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SCYNEXIS Announces FDA Agreement with Company-Proposed Phase 3 Vulvovaginal Candidiasis Program for Oral Ibrexafungerp

Successful End-of-Phase 2 meeting provides clear regulatory path for both acute and recurrent VVC indications

On target to initiate Phase 3 registration program in the fourth quarter of 2018

JERSEY CITY, N.J., Oct. 23, 2018 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ:SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today announced the successful completion of an End-of-Phase 2 Meeting with the U.S. Food and Drug Administration (FDA) for its lead product candidate, ibrexafungerp (formerly SCY-078), for patients with vulvovaginal candidiasis (VVC). The FDA has agreed with the Company's proposed overall design of the Phase 3 registration program to support approval of oral ibrexafungerp for the treatment of VVC and prevention of recurrent VVC. SCYNEXIS expects to initiate the program in the fourth quarter of 2018.

Ibrexafungerp, the first representative of a novel oral and intravenous (IV) triterpenoid antifungal family, is in clinical development for the treatment of multiple serious fungal infections, including VVC, invasive candidiasis (IC), invasive aspergillosis (IA) and refractory invasive fungal infections. If approved, Ibrexafungerp would be the only oral alternative to azoles for the treatment of VVC and prevention of recurrent VVC.

"We are very pleased with the outcome of our End-of-Phase 2 meeting with the FDA, which provides a clear and straightforward regulatory path towards approval in both acute and recurrent VVC," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "With only one oral treatment option currently available for women with VVC, and no approved products for recurrent VVC, we believe oral ibrexafungerp can address the unmet needs in this highly prevalent infection, with the potential of achieving U.S. peak sales of $400-$600 million. Based on the positive feedback from the FDA, we reaffirm our guidance to initiate our registration program by year-end. With a cash runway into 2020, we are well-positioned to successfully execute our Phase 3 program, with a plan to file a New Drug Application (NDA) for the treatment of VVC in 2020."

The VVC registration program will be comprised of three global, multi-center, randomized, double-blind, placebo-controlled trials designed to demonstrate superiority of oral ibrexafungerp vs. placebo:

- **Treatment of VVC**: Two Phase 3 clinical trials will evaluate the safety and efficacy of the one-day, oral 600mg dose of ibrexafungerp (two doses of 300mg 12 hours apart), compared to placebo, in approximately 700 patients total (approximately 350 patients per trial). Patients with a diagnosis of VVC will be randomized to ibrexafungerp or placebo in a 2:1 ratio. Similar to the design of the Phase 2 DOVE study, the primary endpoint of each trial will be clinical cure rate (complete resolution of all signs and symptoms [S&S]) at the Test-of-Cure visit (Day 10). Secondary endpoints include mycological eradication, need for antifungal rescue therapy and change in S&S scores at Day 10 and at the follow-up visit (Day 25).
- **Prevention of Recurrent VVC**: One Phase 3 clinical trial will evaluate the safety and efficacy of the oral 600mg dose of ibrexafungerp (two doses of 300mg 12 hours apart) given once-a-month for six months, compared to placebo, in approximately 350 patients. Patients with a diagnosis of VVC and a history of at least three episodes of VVC in the past 12 months (including the current episode) will be randomized to ibrexafungerp or placebo in a 1:1 ratio after successful treatment of the active infection. The primary endpoint of the trial will be the percentage of patients without recurrence of VVC through the Test-of-Cure visit (Week 24). Secondary endpoints include time to first recurrence, mycological eradication and percentage of patients without recurrence of VVC through the treatment and subsequent follow-up period.

Pending successful completion of these trials, the Company anticipates filing an initial NDA for oral ibrexafungerp for the treatment of VVC in 2020 and a supplemental NDA for the prevention of recurrent VVC in 2021.

"Our Phase 2b DOVE study showed oral ibrexafungerp to have high clinical cure and mycological eradication rates, sustained clinical benefit compared to fluconazole and a favorable tolerability profile," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "Based on these positive clinical data, we are confident in our ability to conduct a successful registration program that will demonstrate statistical superiority of ibrexafungerp over the control. In addition, the differentiated attributes of ibrexafungerp versus fluconazole for this indication, most notably its fungicidal activity against *Candida* spp. including azole-resistant strains, enhanced antifungal activity in the acidic conditions of the vaginal environment and the fact that it has shown no adverse impact on embryo/fetal development in pre-clinical studies, will provide significant benefits to women not well-served by current treatments."

In May 2018, SCYNEXIS announced the receipt of Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA for the treatment of VVC and prevention of recurrent VVC. QIDP designation provides eligibility for priority review and an additional five years of market exclusivity in the U.S. for ibrexafungerp. The FDA's Fast Track Drug Development Program is a process designed to expedite the development and review of drugs to treat serious conditions and fill unmet medical needs.

About Vulvovaginal Candidiasis (VVC)
VVC, commonly known as a "vaginal yeast infection," is the second most common cause of vaginitis and is usually caused by *Candida albicans*. 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 8% of the 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 over-the-counter (OTC) topical azole antifungals (clotrimazole, miconazole, and others) and the prescription oral azole antifungal, fluconazole. Fluconazole, the only orally-administered antifungal currently approved for acute VVC in the U.S., reported a 55% therapeutic cure rate in its label, 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 treatment of recurrent VVC.

About Ibrexafungerp (formerly SCY-078)
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 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 QIDP and Fast Track designations for the formulations of ibrexafungerp for the indications of IC (including candidemia), IA and VVC, and has granted Orphan Drug Designation for the IC and IA indications.

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, discovering and developing 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 2 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, statements regarding: expectations for the timing of initiation of clinical trials, anticipated timing of the filing of an NDA for acute VVC in 2020 and recurrent VVC in 2021: 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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