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SCYNEXIS Announces Initiation of Dosing in Phase 2 Study Evaluating Oral SCY-078 in Vulvovaginal Candidiasis

Study initiation marks important milestone following promising clinical results in previous Phase 2 study

Additional pre-clinical results for VVC to be presented at upcoming 2017 IDSOG Annual Meeting

JERSEY CITY, N.J., Aug. 03, 2017 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ:SCYX), a biotechnology company delivering innovative anti-infective therapies for difficult-to-treat and often life-threatening infections, today announced the first patient has been dosed in a Phase 2 study of oral SCY-078 for the treatment of vulvovaginal candidiasis (VVC), also known as vaginal yeast infection. SCY-078 would potentially be the first oral and intravenous (IV) representative of a novel triterpenoid antifungal family with fungicidal activity against *Candida*. Top-line results from this study are expected in mid-2018.

"SCY-078 demonstrated the potential to provide high clinical cure rates (78% vs. 66% for fluconazole) for women suffering from VVC in the proof-of-concept Phase 2 study we completed last year, making it the first novel triterpenoid antifungal agent with fungicidal activity for women with VVC," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "We were also encouraged by the four-month follow-up data that showed a lower recurrence rate (4% vs. 15% for fluconazole), indicating the potential of SCY-078 to become an important treatment option for patients suffering from recurrent VVC, where the unmet need is significant."

"In multiple clinical studies, SCY-078 has demonstrated a broad spectrum of activity across a range of *Candida* isolates, supporting the potential clinical utility of SCY-078 against a number of life-threatening and mucocutaneous infections," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "We believe SCY-078's key attributes, such as fungicidal activity against *Candida* and high-tissue penetration, can be major differentiators in treating VVC infections and preventing recurrence. The commencement of this Phase 2 study is another important step in proving the flexibility of use and potential clinical benefits of this novel product against fungal infections, including multidrug-resistant strains."

About the DOVE Study

The Phase 2 clinical trial is a randomized, multicenter, double-blind, active-controlled, dose-finding study designed to evaluate the safety and efficacy of oral SCY-078 vs. oral fluconazole in adult female patients. Approximately 180 patients with moderate to severe acute VVC will be randomized to one of five different regimens of SCY-078 or oral fluconazole, the current standard of care. The study will assess the efficacy, safety, tolerability and pharmacokinetics of SCY-078. Efficacy will be measured by the percentage of patients with clinical cure (complete resolution of signs and symptoms) at the test-of-cure visit at day 10 (primary endpoint) and at a follow-up visit on day 25. Other efficacy assessments will include mycological eradication (negative fungal culture) at the same time points.

About SCY-078

SCY-078 is an antifungal agent in clinical development for the treatment of fungal infections caused by *Candida* and *Aspergillus* species. SCY-078 is a triterpenoid, semi-synthetic derivative of the natural product enfumafungin—a structurally distinct and novel class of glucan synthase inhibitor. SCY-078 combines the well-established activity of glucan synthase inhibitors with the potential flexibility of having IV and oral formulations. By belonging to a chemical class distinct from other antifungals, SCY-078 has shown *in vitro* and *in vivo* activity against multi-drug resistant pathogens, including azole- and echinocandin-resistant strains. The U.S. Food and Drug Administration granted Fast Track, Qualified Infectious Disease Product and Orphan Drug Designations for the formulations of SCY-078 for the indications of invasive candidiasis (including candidemia) and invasive aspergillosis.

About Vulvovaginal Candidiasis (VVC)

VVC, commonly known as a yeast infection, is usually caused by *Candida albicans*. Typical symptoms include pruritus, vaginal soreness, irritation and abnormal vaginal discharge. An estimated 75% of women will have at least one episode of VVC during their lifetime and 40-45% will experience two or more episodes. As many as 8% of these patients suffer from recurrent VVC, defined as experiencing at least four episodes a year. 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% per the label. There are no products currently approved for the treatment of recurrent VVC.

About SCYNEXIS

SCYNEXIS, Inc. 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 the first representative of a novel oral and intravenous triterpenoid antifungal family and is in Phase 2 clinical development for the treatment of several fungal infections, including serious and life-threatening invasive fungal infections. For more information, visit www.scynexis.com.

Forward Looking Statement

Statements contained in this press release maybe, "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' ability to successfully develop SCY-078, including SCYNEXIS' ability to resolve the FDA's concerns to lift the clinical hold on the IV formulation of SCY-078 on a timely basis, if at all, and obtain FDA approval for SCY-078; the expected costs of studies and when they might begin or be concluded; and SCYNEXIS' reliance on third parties to conduct SCYNEXIS' clinical studies. These and other risks are described more fully in SCYNEXIS' 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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