

October 31, 2019



SCYNEXIS Announces Oral Presentation of Data from Ibrexafungerp Phase 2b DOVE Study at the 3rd ISIDOG Congress

Presentation will detail ibrexafungerp's improved trend in signs and symptoms versus fluconazole on a per patient basis

In the DOVE study, fluconazole was the predominant rescue therapy when patients in the fluconazole arm failed therapy, underscoring the need for new VVC therapeutic options

JERSEY CITY, N.J., Oct. 31, 2019 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today announced that data from a post-hoc analysis of the Phase 2b DOVE study investigating the safety and efficacy of oral ibrexafungerp versus standard of care fluconazole as a treatment for moderate-to-severe acute vulvovaginal candidiasis (VVC) will be presented at the 3rd International Society of Infectious Diseases in Obstetrics and Gynecology (ISIDOG) Congress occurring October 31- November 2, 2019 in Porto, Portugal. Ibrexafungerp (formerly SCY-078), the first representative of a novel triterpenoid antifungal family being developed for oral and intravenous usage, is in clinical development for the treatment of mucocutaneous and invasive fungal infections, including many infections that have shown resistance to existing therapies.

Details for the upcoming presentation are as follows:

ISIDOG 2019

Title: [A Phase 2b, Dose-Finding Study Evaluating Oral Ibrexafungerp in Moderate to Severe Acute Vulvovaginal Candidiasis \(DOVE\)](#)

Presenter: Nkechi Azie, MD

Date and Time: Saturday, November 2, 2019, 8:00 am – 9:30 am WET

Oral Presentation #: OC 12

Session: Free Communications IV

Location: Hotel Ipanema Park, Porto, Portugal

In a randomized, double-blind, double-dummy Phase 2b study, subjects received either one of five oral ibrexafungerp dose regimens (750mg-QD one day, 300mg-BID one day, 450mg-BID one day, 150mg-BID for three days, and 300-BID for three days) or an active comparator dose of oral fluconazole (FLU) (150mg single dose). Subjects were then evaluated for clinical cure and mycological eradication at Day-10 Test-of-Cure (T.O.C) and Day-25 Follow-up (F.U.). Subjects that received the ibrexafungerp dose of 300mg BID for one day (600mg-dose) showed the optimal combination of clinical response and tolerability.

Physicians could provide rescue therapy for subjects at any time point during the study. There was only one patient (4%) in the ibrexafungerp 600mg-dose arm requiring rescue therapy compared to seven patients (29%) in the fluconazole arm. Rescue therapy provided to patients was predominantly oral fluconazole, highlighting the need for new therapies of a different therapeutic class. Mean signs and symptoms (S&S) scores for patients at both T.O.C. and F.U. were worse for the fluconazole arm compared to the ibrexafungerp arm. Additionally, patients on ibrexafungerp trended toward improvement in vaginal S&S scores during the study, whereas patients on fluconazole trended toward a worsening of vaginal S&S. The analysis further demonstrates the potential of ibrexafungerp as a differentiated treatment for VVC patients.

The ISIDOG 2019 presentation will be available on the [SCYNEXIS website](#).

About Vulvovaginal Candidiasis (VVC)

VVC, commonly known as a "vaginal yeast infection," is the second most common cause of vaginitis. Although these infections are frequently caused by *Candida albicans*, fluconazole-resistant *Candida* strains, such as *Candida glabrata*, have been reported to become increasingly more common. 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, excoriation of vaginal mucosa 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. Approximately 6-8% of women with VVC suffer from recurrent disease, defined as experiencing at least three episodes within a 12-month period.

Current treatments for acute VVC include several topical azole antifungals (clotrimazole, miconazole, and others) and fluconazole, the only orally-administered antifungal currently approved for acute VVC in the U.S. Fluconazole reported a 55% therapeutic cure rate in its label, which now also includes warnings of potential for fetal harm, illustrating the need for new oral alternatives. The needs of women with moderate-to-severe VVC, recurrent VVC, VVC caused by fluconazole-resistant *Candida* spp. or VVC during child-bearing age are not fully addressed by oral fluconazole or topical products. In addition, there are no oral alternatives for VVC patients who do not respond to or tolerate fluconazole, and there are no FDA-approved products for the prevention of recurrent VVC.

About Ibrexafungerp

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an investigational antifungal agent and 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 oral and intravenous (IV) formulations. Ibrexafungerp 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 antifungal activity, *in vitro* and *in vivo*, against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. The FDA has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the formulations of ibrexafungerp for the indications of invasive candidiasis (IC) (including candidemia), invasive aspergillosis (IA) and VVC (including prevention of recurrent VVC) and has granted Orphan Drug Designation for the IC and IA indications. Ibrexafungerp is formerly known as SCY-078.

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, having discovered and developed more than 30 innovative medicines over a broad range of therapeutic areas. SCYNEXIS's lead product candidate, ibrexafungerp (formerly known as SCY-078), is a novel IV/oral antifungal agent in Phase 3 clinical and preclinical development for the treatment of multiple serious and life-threatening invasive fungal infections caused by *Candida*, *Aspergillus* and *Pneumocystis* species. For more information, visit www.scynexis.com.

Forward Looking Statement

Statements contained in this press release regarding expected future events or results 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 ibrexafungerp. 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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