

April 25, 2017



# Eight Data Presentations at ECCMID Showcase the Broad Applicability of SCYNEXIS' Lead Anti-infective Candidate SCY-078

*Presentations support SCY-078's potential as a novel treatment for Candida infections including multidrug-resistant strains*

*Favorable safety profile of SCY-078 supported by clinical studies presented*

*Conference call to review ECCMID SCY-078 data to be held April 25 at 4:05 p.m. ET*

JERSEY CITY, N.J., April 25, 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 results showing evidence of activity of the company's lead product candidate [SCY-078](#) against fungal infections in multiple settings and indications. These results were described in a total of eight oral and poster presentations at the [27<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases \(ECCMID\)](#), held April 22 through 25, 2017 in Vienna, Austria.

The first oral presentation (#OS0846) described new data from a multicenter Phase 2 trial that examined oral SCY-078 compared with standard-of-care (oral fluconazole or intravenous micafungin) following initial intravenous (IV) echinocandin therapy for the treatment of invasive candidiasis. SCY-078 demonstrated safety among all treatment groups and achieved a global response rate similar to standard-of-care. Additionally, an estimated dose to achieve target exposure was identified. The findings support the use of oral SCY-078 in the treatment of invasive candidiasis following initial IV echinocandin therapy.

"We're seeing a rising incidence of patients becoming resistant to today's current therapies treating invasive candidiasis, which poses a global health threat," said Peter G. Pappas, M.D., lead investigator on the study and Professor at the University of Alabama at Birmingham. "The discovery and development of potentially novel therapies, like SCY-078, are vital to the management of these invasive and life-threatening infections."

The second oral presentation (#EP0698) described the antifungal activity of SCY-078 against the emerging drug-resistant fungal infection *Candida auris*. In this preclinical study, SCY-078 impacted the growth morphology and biofilm formulation of these invasive and life-threatening fungal species. Results showed potent activity of SCY-078 against all strains at concentrations indicative of a potential clinically-relevant effect.

"*Candida auris* is an emerging, multidrug-resistant fungal species now infecting patients globally, with a mortality rate of approximately 60%," said Mahmoud Ghannoum, Ph.D.,

Professor at the Center for Medical Mycology in the Department of Dermatology at Case Western Reserve School of Medicine. “Given that certain fungal strains that have been isolated from patients have proven to be resistant to all commercially available antifungal drugs, the need for effective new therapies has become a dire global health need.”

The remaining presentations – all delivered via poster presentations – detailed the results of six separate studies, which assessed the safety, efficacy, and pharmacokinetics of SCY-078 across both *Aspergillus* and *Candida* strains. All studies supported the significant antifungal activity and positive safety profile found to date. Conclusions from the poster presentations included:

• ***In vitro* synergies of SCY-078 in combination with other antifungals against *Aspergillus***

- The combination of SCY-078 with three antifungals (amphotericin B, voriconazole and isavuconazole) demonstrated synergy in the majority of strains tested

• **Safety and efficacy of SCY-078 in two Phase 1 drug-drug interaction studies**

- Co-administration with tacrolimus had no effect on maximum blood levels and only mild effect on AUC, indicating a low risk for a clinically-meaningful interaction
- SCY-078 also demonstrated compatibility with rosiglitazone, suggesting low risk for interaction with drugs metabolized via CYP enzymes

• **Additional posters confirming SCY-078’s broad spectrum of activity in clinical and pre-clinical settings**

- Evidence of potent antifungal effect in a proof-of-concept study for vulvovaginal candidiasis infections
- High *in vitro* activity against invasive *Candida* isolates in biofilms comparable to micafungin
- High antifungal activity found against 178 *Candida* isolates from Europe through CLSI and EUCAST procedures

“The wide range of clinical and non-clinical results from the SCY-078 development program at ECCMID provide further evidence of its strong anti-fungal effect and the significant impact it could have in treating patients, both as a stand-alone treatment and in combination with currently marketed drugs,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “These results support our commitment to building not only next-generation therapeutics but a platform of much-needed, potent, safe, flexible and easy-to-administer anti-infective alternatives.”

