

April 30, 2021



# SCYNEXIS Presents Data at 2021 ACOG Demonstrating the Positive Outcome and Sustained Response of Investigational Oral Ibrexafungerp (Brexafemme™) in Difficult-to-Treat Patients with Vaginal Yeast Infections

- *A single-day dose of oral ibrexafungerp demonstrates positive clinical outcomes in difficult-to-treat vulvovaginal candidiasis (VVC) patient populations: those with non-albicans Candida VVC and/or severe VVC*
- *Brexafemme, the expected trade name for ibrexafungerp, an oral antifungal product candidate for the treatment of vaginal yeast infections, is under regulatory review by the FDA, with a PDUFA target action date set for June 1, 2021*

JERSEY CITY, N.J., April 30, 2021 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: [SCYX](#)), a biotechnology company pioneering innovative medicines to overcome and prevent difficult-to-treat and drug-resistant infections, presented posters on two data sets from the Company's Phase 3 VANISH Program demonstrating the therapeutic potential of ibrexafungerp (Brexafemme) as a treatment for vulvovaginal candidiasis (VVC), also known as vaginal yeast infection, at the 2021 American College of Obstetricians and Gynecologists (ACOG) Annual Meeting, taking place virtually from April 30 – May 2, 2021.

Presentation highlights are as follows:

**Title:** Phase 3 Oral Ibrexafungerp Study in Vulvovaginal Candidiasis (VANISH-303): Outcomes in Non-*albicans Candida* spp.

**Poster #:** ID961398

**Authors:** Dr. Nkechi Azie, Dr. David Angulo, Dr. Paul Nyirjesy

**Summary:** A sub-analysis of the VANISH-303 study identified 19 patients in the ibrexafungerp arm (300 mg BID, one-day oral dose) with non-*albicans Candida* (NAC) VVC. The current treatment recommendation is 7-14 days of topical azoles; fluconazole is not recommended. Treatment with ibrexafungerp resulted in a 42.1% clinical cure rate, defined as complete resolution of all Vaginal Signs and Symptoms (VSS=0) at the Day-10 test-of-cure visit, and 52.6% symptom resolution at the Day-25 follow-up visit. This analysis shows that clinical outcomes for NAC VVC patients on ibrexafungerp are comparable to all patients in the study. Furthermore, the trend of more patients having positive clinical outcomes and sustained response with ibrexafungerp by Day 25 was observed in all patients and the NAC sub-population.

**Title:** Efficacy and Safety of Oral Ibrexafungerp in the treatment of Vulvovaginal Candidiasis: A Phase 3 Study (VANISH-306)

**Poster #:** ID957079

**Authors:** Dr. Nkechi Azie, Dr. David Angulo, Dr. Ryan Sobel

**Summary:** The VANISH-306 study evaluated the safety and efficacy of oral ibrexafungerp as a treatment for patients with VVC (mITT 272 subjects). Severe VVC patients (VSS>7), categorized as complicated patients, accounted for 91.9% of the patients in the study. Current guidelines recommend that patients with severe symptoms receive a longer course of azole therapy. A one-day dose of oral ibrexafungerp demonstrated superiority to placebo, with clinical cure rate, defined as complete resolution of all Vaginal Signs and Symptoms (VSS=0) at the Day-10 test-of-cure visit, reported as 63.3% in the treatment arm vs. 44.0% in the placebo arm (p=0.007). Additionally, mycological eradication and clinical improvement, defined as VSS equal to 1 or 0, was seen in 58.5% and 72.3% of patients in the treatment arm, respectively, at the Day-10 test-of-cure visit (p<0.001, p<0.01). A one-day oral dose of ibrexafungerp may provide a treatment alternative for patients with VVC in the future, including severe cases where currently available treatments may not be satisfactory.

“*Candida albicans* has been the prominent species causing vaginal yeast infections, however, we are seeing a notable shift in the etiology candidiasis with non-*albicans Candida* species gaining prominence. Fluconazole is not recommended for treatment of non-*albicans Candida* VVC, often because of a high rate of resistance, leaving no oral treatment options for this difficult-to-treat patient population,” said Nkechi Azie, M.D., Vice President, Clinical Development and Medical Affairs of SCYNEXIS. “The data sets presented today show ibrexafungerp’s potential to treat a broad range of *Candida* species, including azole-resistant strains, as well as patients with severe VVC.”

Dr. Marco Taglietti, President and Chief Executive Officer of SCYNEXIS added, “Last year, an estimated 9.5 million women in the U.S. received prescriptions for vaginal yeast infections, however, about 40% of them required multiple prescriptions, illustrating a growing need for new treatment options. We believe our oral, fungicidal, non-azole candidate, ibrexafungerp, if approved for the treatment of vaginal yeast infections, may provide a significant benefit for clinicians and patients not satisfied with existing azole-based therapies.”

Brexafemme, the expected trade name for ibrexafungerp, an oral antifungal product candidate for the treatment of vaginal yeast infections, is under regulatory review by the U.S. Food and Drug Administration (FDA) with a PDUFA target action date set for June 1, 2021. The New Drug Application submission to the FDA was supported by positive data from two Phase 3, randomized, double-blind, placebo-controlled, multi-center studies (VANISH-303 and VANISH-306) in which oral ibrexafungerp demonstrated statistical superiority with a favorable tolerability profile.

All posters are live via the ACOG virtual meeting platform starting April 30<sup>th</sup> at 11 am ET. Register to attend via [Link](#).

The posters will be made be available for 3 months and can be found on the SCYNEXIS website at: <https://www.scynexis.com/news-media/events>

### **About Brexafemme™ (ibrexafungerp)**

Brexafemme is the expected trade name for ibrexafungerp, an oral antifungal product candidate under regulatory review 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. A New Drug Application (NDA) for Brexafemme is under review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) action date of June 1, 2021. The NDA is 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 statistically superior efficacy and a favorable tolerability profile in women with VVC. If approved, Brexafemme would represent the first novel antifungal class in over 20 years and would be the first and only non-azole oral treatment for vaginal yeast infections.

### **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.

Current treatments for VVC include several topical azole antifungals and oral fluconazole, which is the only orally administered antifungal currently approved for the treatment of VVC in the U.S. and which accounts for over 90% of the prescriptions written for this condition every year. Fluconazole reported a 55% therapeutic cure rate in its label, which now also includes warnings of potential fetal harm, illustrating the need for new oral alternatives. In addition, there are many women who often do not respond to or do not tolerate fluconazole, such as women with persistent (“chronic”) infections, recurrent infections (four or more recurrences in a 12-month period), Non-*albicans*/azole-resistant *Candida* strains (e.g., *Candida glabrata*), diabetic patients, especially with poorly controlled glycemia, and obese patients. These women could benefit from a non-azole, and preferably, oral treatment

option.

### **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. Our lead candidate, ibrexafungerp (formerly known as SCY-078), is a broad-spectrum, IV/oral antifungal agent representing a novel therapeutic class, currently under regulatory review for the treatment of vaginal yeast infection, also known as vulvovaginal candidiasis (VVC), and in late-stage development for the treatment of life-threatening fungal infections in hospitalized patients. The SCYNEXIS team has deep expertise in anti-infective drug development and marketing, which can be leveraged to advance ibrexafungerp from clinical development to commercialization. For more information, visit [www.scynexis.com](http://www.scynexis.com).

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The logo for SCYNEXIS features the word "SCYNEXIS" in a bold, sans-serif font. The letters "SCY" are in purple, "NEX" is in orange, and "IS" is in purple. A small orange circle is positioned above the letter "X".

Source: Scynexis