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# SCYNEXIS Presents Positive Data from Phase 3 CANDLE Nested Sub-Study Investigating Ibrexafungerp in Women with Recurrent Yeast Infections Who Failed Fluconazole During the ISSVD XXVI World Congress and International Vulvovaginal Disease Update

- Data show that 71% of 24 patients with recurrent vulvovaginal candidiasis (RVVC) who failed to respond to a three-day regimen of fluconazole achieved a substantial reduction or complete elimination of signs and symptoms after receiving a one-day treatment with ibrexafungerp.

- Data show ibrexafungerp is a promising option for the potential treatment of women with acute VVC not responsive to a fluconazole seven-day regimen (three doses).

- SCYNEXIS plans to present CANDLE main study results this summer at the Infectious Diseases Society for Obstetrics and Gynecology (IDSOG) Annual Meeting in Boston, August 4-6, 2022.

JERSEY CITY, N.J., July 19, 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 presentation of positive outcomes from the CANDLE 304s nested sub-study investigating oral ibrexafungerp in patients with recurrent vulvovaginal candidiasis (RVVC) who failed fluconazole treatment. The results were presented during the International Society for the Study of Vulvovaginal Diseases (ISSVD) XXVI World Congress and International Vulvovaginal Disease Update 2022 held in Dublin, Ireland, July 15-20, 2022.

“We are thrilled to present these data demonstrating positive outcomes in RVVC patients who failed fluconazole therapy for an acute VVC episode,” said Nkechi Azie, M.D., Vice President, Clinical Development and Medical Affairs at SCYNEXIS. “The response to ibrexafungerp in this clinically challenging population is extremely encouraging and further demonstrates the potential efficacy of ibrexafungerp to treat recurrent yeast infections in patients with limited treatment options. We hope to expand upon these data with the recently announced Phase 3b VANQUISH study.”

The CANDLE open-label sub-study enrolled 24 patients who failed to respond to an initial three-doses of fluconazole given over seven days. Fluconazole failure was defined as

persistent vaginal signs and symptoms (VSS) score equal to or greater than three after therapy. Participants received a one-day treatment of ibrexafungerp (300 mg BID). In this population, 71% of patients (17 of 24) achieved a significant reduction or elimination of signs and symptoms after treatment with ibrexafungerp.

This positive trend was also confirmed in the subset of subjects who in addition to having a clinical failure also had persistent positive cultures after fluconazole treatment (microbiological failure). Favorable clinical response after a single day of ibrexafungerp was reported in eight of 10 subjects (80%) in this sub-group.

SCYNEXIS plans to present CANDLE main results next month during the Infectious Diseases Society for Obstetrics and Gynecology (IDSOG) Annual Meeting being held in Boston, August 4-6, 2022.

In addition, SCYNEXIS recently announced the first patient enrolled in its Phase 3b, open-label, multicenter VANQUISH study to evaluate the efficacy, safety and tolerability of oral ibrexafungerp as a treatment for complicated vulvovaginal candidiasis (VVC) in patients who have failed treatment with fluconazole, based on mycological and clinical outcomes. Complicated patients include patients with recurrent VVC, those with VVC caused by non-*albicans Candida* species and those with diabetes, immunocompromising conditions (e.g., HIV), or immunosuppressive therapy (e.g., corticosteroids).

In June, SCYNEXIS submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for an additional indication for BREXAFEMME® (ibrexafungerp tablets) for the prevention of RVVC. The submission was based on positive results from the CANDLE study, which showed that ibrexafungerp successfully achieved statistically significant superiority over placebo for the primary and key secondary study endpoints.

**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 Ibrexafungerp**

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an antifungal agent and the first representative of a novel class of structurally-distinct glucan synthase inhibitors, triterpenoids. This agent combines the well-established activity of glucan synthase inhibitors with the potential flexibility of having oral and intravenous (IV) formulations. Ibrexafungerp is in late-stage investigation and development for multiple indications, including life-threatening fungal infections caused primarily by *Candida* (including *C. auris*) and *Aspergillus* species in hospitalized patients. It has demonstrated broad-spectrum antifungal activity, *in vitro* and *in vivo*, against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. The U.S. Food and Drug Administration (FDA) approved BREXAFEMME® (ibrexafungerp tablets) on June 1, 2021. The FDA also granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the oral and IV formulations of ibrexafungerp for the indications of invasive candidiasis (IC), including candidemia, and invasive aspergillosis (IA) and has granted Orphan Drug Designation for the IC and IA indications. The European Medicines Agency (EMA) has granted ibrexafungerp Orphan Medicinal Product designation for the indication of IC. Ibrexafungerp is formerly known as SCY-078.

**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. 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.

## 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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