December 1, 2022

SCYNEXIS Announces FDA Approval of Second Indication for BREXAFEMME® (ibrexafungerp tablets) for Reduction in Incidence of Recurrent Vulvovaginal Candidiasis

- BREXAFEMME, an oral, non-azole medication, is the first and only FDA-approved therapy for both the treatment of vulvovaginal candidiasis (VVC) and the reduction in the incidence of recurrent VVC.
- Approval is based on pivotal Phase 3 CANDLE data demonstrating statistically significant superiority of ibrexafungerp over placebo for primary and key secondary endpoints.

JERSEY CITY, N.J., Dec. 01, 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 that the U.S. Food and Drug Administration (FDA) has approved a second indication for BREXAFEMME® (ibrexafungerp tablets) for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC).

“We are proud to be continuous innovators in the anti-infective space, and to provide a groundbreaking antifungal treatment option proven to reduce recurrence in women suffering from repeated vaginal yeast infections,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “BREXAFEMME was already the only non-azole oral therapy available for VVC and is now the only therapy FDA-approved for both VVC and RVVC. This exciting second indication supports our mission to arm both patients and healthcare providers with innovative solutions in the fight against severe fungal infections.”

The approval is based on positive results from the pivotal Phase 3 CANDLE study that evaluated the safety and efficacy of monthly dosing of ibrexafungerp to reduce the incidence of RVVC. Results showed that 65.4% of patients receiving ibrexafungerp achieved clinical success by having no recurrence at all, either culture-proven, presumed, or suspected, through Week 24 compared to 53.1% of placebo-treated patients (p=0.02). The advantage of ibrexafungerp over placebo was sustained over the three-month follow-up period and remained statistically significant (p=0.034). In the study, ibrexafungerp was generally safe and well-tolerated. The most commonly reported adverse events were headaches or were gastrointestinal in nature (i.e., diarrhea, nausea), and were mostly mild and generally consistent with the previous BREXAFEMME label.

“BREXAFEMME, which has the ability to kill the infection-causing fungi, also can reduce the

incidence of VVC episodes, benefiting many patients who have repeated infections and inadequate treatment options," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "We thank all the clinical investigators and patients who participated in our CANDLE study who made this achievement possible."

BREXAFEMME is now available to appropriate patients for both the VVC and RVVC indications, while the Company pursues a U.S. commercialization partner to maximize the drug's promotional reach and commercial value.

About BREXAFEMME® (ibrexafungerp tablets)

BREXAFEMME is a novel oral antifungal approved in June 2021 by the U.S. Food and Drug Administration for the treatment of vulvovaginal candidiasis (VVC). BREXAFEMME received approval for a second indication on November 30, 2022, for reduction in the incidence of recurrent VVC. Its mechanism of action, glucan synthase inhibition, is fungicidal against Candida species, meaning it kills fungal cells. 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 post-menarchal pediatric females with vulvovaginal candidiasis (VVC) and for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC).

DOSAGE AND ADMINISTRATION

The recommended dosage of BREXAFEMME for treatment of VVC is 300 mg (two tablets of 150 mg) administered approximately 12 hours apart (e.g., in the morning and in the evening) for one day, for a total daily dosage of 600 mg (four 150 mg tablets). The recommended dosage of BREXAFEMME in adult and post-menarchal females to reduce the incidence of RVVC is 300 mg (two tablets of 150 mg) administered approximately 12 hours apart (e.g., in the morning and in the evening) for one day, for a total daily dosage of 600 mg (four 150 mg tablets) monthly for 6 months. BREXAFEMME may be taken with or without food.

IMPORTANT SAFETY INFORMATION

There is a risk of embryo-fetal toxicity based on findings from animal studies. BREXAFEMME use is contraindicated in pregnancy.

- For females of reproductive potential, verify that the patient is not pregnant prior to initiating treatment with BREXAFEMME. Reassessment of pregnancy status prior to each dose is recommended when BREXAFEMME is used monthly for 6 months for reduction in the incidence of RVVC.
- Advise females of reproductive potential to use effective contraception during treatment of VVC and throughout the 6-month treatment period for reduction in the incidence of RVVC with BREXAFEMME and, for 4 days after the last dose.

BREXAFEMME is contraindicated in patients with a history of hypersensitivity to ibrexafungerp.

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%) of VVC were diarrhea, nausea, abdominal pain, dizziness, and vomiting. Most common adverse reactions observed in a clinical trial of RVVC were headache, abdominal pain, diarrhea, nausea, urinary tract infection and fatigue.

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, including boxed warning.

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, for its first indication in vulvovaginal candidiasis (VVC), followed by a second indication on November 30, 2022, for reduction in the incidence of recurrent VVC. In addition, late-stage clinical investigation of 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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