

June 27, 2018



## **SCYNEXIS Announces the Presentation of SCY-078 Data at the Teratology Society 58th Annual Meeting**

**SCY-078 shows no impact on fertility or early embryonic development in pre-clinical studies, a differentiator vs. current treatments**

**SCY-078 has the potential to provide a safer treatment option for pregnant women experiencing fungal infections and for patients who may become pregnant while on antifungal therapy**

JERSEY CITY, N.J., June 27, 2018 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ:SCYX), a biotechnology company developing innovative therapies for difficult-to-treat and often life-threatening infections, today announced the presentation of data at the Teratology Society 58<sup>th</sup> Annual Meeting, June 23-27, 2018 in Clearwater, Florida. SCY-078, the first representative of a novel oral and intravenous (IV) triterpenoid antifungal family, is in clinical development for the treatment of multiple serious fungal infections, including vulvovaginal candidiasis (VVC), invasive candidiasis (IC), invasive aspergillosis (IA) and refractory invasive fungal infections.

"The treatment of fungal infections during pregnancy has long been challenging due to the well-known developmental toxicities associated with existing antifungal treatments," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "These studies provide evidence that SCY-078 does not exhibit developmental or reproductive toxicity when administered to animals before and/or during gestation. The absence of teratogenicity is a critical differentiator for SCY-078, as the majority of currently available antifungal therapies, including azoles, are associated with fertility and early embryonic development toxicities."

The poster, titled "**SCY-078, a Novel IV/Oral Triterpenoid Antifungal Treatment, is Not Embryo/Feto-toxic**," describes the results of pre-clinical studies designed to assess the impact of SCY-078 on reproductive potential, mating behavior, and embryonic and fetal development. To assess the impact on reproductive potential, SCY-078 was administered to Wistar rats prior to and during mating; then continuously through early gestation to assess the impact on early pregnancy and to the conceptus. Additionally, to assess the impact of SCY-078 on the embryo-fetal development, SCY-078 was administered to Wistar rats and Dutch-belted rabbits throughout the period of organogenesis. At doses greater than the efficacious clinical exposure, sexual function, maturation of gametes, estrous cycles, pregnancy rates and implantation were comparable to vehicle control; rats and rabbits receiving oral SCY-078 showed no enhanced toxicities relative to those noted in studies conducted with non-pregnant females, there was no increase in embryo-fetal loss, and evaluations of fetal development revealed no SCY-078-related anomalies in the rats or rabbits.

"These results represent an important positive first step in determining the safety of SCY-078 use during pregnancy, a critical aspect for female patients and their physicians," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "Oral fluconazole, the standard of care for VVC, has warnings when used by pregnant women or women in child-bearing age, in whom VVC infections occur more frequently. We are extremely encouraged by these results as we continue to work toward advancing the development of oral SCY-078 in VVC and other indications, including reporting the topline results from our Phase 2b DOVE study by July 2018."

The poster is available on the [Scientific Publications page](#) of the SCYNEXIS website.

### **About the DOVE Study**

The Phase 2b study is a randomized, multi-center, double-blind, active-controlled, dose-finding study designed to evaluate the safety, efficacy, tolerability and pharmacokinetics of oral SCY-078 compared to oral fluconazole in adult, female patients with moderate to severe acute VVC. A total of 186 patients were randomized to one of five different dosing regimens of oral SCY-078 or oral fluconazole, the current standard of care treatment for VVC. The primary objective of the study is to identify the recommended dose of oral SCY-078 to be used in the Phase 3 clinical program. The primary endpoint of the study is efficacy as measured by the percentage of patients with clinical cure, defined as complete resolution of signs and symptoms, at the test-of-cure visit (Day 10). Secondary endpoints, such as clinical cure rate at the follow-up visit (Day 25) and mycological eradication (negative fungal culture) at both time points, will also be evaluated.

### **About Vulvovaginal Candidiasis**

VVC, commonly known as a "vaginal yeast infection," is the second most common cause of vaginitis and is usually caused by *Candida* spp. 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 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. 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. VVC episodes include the following:

- *Uncomplicated cases.* These are sporadic mild-to-moderate infections typically caused by *C. albicans* spp. in a normal host. They represent the majority of the VVC episodes; and
- *Complicated cases.* These represent the remaining episodes and include: severe infections, recurrent cases, infections caused by non-*albicans Candida* spp., and/or observed in an abnormal host.

Current treatments for acute VVC include over-the-counter (OTC) topical azole antifungals (clotrimazole, miconazole, and others) and the use of the prescription oral azole antifungal, fluconazole. Fluconazole is the only orally-administered antifungal currently approved for acute VVC in the U.S., with a therapeutic cure rate of 55% as reported in its label. Uncomplicated acute VVC cases are often effectively treated with topical agents and/or with one to three doses of oral fluconazole. However, management of VVC during pregnancy, moderate-to-severe VVC, recurrent VVC and VVC caused by fluconazole-resistant *Candida* spp., are not fully addressed by oral fluconazole. In addition, there are no

oral alternatives for VVC patients who do not respond to or tolerate fluconazole, and there are no U.S. Food and Drug Administration (FDA)-approved products for the treatment of recurrent VVC.

### **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 multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. The FDA has granted QIDP and Fast Track designations for the formulations of SCY-078 for the indications of IC (including *candidemia*), 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 developing innovative 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 pre-clinical 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](http://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 and the timing of data review of clinical trials, 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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