September 18, 2019

SCYNEXIS Completes Last-Patient/Last-Visit Ahead of Schedule in the First Phase 3 Study (VANISH 303) of Oral Ibrexafungerp for the Treatment of Vulvovaginal Candidiasis (VVC)

- Top-line results for VANISH 303 Phase 3 study expected by year-end 2019, earlier than previously anticipated

- Enrollment also exceeding expectations in the second Phase 3 study (VANISH 306), with its top-line results now expected in early second quarter of 2020

- NDA submission of oral ibrexafungerp for the treatment of VVC on track as anticipated in the second half of 2020

JERSEY CITY, N.J., Sept. 18, 2019 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today announced completion of the last-patient/last-visit in its Phase 3 VANISH 303 study, and that it expects to release top-line data earlier than previously reported. Ibrexafungerp (formerly SCY-078) is the first representative of a novel family of antifungal compounds referred to as triterpenoids. SCYNEXIS is developing ibrexafungerp for the treatment of both serious outpatient fungal infections as well as hospital-based, life-threatening fungal infections.

"I am proud to report that our VVC clinical studies are progressing ahead of schedule, showing the execution strength of our team. The last patient has completed her last visit in our first Phase 3 study, VANISH 303, and we now expect top-line data by the end of this year," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "Additionally, enrollment is also advancing ahead of expectations in our second Phase 3 study, VANISH 306, with data now anticipated in early second quarter of 2020."

Dr. Taglietti continued, "The rapid enrollment observed in our VVC studies reaffirms our belief that a large number of patients and their treating physicians are not satisfied with existing therapies and are looking for alternatives. It provides validation of our VVC commercial expectations for ibrexafungerp, as a non-azole, fungicidal, oral agent. We remain on-track for a New Drug Application (NDA) submission in the second half of 2020."

Ibrexafungerp Update:

Significant progress made in the Phase 3 VANISH program evaluating the safety and efficacy of oral ibrexafungerp (300mg BID for one day) for the treatment of VVC

- The VANISH program is comprised of two Phase 3, randomized, double-blind, placebo-controlled, multi-center studies:
  - The VANISH 303 study was conducted in U.S. centers and enrolled 376 patients. The last patient has now completed her final visit, ahead of schedule. Top-line data from the study is now expected by year-end 2019. More information about this study can be found at: https://clinicaltrials.gov/ct2/show/NCT03734991.
  - The VANISH 306 study is expected to enroll approximately 360 patients from sites in the U.S. and Europe; the enrollment rate is also exceeding expectations, and the Company now anticipates top-line data in early second quarter of 2020. More information about this study can be found at: https://clinicaltrials.gov/ct2/show/NCT03987620.
- All NDA preparatory activities remain on track to support a planned NDA submission in the second half of 2020.

About Vulvovaginal Candidiasis (VVC)

VVC, commonly known as a "vaginal yeast infection," 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 acute VVC include several topical azole antifungals (clotrimazole, miconazole, and others) and fluconazole, the only orally-administered antifungal currently approved for acute 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 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 (including prevention of recurrent 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. SCYNEXIS'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*, *Aspergillus* and *Pneumocystis* 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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ibrexafungerp-for-the-treatment-of-vulvovaginal-candidiasis-vvc-300920344.html

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