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SCYNEXIS Pivotal Phase 3 VANISH-306 Trial Results Published in the International Journal of Obstetrics and Gynaecology (BJOG) Demonstrate Statistical Superiority of BREXAFEMME® (Ibrexafungerp Tablets) Over Placebo for Vaginal Yeast Infection

- Patients receiving one-day treatment with oral ibrexafungerp had significantly higher rates of clinical cure, mycological eradication, and clinical improvement at Day-10 compared to placebo-treated patients.
- Ibrexafungerp demonstrated sustained clinical effect at Day-25 follow-up with 73.9% of treated patients achieving a complete resolution of signs and symptoms.
- The Phase 3 VANISH clinical trial program (VANISH-303 and VANISH-306) supported the approval of BREXAFEMME by the U.S. Food and Drug Administration (FDA) in June 2021.

JERSEY CITY, N.J., Nov. 23, 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 the peer-reviewed publication of results from its Phase 3 VANISH-306 study in the *International Journal of Obstetrics and Gynaecology (BJOG)*. Results from the VANISH-306 study show that treatment with oral ibrexafungerp achieved superiority over placebo with a high degree of statistical significance on key study endpoints and was generally safe and well-tolerated.

The VANISH development program's two pivotal Phase 3 superiority studies, VANISH-303 and VANISH-306, supported the U.S. Food and Drug Administration's (FDA) June 2021 approval of BREXAFEMME® (ibrexafungerp tablets) as a treatment for vulvovaginal candidiasis (VVC), also known as vaginal yeast infection. Please see prescribing information here.

"Ibrexafungerp is a first-in-class, one-day oral therapy that blocks glucan synthase, an enzyme critical for the maintenance of the fungal cell wall, and has shown *in vitro* fungicidal activity against multiple different *Candida* species strains, including those that are echinocandin and azole resistant," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "We believe the publication of findings from our VANISH-306 study will provide clinicians with valuable knowledge regarding the efficacy and safety of this groundbreaking treatment as a potent therapeutic option for possibly millions of women across the country."

VANISH-306 was a global, multi-center, randomized, double-blind, placebo-controlled study that evaluated the efficacy and safety of oral ibrexafungerp vs. placebo in women over the age of 12 with VVC. Ibrexafungerp demonstrated statistical superiority over placebo in the primary endpoint and all key secondary endpoints. At the test-of-cure (TOC) Day-10 visit, patients receiving ibrexafungerp had significantly higher rates of clinical cure vs. placebo (63.3% [119/188] vs. 44.0% [37/84]; P=0.007), which was defined as complete resolution of vulvovaginal signs and symptoms (VSS=0) without need for further antifungal treatment or topical drug therapy before or at the TOC visit. Day-10 results also showed significantly higher rates for ibrexafungerp vs. placebo in mycological eradication (58.5% [110/188] vs. 29.8% [25/84]; *P*<0.001), and clinical improvement (72.3% [136/188] vs. 54.8% [46/84]; *P*=0.01). Ibrexafungerp was generally well tolerated. Reported adverse events were primarily gastrointestinal and mild to moderate in severity.

In addition, at the Day-25 visit, symptom resolution was sustained and further increased with ibrexafungerp compared to placebo (73.9% vs. 52.4%; P=0.001). Significant results were also seen in patients with *C. albicans* at baseline, with complete symptom resolution (77.0% [127/165] of patients receiving ibrexafungerp compared to placebo (52.6% [40/76]; *P*<0.001).

The full VANISH-306 trial publication in BJOG can be found online here.

About the VANISH Program

The VANISH development program was comprised of two pivotal Phase 3, randomized, double-blind, placebo-controlled, multi-center studies designed to demonstrate superiority of oral ibrexafungerp versus placebo in patients with vulvovaginal candidiasis (VVC). Patients with a VVC infection and vulvovaginal signs and symptoms (VSS) score of four or greater on a scale of zero to 18 (maximum severity) were randomized to ibrexafungerp (two doses of 300 mg, 12 hours apart for one day) or placebo in a 2:1 ratio. The primary endpoint of each trial was clinical cure rate, defined as the complete resolution of all signs and symptoms (VSS=0) at the test-of-cure (TOC) visit (Day-10). Secondary endpoints included mycological eradication and change in VSS scores compared to baseline at Day-10 and at the follow-up visit at Day-25. VANISH-303 (NCT03734991) was conducted in the U.S., and VANISH-306 (NCT03987620) enrolled patients from sites in the U.S. and Europe. The studies were funded by SCYNEXIS.

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.[1] 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.[2]

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.[3] 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.[4]

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 ≥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.

For more information, visit 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.

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[1] Berkow, E. L., & Lockhart, S. R. (2017). Fluconazole resistance in *Candida* species: a current perspective. *Infection and drug resistance*, *10*, 237–245. https://doi.org/10.2147/IDR.S118892.

[2] Zeng, X., Zhang, Y., Zhang, T., Xue, Y., Xu, H., & An, R. (2018). Risk Factors of Vulvovaginal Candidiasis among Women of Reproductive Age in Xi'an: A Cross-Sectional Study. *BioMed research international*, *2018*, 9703754. https://doi.org/10.1155/2018/9703754.

[3] BREXAFEMME® U.S. prescribing information. June 2021.

[4] Nosanchuk J. D. (2006). Current status and future of antifungal therapy for systemic mycoses. *Recent patents on anti-infective drug discovery*, *1*(1), 75–84. https://doi.org/10.2174/157489106775244109.

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