SCYNEXIS's Oral SCY-078 Receives FDA QIDP and Fast Track Designations for the Treatment of VVC and Prevention of Recurrent VVC

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QIDP provides five additional years of market exclusivity, and Fast Track expedites the regulatory path
Enrollment completed in Phase 2b DOVE study in VVC; on-track for top-line data by July 2018
Initiation of Phase 3 registration program in VVC planned for the fourth quarter of 2018, with potential NDA filing in 2020

JERSEY CITY, N.J., May 1, 2018 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ:SCYX), a biotechnology company delivering innovative anti-infective therapies for difficult-to-treat and often life-threatening infections, today announced that the U.S. Food and Drug Administration (FDA) has granted both Qualified Infectious Disease Product (QIDP) and Fast Track designations for the oral formulation of SCY-078, SCYNEXIS's novel oral and intravenous antifungal agent, for the treatment of vulvovaginal candidiasis (VVC) and for the prevention of recurrent VVC. Additionally, SCYNEXIS today announced it has completed enrollment in the Phase 2b, dose-finding study of oral SCY-078 for the treatment of VVC (the DOVE study), with release of top-line data expected by July 2018.

"These designations from the FDA for the treatment of VVC and prevention of recurrent VVC highlight the significant unmet needs faced by women suffering from these widespread infections," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "We believe SCY-078 will provide a beneficial treatment option for healthcare providers and women not satisfied with existing therapies. Moreover, we can now make use of the QIDP and Fast Track designations across all current SCY-078 development programs, including VVC, invasive candidiasis and invasive aspergillosis."

"We recently completed enrollment in the Phase 2b DOVE study, enrolling more than 180 women with moderate to severe acute VVC," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "This study is designed to assess the efficacy, safety, tolerability and pharmacokinetics of five different regimens of oral SCY-078 to identify the optimal dose to be tested in a Phase 3 registration program, which is anticipated to start in the fourth quarter of 2018."

The QIDP designation, provided under the 2012 U.S. Generating Antibiotic Incentives Now (GAIN) Act, allows SCYNEXIS to have priority review, eligibility for Fast Track status, and an additional five years of market exclusivity in the U.S. for SCY-078.

The FDA's Fast Track Drug Development Program is a process designed to facilitate the development and expeditious review of drugs to treat serious conditions and fill unmet medical needs. The Fast Track designation allows for more frequent interaction with the FDA review team to discuss critical development issues such as study design, required safety data to support approval, and the structure and content of a New Drug Application (NDA). Additionally, should the FDA determine that a Fast Track product may be effective after their preliminary evaluation of clinical data submitted by a sponsor, the FDA may also consider reviewing portions of a marketing application before the sponsor submits the complete application, known as a "rolling" NDA.

About Vulvovaginal Candidiasis (VVC)
VVC, commonly known as a "yeast infection," is usually caused by *Candidaalbicans,* and typical symptoms include pruritus, vaginal soreness, irritation and abnormal vaginal discharge. An estimated 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. As many as 8% of the women with VVC suffer from recurrent disease, defined as experiencing at least four episodes within a 12-month period. Current treatments for VVC include topical antifungals and the use of prescription oral antifungals such as fluconazole, which has a therapeutic cure rate of 55% as reported in the label. There are no products currently approved for the treatment of recurrent VVC. Most VVC infections occur in women of childbearing potential, and FDA has advised caution in prescribing oral fluconazole for the treatment of VVC during pregnancy.

About SCY-078
SCY-078 is an investigational antifungal agent that is a semi-synthetic derivative of the natural product enfumafungin. SCY-078 is 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 IV and oral formulations. SCY-078 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 of anti-fungal activity, *in vitro* and *in vivo*, against multi-drug resistant pathogens, including azole- and echinocandin-resistant strains. The FDA has granted QIPD and Fast Track designations for the formulations of SCY-078 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.

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 delivering innovative anti-infective 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, SCY-078, is a novel IV/oral antifungal agent in Phase 2 clinical and preclinical development for the treatment of several 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, including but not limited to the Company's plans regarding clinical developments, timing of data review for the DOVE trial and possible initiation of a Phase 3 registration program in VVC, 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 SCY-078; 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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