February 10, 2022

# SCYNEXIS Announces Positive Results from Its Pivotal Phase 3 CANDLE Study of Oral Ibrexafungerp for Prevention of Recurrent Vaginal Yeast Infections, Clearing the Way for Regulatory Submission and Potential Approval of Additional Indication by End of 2022

- Ibrexafungerp, the only fungicidal oral treatment for vaginal yeast infections, successfully achieved statistically significant superiority over placebo for the primary and key secondary study endpoints.
- SCYNEXIS will submit a supplemental New Drug Application (sNDA) for BREXAFEMME® (ibrexafungerp tablets) for the prevention of recurrent vaginal yeast infections (rVVC) in the first half of 2022 with anticipated approval by the end of the year.
- Additionally, a one day treatment of ibrexafungerp achieved a substantial reduction or complete elimination of symptoms in a subset of study patients who failed to respond to a three-day regimen of fluconazole.
- In the study, ibrexafungerp was generally safe and well-tolerated with findings consistent with the existing BREXAFEMME label.
- SCYNEXIS will host a conference call today, **February 10 at 8:30 a.m. ET.**

JERSEY CITY, N.J., Feb. 10, 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 positive results 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 Company plans to submit the results to the U.S. Food and Drug Administration (FDA) in the first half of 2022 and anticipates receiving approval by year-end.

"Ibrexafungerp is the only oral fungicidal agent to successfully complete pivotal trials in both the acute treatment and prevention of yeast infections. As the only non-azole, we believe ibrexafungerp is changing how yeast infections are treated," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "These important results support an additional indication for BREXAFEMME for the prevention of rVVC. This exciting

achievement is another step in our efforts to bring to market meaningful and innovative solutions in the fight against a broad range of fungal infections and enhance shareholder value."

This trial was conducted under a Special Protocol Assessment (SPA), a process in which sponsors work with FDA to reach agreement on the design and size of a clinical trial to adequately address scientific and regulatory requirements for a study that could support marketing approval.

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 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). Secondary endpoints were consistent with the results of the primary analysis, and will be presented at a future medical meeting.

The study also evaluated an additional group of 24 patients who failed to respond to the initial three-day regimen of fluconazole and received a one-day open-label treatment course of ibrexafungerp (300 mg BID). In those patients treated with ibrexafungerp 71% successfully achieved 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 events were headaches and gastrointestinal events, which were mostly mild and generally consistent with the current BREXAFEMME label.

"After developing ibrexafungerp as the first approved oral non-azole agent to treat VVC, this study shows that it also prevents recurrences of the disease, as well as helps patients who failed to respond to multiple doses of fluconazole," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "We are excited to see these important results that further demonstrate the unmatched abilities of ibrexafungerp as a powerful oral antifungal therapy with potential broad utility against fungal infections. This is excellent news for women seeking relief from challenging and recurring yeast infections. We would like to thank all the patients and investigators who participated in this study and contributed to progressing the development of this innovative antifungal agent."

**Conference call and webcast details**

A conference call to discuss the results will be held at 8:30 a.m. EST

Investors (domestic): (877) 705-6003
Investors (international): (201) 493-6725

Conference ID: 13727104
Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1529072&tp_key=4c9cca34e0

**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 (300mg 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 (300mg 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 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 IV and oral 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. Ibrexafungerp is formerly known as SCY-078.

**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 full 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 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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