August 4, 2022

SCYNEXIS Presents Positive Data from Its Pivotal Phase 3 CANDLE Study of Oral Ibrexafungerp for Prevention of Recurrent Vaginal Yeast Infections During the 2022 IDSOG Annual Meeting

- The CANDLE study met its primary endpoint, with 65.4% of patients with recurrent vulvovaginal candidiasis (RVCC) who received monthly single-day ibrexafungerp treatment achieving clinical success with no recurrence at all, either culture-proven, presumed or suspected.

- Ibrexafungerp achieved statistically significant superiority over placebo in both primary and key secondary endpoints, including no mycologically proven recurrence in 70.8% of patients.

- In a nested sub-study of ibrexafungerp in RVVC patients who failed to respond to a three-day initial regimen of fluconazole, one-day treatment with ibrexafungerp achieved a substantial reduction or complete elimination of symptoms in 71% of patients.

- SCYNEXIS has submitted a supplemental New Drug Application (sNDA) for a label expansion to include the prevention of RVCC and anticipates final review by the U.S. Food and Drug Administration with a regulatory decision target date of November 30, 2022.

JERSEY CITY, N.J., Aug. 04, 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 its global Phase 3 CANDLE study investigating the safety and efficacy of oral ibrexafungerp for prevention of recurrent vulvovaginal candidiasis (RVVC), also known as vaginal yeast infection. The results were presented during the Infectious Diseases Society for Obstetrics and Gynecology (IDSOG) Annual Meeting being held in Boston August 4-6, 2022.

“We are pleased to present these results from our pivotal CANDLE study demonstrating positive outcomes in RVVC patients,” said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. “As the only fungicidal oral treatment for vaginal yeast infections, ibrexafungerp continues to demonstrate its ability to not only treat acute infections but also prevent recurrences of the disease. Importantly, in the nested sub-study ibrexafungerp also showed benefit to patients who failed to respond to multiple doses of fluconazole, illustrating its potential role in these difficult-to-treat infections.”

The Phase 3 CANDLE study evaluated 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. All patients initially received a three-day regimen of fluconazole, and responders were randomized to receive either 300 mg ibrexafungerp BID or matching placebo one day a month, for six months. The primary endpoint was efficacy as measured by the percentage of subjects with clinical success at test-of-cure (24 weeks).

The study met its primary endpoint, with 65.4% of patients who received monthly single-day ibrexafungerp treatment achieving clinical success with no recurrence at all, either culture-proven, presumed or suspected, through Week 24, compared to 53.1% of placebo-treated patients (p=0.02). In addition, ibrexafungerp demonstrated superiority over placebo in preventing mycologically proven recurrence of RVVC through Week 24, a key secondary endpoint. No mycologically proven recurrence was detected in 70.8% of patients receiving ibrexafungerp, compared to 58.5% of placebo-treated patients (p=0.019). The advantage of ibrexafungerp over placebo was sustained over the three-month follow-up period and remained statistically significant in both primary and secondary endpoints (p=0.034 and 0.029, respectively).

In addition, the study evaluated a sub-group of 24 patients who failed to respond to the initial three doses of fluconazole 150 mg on Days 1, 3, and 7. Sub-study participants received a one-day open-label treatment course of ibrexafungerp (300 mg BID). Results show that 71% of patients in the ITT population (vaginal signs and symptoms (VSS) score greater than or equal to 3; N=24) achieved a significant reduction or elimination of signs and symptoms following ibrexafungerp treatment. In addition, 80% of the mITT population (mycologically proven VVC after treatment with fluconazole; N=10) had a significant reduction or elimination of signs and symptoms.

In the study, ibrexafungerp was generally safe and well-tolerated. There were no serious drug-related adverse events, and no patients treated with ibrexafungerp discontinued therapy due to adverse events. 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.

“These important results highlight ibrexafungerp as a potential oral antifungal therapy that may transform how yeast infections are treated and provide an effective alternative for women with challenging and recurring yeast infections,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “Taken together, these outcomes paint a fuller picture of the potential broad utility of ibrexafungerp, as well as support an additional indication for BREXAFEMME. If approved for prevention of RVVC, ibrexafungerp would have the broadest label in the U.S. for treatment of VVC and prevention of recurrent yeast infection, providing an important treatment option to address this significant unmet need.”

Positive results from the CANDLE study were the basis of SCYNEXIS’s June 2022 sNDA submission to the U.S. Food and Drug Administration (FDA) for an additional indication for BREXAFEMME® (ibrexafungerp tablets) for the prevention of RVVC. The FDA granted the submission Priority Review and assigned the Prescription Drug User Fee Act (PDUFA) target decision date of November 30, 2022.

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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