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SCYNEXIS Pivotal Phase 3 VANISH-303 Trial Results Published in Clinical Infectious Diseases Demonstrate Significant Superiority of Ibrexafungerp Over Placebo for Treatment of Vaginal Yeast Infection

- In the Phase 3 VANISH-303 study, ibrexafungerp demonstrated significantly higher rates of clinical cure and infection eradication versus placebo.
- *Post hoc* analysis found ibrexafungerp demonstrated consistent efficacy in important patient sub-populations, characterized by race/ethnicity and body mass index.
- In the Phase 2 DOVE study, ibrexafungerp demonstrated similar efficacy to the current standard of care at the Day 10 visit with sustained efficacy at the Day 25 follow-up visit.

JERSEY CITY, N.J., Oct. 21, 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 the peer-reviewed publication of results from its Phase 3 VANISH-303 and Phase 2 DOVE studies in the Infectious Diseases Society of America's *Clinical Infectious Diseases.*

Findings from the pivotal Phase 3 VANISH-303 clinical trial led to the June approval by the U.S. Food and Drug Administration (FDA) of BREXAFEMME® (ibrexafungerp tablets) for the treatment of vulvovaginal candidiasis (VVC), the first new antifungal class of therapy in more than 20 years.

"We hope the publication of these important findings from the groundbreaking research of our VANISH-303 study will provide clinicians valuable insight regarding the efficacy and safety of ibrexafungerp for the treatment of vaginal yeast infections," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "With a distinct mechanism of action that effectively kills the fungi responsible for the infection, this treatment is an additional option for women across the country."

Publication Details

- **Ibrexafungerp versus placebo for vulvovaginal candidiasis treatment: a Phase 3, randomized, controlled superiority trial (VANISH-303)** – The randomized, double-blind, placebo-controlled study evaluated the efficacy and safety of oral ibrexafungerp for the treatment of VVC, also known as vaginal yeast infection.

- The study found that oral ibrexafungerp was statistically superior versus placebo in completely resolving signs and symptoms of VVC at Day 10 (50.5% [95/188] vs 28.6% [28/98], respectively; P=0.001) without the need for additional antifungal treatments, including topicals.
- Results also showed superior mycological eradication (49.5% [93/188] vs 19.4% [19/98]; P<0.001), when compared with placebo.
- Symptom resolution was sustained and further increased with ibrexafungerp compared with placebo (59.6% [112/188] vs 44.9% [44/98]; P=0.009) at follow-up.
- *Post hoc* analysis showed similar rates of clinical cure and clinical improvement at test-of-cure for African American patients (54.8% [40/73] and 63.4% [47/73], respectively) and patients with a body mass index >35 (54.5% [24/44] and 68.2% [30/44], respectively) compared with overall rates.
- Ibrexafungerp was well-tolerated. Adverse events were primarily gastrointestinal in nature and mild in severity.

The full Phase 3 VANISH-303 trial publication can be foundhere.

- **Phase 2 randomized study of oral ibrexafungerp vs. fluconazole in vulvovaginal candidiasis** – The results of the double-blind, randomized, dose-finding DOVE study, evaluated different regimens of ibrexafungerp and included fluconazole as comparator, the standard of care for the treatment of moderate to severe VVC. The study was designed to guide dose selection for the Phase 3 program and was not powered to demonstrate statistical differences among the groups. Patients with composite vulvovaginal signs and symptoms (VSS) scores greater than or equal to seven (≥7) were randomized equally to six treatments groups: five different dose regimens of oral ibrexafungerp or oral fluconazole 150 mg. The primary endpoint was the percentage of patients with a clinical cure, defined as complete resolution of VVC signs and symptoms at the test-of-cure visit on Day 10. Symptom resolution was also evaluated at Day 25.
  - The study identified the ibrexafungerp oral dose regimen of 300mg BID for one day as optimal for the Phase 3 program. The Day 10 clinical cure rate reported for this regimen was 51.9%, and 70.4% of patients reported no symptoms at Day 25. The active comparator (fluconazole) resulted in a Day 10 cure rate of 58.3% and 50.0% of patients with no symptoms at Day 25.*
  - The use of rescue antifungal medication during the study was reported in 3.7% of patients receiving the selected dose regimen of ibrexafungerp. For the same analysis, 29.2% of patients receiving fluconazole received rescue antifungal medications.*
  - Ibrexafungerp was well-tolerated, with the most common treatment-related adverse events being mild gastrointestinal events.

*It should not be inferred from these results that a claim of superiority of ibrexafungerp over fluconazole for the treatment of vulvovaginal candidiasis is being made.

The full Phase 2 DOVE publication can be foundhere.

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.

CONTACT:

Investor Relations
Irina Koffler
LifeSci Advisors
Tel: (646) 970-4681
ikoffler@lifesciadvisors.com

Media Relations
Gloria Gasaatura
LifeSci Communications
Tel: (646) 970-4688
ggasaatura@lifescicomms.com

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Source: Scynexis