

August 14, 2017



# SCYNEXIS Presents New Data Supporting Oral SCY-078 for the Clinical Treatment of Vulvovaginal Candidiasis Infections at the 2017 IDSOG Annual Meeting

*Potent anti-Candida activity shown in vaginal acidic pH and high penetration into vaginal tissue*

*Positive efficacy data reported from proof-of-concept Phase 2 VVC study*

JERSEY CITY, N.J., Aug. 14, 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 reported data for SCY-078, the Company's lead clinical development candidate, which were presented at the [2017 Infectious Diseases Society for Obstetrics and Gynecology](#) (IDSOG) Annual Meeting, August 10-12, 2017 in Park City, UT. SCY-078 is the first representative of a novel oral and intravenous (IV) triterpenoid antifungal family in Phase 2 clinical development for the treatment of several fungal infections, including vulvovaginal candidiasis (VVC) infections, commonly known as yeast infections.

"The data presented at IDSOG highlight SCY-078's high penetration into vaginal tissue after oral administration and its potent anti-*Candida* activity in acidic pH conditions, characteristic of the vaginal setting. Additionally, the data showcase the efficacy of SCY-078 vs. fluconazole observed in our prior Phase 2 study in patients with VVC," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "These data affirm the potential clinical utility of oral SCY-078 and justify its continued development as a treatment for VVC. We remain encouraged by the collective data that reveal SCY-078's potential as an important treatment option for women suffering from VVC, including those struggling with recurrent episodes."

"These data add to the growing body of evidence demonstrating oral SCY-078's potential efficacy against *Candida* in the vulvovaginal setting," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "With the recent initiation of our Phase 2 dose-finding study evaluating oral SCY-078 in female patients with VVC (the DOVE study), we are continuing to maximize the value of the SCY-078 platform by advancing the oral formulation of SCY-078. The DOVE study is a critical step towards our goal to provide a treatment option for VVC patients, particularly those with recurrent VVC, for which there are currently no approved therapies."

## **SCY-078 Showed Enhanced Potency Against *Candida* in Acidic Environments**

The first poster, "The Effect of pH on the *In Vitro* Antifungal Activity of SCY-078," presented results of a study showing the *in vitro* activity of SCY-078 against vaginal isolates of *Candida glabrata* and *Candida albicans* as compared to other antifungals in neutral and acidic pH

levels, representing the acidic environment of the vagina. SCY-078 exhibited enhanced potency against the *Candida* isolates in these acidic pH environments whereas fluconazole, consistent with previous reports, showed reduced potency under acidic conditions.

### **SCY-078 Showed High Vaginal Tissue Concentration**

The second poster, “Vaginal Concentrations of SCY-078, a Novel Glucan Synthase Inhibitor, Following Oral Administration in Mice,” presented results of a study on the vaginal tissue distribution of SCY-078 following oral administration in mice. In this study, SCY-078 demonstrated vaginal tissue concentrations that exceed those observed in plasma by several-fold, confirming SCY-078’s ability to readily distribute and accumulate in the vagina.

### **SCY-078 Showed Higher Clinical Cure Rates and a Lower Recurrence Rate than Standard of Care in Previously Conducted VVC Phase 2 Study**

The oral presentation, “A Multicenter, Randomized, Evaluator Blinded, Active-Controlled Study to Evaluate the Safety and Efficacy of Oral SCY-078 vs. Oral Fluconazole in 96 Subjects with Moderate to Severe Vulvovaginal Candidiasis,” presented the positive results of the Phase 2a proof-of-concept trial evaluating the safety and efficacy of oral SCY-078 in female patients with moderate to severe VVC as compared to fluconazole (the SCY-078-203 study). In this trial, oral SCY-078 demonstrated a higher clinical cure rate (78.1%) vs. fluconazole (65.6%) at the test of cure time point (day 24, intent to treat population), as well as a lower recurrence rate (4%) vs. fluconazole (15%) during the four-month follow up period. These data highlight oral SCY-078’s potential as a treatment for VVC and recurrent VVC, most notably its potential efficacy advantages as compared to fluconazole.

### **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 intravenous and oral 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](http://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.

#### **CONTACT:**

Media Relations  
Cammy Duong  
MacDougall Biomedical Communications  
Tel: 781-591-3443  
[cduong@macbiocom.com](mailto:cduong@macbiocom.com)

Investor Relations  
Susan Kim  
Argot Partners  
Tel: 212-203-4433  
[susan@argotpartners.com](mailto:susan@argotpartners.com)



Source: SCYNEXIS, Inc.