drug Administration (FDA) to treat vulvovaginal candidiasis (VVC), commonly referred to as vaginal yeast infection.

“It’s incredibly exciting for all of us at SCYNEXIS to bring this innovative antifungal treatment to the millions of women across the country who suffer from yeast infections,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “This approval is just the first step to potentially building a wide-ranging ibrexafungerp antifungal franchise in multiple indications for broad patient community infections and in the hospital setting for life-threatening invasive fungal infections.”

BREXAFEMME, a one-day oral medication consisting of two pills (150 mg each) in the morning and two in the evening, is the first new antifungal class in more than 20 years.<sup>1</sup>

Christine Coyne, Chief Commercial Officer of SCYNEXIS, added, “Despite the fact that vaginal yeast infections are extremely common with about three out of four women experiencing them at least once in their life, until now there had been limited advancement in this area of women’s health for decades. BREXAFEMME is a truly new, first-in-class fungicidal triterpenoid antifungal, designed to kill the yeast causing the infection, including azole-resistant strains.”

As part of its commitment to ensuring patient access, SCYNEXIS has implemented programs to remove potential barriers and help patients receive treatment. A co-pay assistance savings program is available for eligible commercially insured patients.

Ibrexafungerp has been granted Qualified Infectious Disease Product (QIDP) and Fast Track

designations by the FDA for the treatment of VVC (approved indication) and prevention of recurrent VVC (in late-stage clinical investigation). Under QIDP designation, BREXAFEMME has 10 years of market exclusivity in the U.S., five years of new chemical entity exclusivity plus five additional years of exclusivity extension due to the QIDP designation. BREXAFEMME is also protected by multiple patents, with expected patent protection until at least 2035.

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

### **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.<sup>4</sup> 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.<sup>1</sup>

### **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](http://www.fda.gov/medwatch).

For more information, visit [www.brexafemme.com](http://www.brexafemme.com). Please click [here](#) for full 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](http://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: the commercial launch of BREXAFEMME is scheduled in the second half of 2021; the commercial potential for ibrexafungerp; expected duration of commercial exclusivity; SCYNEXIS' financial position will enable it to execute on its commercial plans; and SCYNEXIS' expectation that it will be submitting a supplemental NDA in the first half of 2022 for the use of BREXAFEMME for the prevention of recurrent VVC. 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; risks inherent in SCYNEXIS' ability to successfully develop and obtain FDA approval for ibrexafungerp for additional indications; unexpected delays may occur in the timing of acceptance by the FDA of an NDA submission; the expected costs of studies and when they might begin or be concluded; SCYNEXIS' need for additional capital resources; and SCYNEXIS' reliance on third parties to conduct SCYNEXIS' clinical studies and 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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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> BREXAFEMME<sup>®</sup> U.S. prescribing information. June 2021.

A document accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/d5300543-5d8a-4b1e-a162-0ee8121cacea>

Photos accompanying this announcement are available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/8ac21fa3-aefd-452c-a9ab-5a1b3ad7f4f8>

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Source: Scynexis

**BREXAFEMME® (ibrexafungerp tablets)**



**Product Image #1**

**BREXAFEMME® (ibrexafungerp tablets)**



**Package Image #2**

**BREXAFEMME® (ibrexafungerp tablets)**



**Product Logo**

**SCYNEXIS Logo**



**SCYNEXIS Company Logo**