

October 13, 2021



# **SCYNEXIS to Present Pooled Data Analysis Results Demonstrating Consistent Efficacy and Safety Outcomes Across Two Phase 3 VANISH Clinical Trials of Oral Ibrexafungerp Therapy for Vaginal Yeast Infection at October Medical Conferences**

JERSEY CITY, N.J., Oct. 13, 2021 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company pioneering innovative medicines to overcome and prevent difficult-to-treat and drug-resistant infections, today announced presentations of a pooled data analysis from its successful VANISH clinical development program during two October medical meetings: the Nurse Practitioners in Women's Health (NPWH) 24th Annual Premier Women's Healthcare Conference and the 4th Congress of the International Society for Infectious Diseases in Obstetrics and Gynecology (ISIDOG).

"Prior to the approval this year of BREXAFEMME<sup>®</sup> (ibrexafungerp tablets), the treatment landscape for vaginal yeast infections had not seen a new class of antifungals since the 1990s despite the fact that three out of four women suffer from this condition at least once over the course of their lives," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "We are deeply committed to innovation in the field of women's health and are extremely pleased to be able to share this additional pooled data analysis from our groundbreaking VANISH clinical research."

Data Presentation Details:

**24th Annual NPWH Premier Women's Healthcare Conference, October 13-16, 2021**

## **Product Theater:**

**Title:** BREXAFEMME<sup>®</sup> (ibrexafungerp tablets) – A Novel, Oral Treatment for Vulvovaginal Candidiasis

**Location:** Virtual

**Date:** Thursday, October 14, 2021

**Time:** 2:00 p.m. – 3:00 p.m. EDT

## **Poster Presentation:**

**Title:** Efficacy and Safety of Oral Ibrexafungerp in Subjects with Vulvovaginal Candidiasis: Pooled Data from Two Phase 3, Randomized, Blinded, Study vs. Placebo (VANISH-303 and VANISH-306)

**Poster: #326**

Learn more about the NPWH virtual conference [here](#). Meeting attendees can view the conference sessions and posters on demand until January 12, 2022.

#### **4th Congress of the International Society for Infectious Diseases in Obstetrics and Gynecology (ISIDOG), October 14-17, 2021**

##### **Presentation:**

**Session 9, Free Oral Communications #3 (Candida & Other): F.13 Efficacy and Safety of Oral Ibrexafungerp in Subjects with Vulvovaginal Candidiasis: Pooled Data from Two Phase 3, Randomized, Blinded, Study vs. Placebo (VANISH-303 and VANISH-306)**

**Date:** Saturday, October 16, 2021

**Location:** Budapest, Hungary, and online/virtual

**Time:** 2:30 a.m. – 3:50 a.m. EDT / 8:30 a.m. – 9:50 a.m. (CEST)

**Presenter:** Nkechi Azie, M.D., FIDSA, Vice President, Clinical Development and Medical Affairs, SCYNEXIS

Learn more about the ISIDOG 2021 hybrid congress [here](#).

#### **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>1</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>2</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>3</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>4</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). 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).

## CONTACT:

### Investor Relations

Irina Koffler  
LifeSci Advisors  
Tel: (646) 970-4681  
[ikoffler@lifesciadvisors.com](mailto:ikoffler@lifesciadvisors.com)

### Media Relations

Gloria Gasaatura  
LifeSci Communications  
Tel: (646) 970-4688

[ggasaatura@lifescicomms.com](mailto:ggasaatura@lifescicomms.com)

<sup>1</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>2</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>3</sup> BREXAFEMME<sup>®</sup> U.S. prescribing information. June 2021.

<sup>4</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.

The logo for SCYNEXIS, with 'SCY' in purple and 'NEXIS' in orange. The letter 'X' is stylized with a small circle above it.

Source: Scynexis