August 1, 2022

SCYNEXIS Announces U.S. Food and Drug Administration Acceptance and Priority Review of the Supplemental New Drug Application for BREXAFEMME® (ibrexafungerp tablets) for Prevention of Recurrent Vaginal Yeast Infections

- Submission has been granted priority review and given a target regulatory decision date of November 30, 2022.
- If approved for this second indication, BREXAFEMME would be the first and only therapy approved in the U.S. for both the treatment of vulvovaginal candidiasis (VVC) and the prevention of recurrent VVC.
- 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.
- SCYNEXIS will present CANDLE study results this week at the Infectious Diseases Society for Obstetrics and Gynecology (IDSOG) Annual Meeting being held in Boston, August 4-6, 2022.

JERSEY CITY, N.J., Aug. 01, 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 that the U.S. Food and Drug Administration (FDA) has accepted the Company's submission of a supplemental New Drug Application (sNDA) to expand the label of BREXAFEMME® (ibrexafungerp tablets) to include the prevention of recurrent vulvovaginal candidiasis (RVVC). The FDA granted the submission Priority Review and assigned the Prescription Drug User Fee Act (PDUFA) target decision date as November 30, 2022.

If approved for this second indication, BREXAFEMME, an oral non-azole therapy, would be the first and only product approved in the U.S. for both the treatment of vulvovaginal candidiasis (VVC) and the prevention of RVVC, defined as three or more infections in a 12-month period.

"The FDA's acceptance of this submission is excellent news for patients, and it brings us another step closer to our vision of addressing significant unmet needs in women's health," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "Our pivotal

CANDLE study was the basis of the sNDA submission, and we look forward to presenting details of these data to the medical community."

SCYNEXIS will present CANDLE study results this week at the Infectious Diseases Society for Obstetrics and Gynecology (IDSOG) Annual Meeting being held in Boston August 4-6, 2022.

Ibrexafungerp is designated by the FDA as a qualified infectious disease product (QIDP), allowing for a six-month priority review.

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 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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