July 24, 2019

SCYNEXIS Announces Special Protocol Assessment (SPA) Agreement with FDA for Phase 3 Study Evaluating Oral Ibrexafungerp for the Prevention of Recurrent Vulvovaginal Candidiasis (VVC) (CANDLE Study)

CANDLE study expected to begin enrolling patients with recurrent VVC, a condition with no FDA-approved therapies, this quarter

An open-label sub-study within CANDLE will explore ibrexafungerp's efficacy in patients who failed treatment with fluconazole

SCYNEXIS reaffirms guidance to submit an initial New Drug Application (NDA) for the treatment of VVC in the second half of 2020 and a supplemental NDA for the prevention of recurrent VVC in 2021

JERSEY CITY, N.J., July 24, 2019 /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 reached an agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) on the design, trial population, endpoints and statistical analysis of the CANDLE study, its pivotal Phase 3 clinical trial of oral ibrexafungerp for the prevention of recurrent VVC. This SPA provides agreement with the FDA that the Phase 3 protocol design adequately addresses efficacy objectives that, if met, would form the primary basis of a regulatory submission for approval of oral ibrexafungerp for the prevention of recurrent VVC, an indication with no FDA-approved therapies. Additionally, a sub-study assessing the efficacy of ibrexafungerp in treating the ongoing acute VVC infections in recurrent VVC patients who failed to sufficiently respond to multiple doses of fluconazole is embedded in the CANDLE study. Enrollment in the CANDLE study is expected to commence this quarter.

Ryan Sobel, M.D., Clinical Assistant Professor at Jefferson Health in Philadelphia, PA, founder of the Center for Vaginal Health and an investigator in SCYNEXIS's Phase 3 VVC program, commented, "We have been highly encouraged by the early clinical safety and efficacy results observed with oral ibrexafungerp in VVC patients, and we look forward to further elucidating its potential for the prevention of recurrent VVC. Together with the two ongoing Phase 3 clinical trials of oral ibrexafungerp for the treatment of VVC (VANISH studies), the CANDLE study may provide clinicians with additional evidence of the potential

of this novel agent to effectively treat VVC and prevent recurrence of the infection, addressing an ongoing unmet need for this patient population."

The CANDLE study is 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 female patients with recurrent VVC (defined as three or more episodes of VVC in the past 12 months). The primary endpoint of the study is efficacy as measured by the percentage of patients with no recurrences of VVC, up through their test-of-cure (TOC) evaluation at week 24. Secondary endpoints of the study include evaluation of VVC recurrences at other time points, time to first recurrence, mycological eradication and quality of life assessments. All patients in the CANDLE study will initially receive three doses of oral fluconazole to treat their acute episode present at screening. Patients who respond to oral fluconazole for their acute episode will be 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 a total of six treatment days. Patients who fail to sufficiently respond to fluconazole treatment for their acute episode will be included in a nested open-label sub-study, in which they will be offered one day of oral ibrexafungerp treatment (300mg BID) for their unresolved acute episode.

The CANDLE study, which is being conducted in female patients age 12 years and older living with recurrent VVC, is expected to enroll approximately 320 subjects from approximately 50 global centers, many of them already enrolling patients in the VANISH Phase 3 program.

More information on the Phase 3 CANDLE study can be found at clinicaltrials.gov.

"VVC is a prevalent and serious condition with significant morbidity, yet there is only one oral option available to treat acute episodes and no product approved for the prevention of recurrent VVC," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "This SPA agreement for the Phase 3 CANDLE study design clarifies the regulatory path to approval in recurrent VVC. The results from this study and the two ongoing acute VVC Phase 3 studies, can support the positioning of oral ibrexafungerp as the leading agent for both treatment of VVC and prevention of recurrent VVC. Moreover, a nested sub-study in the CANDLE study will provide valuable data assessing the efficacy of ibrexafungerp in VVC patients where even multiple doses of fluconazole failed to sufficiently resolve the acute infection, further differentiating ibrexafungerp from currently available treatments."

Special Protocol Assessments

The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed Phase 3 protocols that are intended to form the basis for a NDA. For more information on the SPA process, please visit: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-protocol-assessment-guidance-industry.

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 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 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. 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* 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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