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SCYNEXIS Completes Patient Enrollment Ahead of Schedule in the Second Pivotal Phase 3 Study (VANISH-306) of Oral Ibrexafungerp for the Treatment of Vulvovaginal Candidiasis (Vaginal Yeast Infection)

- Top-line data expected in early second quarter of 2020

- NDA submission of oral ibrexafungerp for the treatment of vaginal yeast infections is on track for the second half of 2020

- Enrollment is ongoing in the Phase 3 CANDLE study of oral ibrexafungerp for the prevention of recurrent vaginal yeast infections, with a supplemental NDA submission anticipated in the second half of 2021

JERSEY CITY, N.J., Feb. 13, 2020 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today announced that it has completed patient enrollment in its global Phase 3 VANISH-306 study to evaluate the safety and efficacy of oral ibrexafungerp as a treatment for women with vulvovaginal candidiasis (VVC), commonly referred to as vaginal yeast infection. Ibrexafungerp, the first agent in a novel therapeutic class, is a broad-spectrum, IV/oral antifungal in late stage development for multiple indications, from the treatment and prevention of vaginal yeast infections to the treatment of life-threatening fungal infections in hospitalized patients.

"Vaginal yeast infections affect up to three out of four women at some point in their lifetimes, yet there is only one oral approved therapy that doesn't work for everyone, so we are committed to providing women with a novel oral alternative," said Marco Taglietti, M.D., president and chief executive officer of SCYNEXIS. "With enrollment now completed in this second pivotal Phase 3 trial (VANISH-306), and pending findings consistent with the previously reported positive results from our first Phase 3 study (VANISH-303), we remain on track to submit an NDA to the FDA for the treatment of VVC in the second half of 2020. Similar to the VANISH-303 study, the enrollment in this second study was completed about four months ahead of schedule, underscoring the global need for new vaginal yeast infection treatment options for both women and physicians."

Dr. Taglietti continued, "While VANISH-303 and VANISH-306 are expected to provide the

clinical evidence to support an indication for the treatment of VVC, enrollment continues in our CANDLE study for the prevention of recurrent VVC, with the potential for ibrexafungerp to be the first and only agent approved for both the treatment of vaginal yeast infections and prevention of recurrence. If approved, ibrexafungerp would represent the first new class of antifungals approved in over 20 years."

The VANISH-306 study enrolled 455 eligible subjects across the U.S. and Europe and randomized in a 2:1 ratio to a one-day treatment of either ibrexafungerp (two doses of 300-mg, 12 hours apart) or matching placebo. The primary endpoint of the study is the percentage of subjects achieving a clinical cure at the test of cure visit. More information about this study can be found at: https://clinicaltrials.gov/ct2/show/NCT03987620.

About the VANISH Program

The VANISH program is comprised of two Phase 3, randomized, double-blind, placebo-controlled, multi-center studies designed to demonstrate superiority of oral ibrexafungerp versus placebo. For each study, patients with a diagnosis of VVC are randomized to ibrexafungerp (two doses of 300mg 12 hours apart for one day) or placebo in a 2:1 ratio. Similar to the design of the Phase 2b DOVE study, the primary endpoint of each trial is clinical cure rate, defined as the complete resolution of all signs and symptoms (S&S) at the Test-of-Cure (TOC) visit (Day 10). Secondary endpoints include mycological eradication and change in S&S scores compared to baseline at both Day 10 and at the follow-up (FU) visit (Day 25). The VANISH-303 study was conducted in U.S. centers and the VANISH-306 study enrolled patients from sites in the U.S. and Europe. The Company anticipates top-line data for the VANISH-306 study in early second quarter of 2020 and plans to submit a New Drug Application (NDA) to the U.S. Food Drug Administration (FDA) for the treatment of VVC in the second half of 2020 based on the results from the VANISH program.

About Vulvovaginal Candidiasis (VVC)

VVC, commonly known as a vaginal yeast infection due to *Candida*, is the second most common cause of vaginitis. Although these infections are frequently caused by *Candida albicans*, fluconazole-resistant *Candida* strains, such as *Candida glabrata*, have been reported to become increasingly more common. VVC can be associated with substantial morbidity, including significant genital discomfort, reduced sexual pleasure, psychological distress and loss of productivity. Typical VVC symptoms include pruritus, vaginal soreness, irritation, excoriation of vaginal mucosa and abnormal vaginal discharge. An estimated 70-75% of women worldwide will have at least one episode of VVC in their lifetime, and 40-50% of them will experience two or more episodes. Approximately 6-8% of women with VVC suffer from recurrent disease, defined as experiencing at least three episodes within a 12-month period.

Current treatments for VVC include several topical azole antifungals (clotrimazole, miconazole, and others) and fluconazole, the only orally-administered antifungal currently approved for the treatment of VVC in the U.S. Fluconazole reported a 55% therapeutic cure rate in its label, which now also includes warnings of potential for fetal harm, illustrating the need for new oral alternatives. The needs of women with moderate-to-severe VVC, recurrent VVC, VVC caused by fluconazole-resistant *Candida* spp. or VVC during child-bearing age are not fully addressed by oral fluconazole or topical products. In addition, there are no oral alternatives for VVC patients who do not respond to or do not tolerate fluconazole, and there

are no FDA-approved products for the prevention of recurrent VVC.

About Ibrexafungerp

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an investigational 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 currently in development for the treatment of fungal infections caused primarily by *Candida* (including *C. auris*) and *Aspergillus* species. It has demonstrated broad-spectrum antifungal activity, *in vitro* and *in vivo*, against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. The FDA has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the formulations of ibrexafungerp for the indications of invasive candidiasis (IC) (including candidemia), invasive aspergillosis (IA) and VVC, and has granted Orphan Drug Designation for the IC and IA indications. Ibrexafungerp is formerly known as SCY-078.

About SCYNEXIS

SCYNEXIS, Inc. (NASDAQ: SCYX) is a biotechnology company committed to positively impacting the lives of patients suffering from difficult-to-treat and often life-threatening infections by developing innovative therapies. The SCYNEXIS team has extensive experience in the life sciences industry, having discovered and developed more than 30 innovative medicines over a broad range of therapeutic areas. The Company's lead product candidate, ibrexafungerp (formerly known as SCY-078), is a novel IV/oral antifungal agent in Phase 3 clinical and preclinical development for the treatment of multiple serious and life-threatening invasive fungal infections caused by *Candida* and *Aspergillus* species. For more information, visit www.scynexis.com.

Forward Looking Statement

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. 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's ability to successfully develop and obtain FDA approval for ibrexafungerp; the expected costs of studies and when they might begin or be concluded; and SCYNEXIS's reliance on third parties to conduct SCYNEXIS's clinical studies. These and other risks are described more fully in SCYNEXIS's filings with the Securities and Exchange Commission, including without limitation, its most recent Annual Report on Form 10-K under the caption "Risk Factors" and 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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