November 3, 2022

Pooled Data from the Pivotal Phase 3 VANISH Program Published in the Journal of Women's Health Demonstrate Significant Efficacy of Ibrexafungerp Over Placebo for Treatment of Vaginal Yeast Infection

- Clinical cure rates, in the pooled analysis, were statistically significantly greater for ibrexafungerp when compared with placebo ($p < 0.0001$).
- In the pooled analysis, patients receiving ibrexafungerp experienced significantly higher rates of clinical improvement, complete symptom resolution, and mycological cure compared to placebo (all $p < 0.0001$).
- Ibrexafungerp demonstrated consistent efficacy in important patient sub-populations, characterized by race, body mass index, symptom severity, and *Candida* species infection.

JERSEY CITY, N.J., Nov. 03, 2022 (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 positive results from a pooled analysis of two Phase 3 studies (VANISH-303 and VANISH-306) in the *Journal of Women's Health.*

"We are proud to have the pooled analysis from our Phase 3 VANISH program published in this important peer-reviewed journal," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS "The publication of these pooled data yield the largest placebo-controlled analysis in the treatment of acute VVC, to our knowledge. We believe these data provide clinicians with valuable insights regarding the safety and consistent efficacy of ibrexafungerp as a potent potential treatment option for a broad spectrum of patients in need."

VANISH-303 and VANISH-306 were Phase 3 randomized, multi-center, double-blind, placebo-controlled studies that evaluated the efficacy and safety of oral ibrexafungerp compared to placebo for the treatment of acute VVC in females over the age of 12.

Key publication highlights:

- In the pooled analysis, ibrexafungerp demonstrated statistical superiority over placebo in all efficacy endpoints.
- Patients receiving ibrexafungerp experienced significantly higher rates at the test-of-cure visit compared to placebo in:

    - Clinical cure (vulvovaginal signs and symptoms (VSS) score = 0) (56.9% [214/376] vs 35.7% [65/182]; p < 0.0001)
    - Clinical improvement (VSS score ≤1) (68.4% [257/376] vs 45.1% [82/182]; p < 0.0001)
    - Complete symptom resolution at the follow-up visit (symptom score = 0 without having received rescue antifungal treatment regardless of having achieved a clinical cure at the test-of-cure visit) (66.8% [251/376] vs 48.4% [88/182]; p < 0.0001)
    - Mycological cure (negative culture for *Candida* species) (54.0% [203/376] vs 24.2% [44/182]; p < 0.0001)
- Patients receiving ibrexafungerp who had severe VVC (VSS score ≥7) (94.1% [354/376]) experienced a clinical cure rate (56.2%) similar to the overall population (56.9%), and clinical cure rates remained unchanged with increasing VSS severity score.
- Ibrexafungerp was well-tolerated in the pooled analysis. Adverse events were primarily gastrointestinal in nature and mild in severity.

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).

The full pooled Phase 3 VANISH trial publication, titled "Oral Ibrexafungerp for Vulvovaginal Candidiasis Treatment: An Analysis of VANISH 303 and VANISH 306," can be found here.

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. 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.

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. Please click here for 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). The U.S. Food and Drug Administration (FDA) approved BREXAFEMME on June 1, 2021. The FDA has accepted the Company's sNDA submission for prevention of recurrent vulvovaginal candidiasis (VVC) and assigned a PDUFA decision date of November 30, 2022. In addition, late-stage clinical investigation of oral ibrexafungerp for the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. For more information, visit www.scynexis.com.

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Source: Scynexis