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SCYNEXIS Announces Submission of Supplemental New Drug Application of ibrexafungerp to the U.S. Food and Drug Administration for an Expanded Indication for the Prevention of Recurrent Vaginal Yeast Infections

- Regulatory submission for the label extension is supported by positive data from the pivotal Phase 3 CANDLE study in which ibrexafungerp successfully achieved statistically significant superiority over placebo for the primary and key secondary study endpoints.
- If approved, BREXAFEMME would be the first and only oral non-azole treatment for the prevention of recurrent vaginal yeast infections.
- In the Phase 3 CANDLE study in RVVC, ibrexafungerp was generally safe and well-tolerated with findings consistent with the existing BREXAFEMME label.

JERSEY CITY, N.J., June 08, 2022 (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 submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) of an additional indication for BREXAFEMME® (ibrexafungerp tablets) for the prevention of recurrent vulvovaginal candidiasis (RVVC).

BREXAFEMME, approved by the U.S. FDA in June 2021 for the treatment of vulvovaginal candidiasis (VVC), is a novel class of antifungal and the first and only oral fungicidal treatment that can cure a vaginal yeast infection in adults and postmenarchal pediatric patients. If approved for the additional indication, BREXAFEMME would be the first and only oral non-azole treatment for the prevention of recurrent yeast infections, defined as three or more episodes of VVC in the previous 12 months.

“This is an exciting and very important step in our efforts to bring our innovative, potent antifungal to market as a new alternative for women who suffer from recurring yeast infections,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “As the only non-azole oral therapy available for VVC, BREXAFEMME is already revolutionizing how yeast infections are treated. Now, based on our pivotal CANDLE trial for RVVC, we see that ibrexafungerp, which can kill the yeast causing the infection, has shown it also can prevent recurrences of the disease and help patients who have failed to respond to multiple doses of fluconazole. We are thrilled about this advancement, which takes us one

step closer to our vision of addressing this significant unmet need in women's health."

The sNDA submission is based on positive results from the SCYNEXIS global Phase 3 study (CANDLE) investigating the safety and efficacy of monthly dosing of ibrexafungerp for prevention of RVVC, which 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, headaches and gastrointestinal in nature (i.e., diarrhea, nausea), were mostly mild and generally consistent with the current BREXAFEMME label.

Ibrexafungerp has been designated by the FDA as a qualified infectious disease product (QIDP), allowing for a 6-month priority review. SCYNEXIS anticipates potential regulatory approval by the end of 2022.

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. BREXAFEMME was approved by the U.S. Food and Drug Administration (FDA) on June 1, 2021. The approval 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 the CANDLE Study

CANDLE was a Phase 3, multi-center, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of oral ibrexafungerp compared to placebo in 260 female patients with RVVC, defined as three or more episodes of VVC in the previous 12 months. The primary endpoint was clinical efficacy as measured by the percentage of subjects with documented Clinical Success (defined as subjects having no culture-proven, presumed or suspected recurrences of VVC through the test-of-cure (TOC) evaluation at Week 24). All patients in the CANDLE study initially received a three-day regimen of oral fluconazole to treat their acute episode present at screening. Patients who responded to oral fluconazole for their acute episode were enrolled in the prevention of recurrence phase of the study and randomized to oral ibrexafungerp (300 mg BID for one day) or placebo, given once per month for six months (a total of six treatment days). Patients who failed to sufficiently respond to fluconazole treatment for their acute episode were included in an open-label sub-study, in which they were offered one day of oral ibrexafungerp treatment (300 mg BID) for the unresolved acute episode.

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, as a broad-spectrum, systemic antifungal for multiple fungal indications in both the community and hospital settings. SCYNEXIS launched 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. In addition, clinical investigation and development of oral ibrexafungerp for the prevention of recurrent vulvovaginal candidiasis (VVC) and the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. For more information, visit 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: progressing filing of an sNDA for RVVC, of ibrexafungerp, its potential use by physicians and patients in multiple healthcare settings. 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: risks inherent in SCYNEXIS' ability to successfully develop and obtain FDA approval for ibrexafungerp for additional indications, including the IV formulation of ibrexafungerp; 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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