

# SCYNEXIS Announces Two Oral Presentations on Pooled Data from the BREXAFEMME (Ibrexafungerp tablets) Phase 3 VANISH Program Demonstrating Consistent Efficacy in the Treatment for Vaginal Yeast Infections at the IDSOG 2021 Virtual Annual Meeting

- *The pooled data from two Phase 3 studies (VANISH-303 and VANISH-306) of one-day oral ibrexafungerp reflect a population that overwhelmingly had severe yeast infections, a condition typically treated with multiple doses of oral fluconazole*
- *Ibrexafungerp demonstrated consistent efficacy in important patient sub-populations, characterized by age, race/ethnicity, body mass index and pathogen types*

JERSEY CITY, N.J., July 29, 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 two oral presentations of oral ibrexafungerp from its Phase 3 VANISH Program at the Infectious Diseases Society for Obstetrics & Gynecology (IDSOG) 2021 Virtual Annual Meeting, held on July 29 and July 30, 2021. The data presented demonstrate oral ibrexafungerp's safety and efficacy as a treatment for vulvovaginal candidiasis (VVC), also known as vaginal yeast infection.

"The data from our Phase 3 VANISH program demonstrated strong efficacy and a favorable tolerability profile in women with vaginal yeast infections and supported the recent FDA approval of BREXAFEMME<sup>®</sup>, which represents the first approved drug in a novel antifungal class in more than 20 years, offering the first and only oral non-azole treatment option for VVC patients," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "We believe that we can continue to build on this momentum in this category with our ongoing Phase 3 CANDLE study investigating ibrexafungerp for the prevention of recurrent VVC and expect to report topline data in the first half of 2022."

## Selected Important Safety Information

Most common adverse reactions observed in clinical trials (incidence  $\geq 2\%$ ) were diarrhea, nausea, abdominal pain, dizziness, and vomiting

See below for complete Important Safety Information

Oral presentation details:

<b>Title</b>	<b>Efficacy and Safety of Oral Ibrexafungerp in Subjects with Vulvovaginal Candidiasis: Pooled Data from Two Phase 3, Randomized, Blinded, Studies vs. Placebo (VANISH-303 and VANISH-306)</b>
<b>Abstract #</b>	<b>2</b>
<b>Presenter</b>	<b>Jack D. Sobel, MD</b>
<b>Session</b>	<b>Scientific Session 1</b>
<b>Highlights</b>	The Phase 3 VANISH-303 and VANISH-306 trials evaluated the safety and efficacy of oral ibrexafungerp as a treatment for patients with VVC. A pooled analysis of 376 patients receiving oral ibrexafungerp and 182 patients receiving placebo found that 94% of ibrexafungerp patients had severe disease. Clinical Cure Rate, defined as complete resolution of all Vaginal Signs and Symptoms (VSS=0) at the Day-10 Test-of-Cure visit, was reported as 56.9% in the treatment arm vs. 35.7% in the placebo arm (p=0.001). Overall, ibrexafungerp was well tolerated, with the most common treatment-related adverse events being gastrointestinal in nature.
<b>Title</b>	<b>Outcomes in Subpopulations from Pooled Phase 3 Clinical Studies of Oral Ibrexafungerp versus Placebo in Patients with Vulvovaginal Candidiasis (VANISH-303 and VANISH-306)</b>
<b>Abstract #</b>	<b>1</b>
<b>Presenter</b>	<b>Tosin Goje, MD</b>
<b>Session</b>	<b>Scientific Session 1</b>
<b>Highlights</b>	The study outlines a sub-population analysis of different patient demographics from the Phase 3 VANISH-303 and VANISH-306 trials evaluating efficacy of oral ibrexafungerp as a treatment for patients with VVC. Clinical Cure, defined as complete resolution of all Vaginal Signs and Symptoms (VSS=0) at the Day-10 Test-of-Cure visit, was 57.0% (n=374) in patients aged <65 years, 52.3% (n=107) in Black patients, 54.7% (n=75) in Hispanic or Latino patients, and 46.2% (n=65) in patients with BMI >35. These results are largely consistent with the overall clinical cure rate reported by the study and support ibrexafungerp's potential to treat all important populations impacted by VVC infections.

All presentations will be available on the SCYNEXIS website in the near future via [link](#).

## About Ibrexafungerp

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an antifungal agent and the first representative of a novel class of structurally-distinct glucan synthase inhibitors, triterpenoids. This agent combines the well-established activity of glucan synthase inhibitors with the potential flexibility of having oral and intravenous (IV) formulations. Ibrexafungerp is in late-stage development for multiple indications, including life-threatening fungal infections caused primarily by *Candida* (including *C. auris*) and *Aspergillus* species in hospitalized patients. It has demonstrated broad-spectrum antifungal activity, *in vitro* and *in vivo*, against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains.

The New Drug Application (NDA) for BREXAFEMME® (ibrexafungerp tablets) was approved by the U.S. Food and Drug Administration (FDA) on June 1, 2021. FDA also granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the IV and oral formulations of ibrexafungerp for the indications of invasive candidiasis (IC) (including

candidemia) and invasive aspergillosis (IA), and has granted Orphan Drug Designation for the IC and IA indications. Ibrexafungerp is formerly known as SCY-078.

### **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 potential clinical utility of ibrexafungerp, continuing to build on the momentum in the VVC category with the ongoing Phase 3 CANDLER study investigating ibrexafungerp for the prevention of recurrent VVC, and the expectation to report topline data in the first half of 2022. 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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The logo for SCYNEXIS, with 'SCY' in purple and 'NEXIS' in orange. The 'X' is stylized with a small circle above it.

Source: Scynexis