

# SCYNEXIS Confirms that BREXAFEMME® (ibrexafungerp tablets) Qualifies for 10 Years of Regulatory Exclusivity for Vaginal Yeast Infections

- BREXAFEMME to receive 5-year exclusivity extension under the GAIN Act for a total of 10 years of regulatory exclusivity
- BREXAFEMME also protected by composition-of-matter patent until 2035
- Commercial launch update call is scheduled for Tuesday, June 29<sup>th</sup> @ 12pm ET

JERSEY CITY, N.J., June 09, 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 the U.S. Food and Drug Administration (FDA) granted BREXAFEMME (ibrexafungerp tablets), five years of exclusivity extension under the Generating Antibiotic Incentives Now (GAIN) Act. This exclusivity will be added to any other applicable exclusivity periods, such as the five years of new chemical entity (NCE) exclusivity, for a combined ten-year period of regulatory exclusivity. BREXAFEMME is also protected by multiple patents, including a composition-of-matter patent covering the ibrexafungerp molecule. With patent term extension, this patent is expected to expire in 2035, providing 14 years of protection from generic competitors in the U.S.

“With our first FDA approval behind us, we are very pleased to receive confirmation of BREXAFEMME’s five years of GAIN Act exclusivity for the treatment of vulvovaginal candidiasis,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “We believe BREXAFEMME is an important treatment option to help patients with often resistant fungal infections and we look forward to educating the healthcare community about the availability of this exciting new product. We will also continue to work hard to fully leverage this regulatory exclusivity and our long patent protection to advance our pipeline of ibrexafungerp indications. Our vision is to create a long-lasting antifungal franchise in both hospital and community settings. We will provide a more comprehensive update on our VVC commercial plans on June 29<sup>th</sup>.”

As a novel antifungal designed to treat serious and life-threatening infections, ibrexafungerp benefitted from Qualified Infectious Disease Product (QIDP) designation, which made it eligible to receive the GAIN Act exclusivity. This act was passed in 2012 for the purpose of stimulating the development and approval of new antibiotic and antifungal drugs.

## About Vulvovaginal Candidiasis

VVC, commonly known as a vaginal yeast infection due to *Candida*, is the second most common cause of vaginitis. Although these infections are 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. VVC can be associated with substantial morbidity, including significant genital discomfort (pain, itching, burning), reduced sexual pleasure and activity, psychological distress (stress, depression, anxiety), embarrassment, reduced physical activity, and loss of productivity. Typical VVC symptoms include pruritus, vaginal soreness, irritation, excoriation of vaginal mucosa and abnormal vaginal discharge. An estimated 70-75% of women worldwide will have at least one episode of VVC in their lifetime, and 40-50% of them will experience multiple episodes.

Currently approved treatments for VVC include BREXAFEMME (ibrexafungerp tablets), several topical antifungals, and oral fluconazole, which is the only other orally administered antifungal approved for the treatment of VVC in the U.S. and which has typically accounted for over 90% of the prescriptions written for this condition every year.

### **About BREXAFEMME® (ibrexafungerp tablets), for oral use**

BREXAFEMME is the trade name for ibrexafungerp, 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. 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. For more information, visit [www.brexafemme.com](http://www.brexafemme.com).

Please click [here](#) for full Prescribing Information.

### **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).

### **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. We are developing our 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. The New Drug Application (NDA) for BREXAFEMME<sup>®</sup> (ibrexafungerp tablets) was approved by the U.S. Food and Drug Administration (FDA) on June 1, 2021. For more information, visit [www.brexafemme.com](http://www.brexafemme.com). We are also continuing late-stage clinical development of ibrexafungerp for the prevention of recurrent VVC as well as the treatment of life-threatening invasive fungal infections in hospitalized patients. 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 potential for ibrexafungerp; expected duration of commercial exclusivity; and SCYNEXIS' vision to create a long-lasting antifungal franchise in both hospital and community settings. 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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A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/1ca08c25-c216-4a0d-b5c3-6801b1410df9>

The logo for SCYNEXIS, featuring the word "SCYNEXIS" in a bold, sans-serif font. The "S" and "Y" are purple, while "CYNEXIS" is orange. A small orange circle is positioned above the "X".

**BREXAFEMME® (ibrexafungerp tablets), for oral use**



**A novel oral antifungal approved for the treatment of vulvovaginal candidiasis (VVC), also known as vaginal yeast infection**

Source: Scynexis