In addition to data presentations, SCYNEXIS provided an overview of its pipeline and recent advances at ECCMID. This overview, along with all presentations and posters, are available at [www.SCYNEXIS.com](http://www.SCYNEXIS.com).

**Conference Call Details**

SCYNEXIS will hold a conference call today at 4:05 p.m. ET to discuss the SCY-078 data presented at ECCMID. SCYNEXIS management will be joined by global thought leaders Mahmoud Ghannoum, Ph.D., Professor and Director of the Center for Medical Mycology at

Case Western Reserve University and University Hospitals Cleveland Medical Center, and Oliver Cornely, M.D., Professor of Internal Medicine and Medical Director, Clinical Trials Center Cologne at the University of Cologne in Germany. The call can be accessed:

U.S. Dial-In Number: 844-309-3707

International Dial-In Number: 661-378-9467

Conference ID: 12180429

The slide and audio webcast can be accessed by visiting the Investors section of the Company's website at <http://ir.scynexis.com>. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the Company's website for 30 days.

### **About SCY-078**

SCY-078 is an oral and IV antifungal agent in Phase 2 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 (similar to echinocandins) with the flexibility of having IV and oral formulations (similar to azoles). 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 oral and IV formulations of SCY-078 for the indications of invasive candidiasis (including candidemia) and invasive aspergillosis.

### **About *Candida auris* Infections**

*Candida auris*, a fungal strain first reported in 2009, has been linked to invasive fungal infections in nine countries, including the U.S., and has caused at least two hospital outbreaks involving more than 30 patients each. The CDC estimates that infections with *C. auris* are associated with a mortality rate of approximately 60% and that some strains of this species of *Candida* have proven to be resistant to all three major classes of antifungal drugs, making treatment difficult. This type of broad resistance to approved antifungal agents has not been observed in other species of *Candida*. Types of infections caused by *C. auris* include bloodstream, wound and ear infections. The fungal strain has also been isolated from respiratory and urine specimens, although it is unclear if it causes infections in the lung or bladder. The CDC is actively tracking *C. auris* infections globally and has already issued an alert to all healthcare facilities classifying this new pathogen as a serious global health threat.

### **About Invasive Candidiasis Infections**

Invasive candidiasis is a serious, often life-threatening infection caused by *Candida* species that typically affects a highly vulnerable population such as immunocompromised patients or patients under intensive care in hospital settings. We estimate that the U.S. annual incidence is approximately 100,000 cases with high mortality rates (i.e., 20-40%) despite currently available antifungal agents. Furthermore, the limited number of antifungal drug classes, consisting of azoles, echinocandins and polyenes, and their widespread use, has led to increased numbers of *candida* infections with drug-resistant strains. The Centers for Disease Control and Prevention (CDC) has listed fluconazole-resistant *Candida* as a serious public health threat requiring prompt and sustained action.

### **About Invasive *Aspergillus* Infections**

Invasive aspergillosis is a serious fungal infection caused by *Aspergillus* species that usually affects people who have weakened immune systems, such as people who have had an organ transplant or a stem cell transplant. Invasive aspergillosis most commonly affects the lungs, but it can also spread to other parts of the body. There are approximately 50,000 cases of invasive aspergillosis reported in the U.S. annually, with a mortality rate as high as 50%. Current standard of treatment is eight to 12 weeks of azoles usually started as IV treatment for one to two weeks followed by oral step-down treatment for several weeks.

### **About Vulvovaginal Candidiasis Infections**

Vulvovaginal Candidiasis (VVC), commonly known as a "yeast infection," is usually caused by *Candida albicans* and 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 fluconazole, which has a therapeutic cure rate of 55% as reported in the label. There are no products currently approved for the treatment recurrent VVC.

### **About SCYNEXIS, Inc.**

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 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.

Cammy Duong  
MacDougall Biomedical Communications  
Tel: 781-235-3060  
cduong@macbiocom.com

Investor Relations  
Susan Kim  
Argot Partners  
Tel: 212-203-4433  
susan@argotpartners.com



Source: SCYNEXIS, Inc.