

June 5, 2019



# **SCYNEXIS to Present Data at ASM Microbe 2019 Demonstrating the Broad Potential Utility of Ibrexafungerp for the Treatment and Prevention of Multiple Severe Fungal Infections**

**New in vivo studies support potential use of ibrexafungerp in skin and invasive infections caused by multidrug-resistant pathogen, *Candida auris***

**New chronic nonclinical toxicity studies demonstrate ibrexafungerp's favorable safety profile, supporting its long-term administration**

**Ibrexafungerp to be highlighted during invited session "Antifungals New and Near"**

JERSEY CITY, N.J., June 5, 2019 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today announced that a total of nine presentations revealing data which further demonstrates the potential of ibrexafungerp as a treatment for invasive fungal infections, will be presented at the American Society for Microbiology (ASM) Microbe 2019, June 20-24, 2019, in San Francisco. Ibrexafungerp (formerly SCY-078), the first representative of a novel triterpenoid antifungal family being developed for oral and intravenous (IV) usage, is in clinical development for the treatment of multiple serious fungal infections, many that have shown resistance to existing therapies.

"New study results to be presented at ASM Microbe further highlight ibrexafungerp's potent activity against difficult-to-treat multidrug-resistant pathogens, such as *Candida auris* and *Candida glabrata*, including strains resistant to echinocandins, the current gold-standard for these infections" said David Angulo, MD, Chief Medical Officer of SCYNEXIS. "Additionally, the favorable results of our long-term toxicology studies reinforce the safety profile of ibrexafungerp, enabling its future potential development as a prophylactic agent and as a treatment for chronic fungal infections. We're thrilled with our strong showing at ASM including a total of nine presentations further demonstrating the versatility and potential utility of ibrexafungerp against a broad range of fungal infections."

Details for the upcoming presentations are as follows:

## **Oral Presentations**

**Title:** [Ibrexafungerp \(SCY-078\)](#)

**Presenter:** David Angulo, MD

**Date and Time:** Monday, June 24, 9:40 am - 10:00 am

**Oral Presentation:** #7

**Session:** S378; Antifungals New and Near

**Location:** 201/202 South

Ibrexafungerp will be highlighted during this special session, "Antifungals New and Near."

The session is designed to identify novel antifungal targets and agents in the early discovery phase as well as an update on novel antifungals in late clinical development.

**Title:** [Efficacy of Ibrexafungerp \(Formerly SCY-078\) in a Murine Therapeutic Model of \*Pneumocystis\* Pneumonia](#)

**Presenter:** Stephen Barat, PhD

**Date and Time:** Monday, June 24, 9:40 am - 10:00 am

**Oral Presentation:** #4

**Session:** S378; Antifungals New and Near

**Location:** 201/202 South

The presentation will highlight results demonstrating that ibrexafungerp shows significant activity in a murine treatment model of *Pneumocystis* pneumonia (PCP). PCP is an opportunistic fungal infection that affects immunocompromised patients, including those infected with HIV, undergoing organ transplants or receiving chemo- or immune-therapy as a cancer treatment. Current therapies to treat PCP have limitations related to efficacy and toxicity. In previously conducted studies, ibrexafungerp showed significant activity in a murine prophylaxis model of PCP. Taken together, these results indicate that ibrexafungerp could potentially be a viable option for managing PCP in immunocompromised patients.

### **Poster Presentations**

**Title:** [Efficacy of Ibrexafungerp \(Formerly SCY-078\) in the Treatment of \*Candida auris\* Cutaneous Infection in a Guinea Pig Model](#)

**Presenter:** Mahmoud Ghannoum, PhD

**Date and Time:** Sunday, June 23, 11:00 am - 1:00 pm

**Poster Presentation #:** AAR-632

**Session:** P583-AAR03

The poster will present *in vivo* results showing that treatment with ibrexafungerp reduced the fungal burden in skin infected with *Candida auris*, when compared to the untreated control, thus suggesting efficacy in the treatment of cutaneous infections and the potential role of ibrexafungerp in *C. auris* skin decolonization.

**Title:** [Efficacy of Oral Ibrexafungerp \(Formerly SCY-078\) in the Treatment of \*Candida auris\* Infection in a Murine Model](#)

**Presenter:** Mahmoud Ghannoum, PhD

**Date and Time:** Sunday, June 23, 11:00 am - 1:00 pm

**Poster Presentation #:** AAR-633

**Session:** P583-AAR03

In this study, data will be presented showing the potent antifungal activity of ibrexafungerp

against *C. auris* strains in a murine mouse model measuring kidney fungal burden and survival rates. Tissue burdens were lower than vehicle controls in all treatment groups, with the highest reduction in tissue burden observed in the 30 mg/kg dosing group. The 14-day survival rate was comparable across groups, with animals in the 10, 20 and 30 mg/kg groups having survival rates of 60, 70 and 60%, respectively, compared to the vehicle group which had a survival rate of 20%.

**Title:** [Preclinical Safety Evaluation of the Novel Antifungal Ibrexafungerp \(formerly SCY-078\) Supports Long-Term Dosing](#)

**Presenter:** Stephen Barat, PhD

**Date and Time:** Sunday, June 23, 11:00 am - 1:00 pm

**Poster Presentation #:** AAR-635

**Session:** P583-AAR03

Results from in vivo studies evaluating the safety of ibrexafungerp will be presented. In these ibrexafungerp studies, genetic toxicity, end organ toxicity from chronic daily dosing (in rats up to 6 months and in dogs up to 9 months) and developmental and reproductive toxicity in rats and/or rabbits from conception to sexual development of the offspring were evaluated. Ibrexafungerp was well-tolerated in both rats and dogs, with end organ toxicity consisting mainly of phospholipidosis. The no-observed-adverse-effect-levels (NOAELs) for end organ toxicity are equivalent to 7-fold and 3-fold multiples (in rats and dogs, respectively) relative to the targeted efficacious human clinical exposures based on data from in vivo murine models of candidiasis and aspergillosis. Results from this preclinical package suggest that ibrexafungerp has a favorable preclinical safety profile and supports the potential for long-term dosing in patients suffering from invasive fungal infections.

**Title:** [Penetration of Ibrexafungerp \(formerly SCY-078\) versus Micafungin at the Site of Infection in an Intra-Abdominal Candidiasis Mouse Model](#)

**Presenter:** Annie Lee, PhD

**Date and Time:** Friday, June 21, 11:00 am - 12:00 pm and 4:00 pm – 5:00 pm

**Poster Presentation #:** AAR-696

**Session:** P436-AAR03

The poster will feature results from a study designed to test ibrexafungerp's penetration in a mouse model of intra-abdominal candidiasis (IAC), a common invasive fungal infection with high mortality. Echinocandins, the current standard of care for the treatment of invasive candidiasis, are not ideal treatment options for IAC given their poor penetration into intra-abdominal tissue and abscesses. In this study, ibrexafungerp penetrated significantly better into intra-abdominal abscesses as compared to micafungin. These data demonstrate that ibrexafungerp holds promise as a potential therapeutic option for IAC patients.

**Title:** [Activity of a Novel 1,3-beta-D-Glucan Inhibitor, Ibrexafungerp \(Formerly SCY-078\), against \*Candida glabrata\*](#)

**Presenter:** Mahmoud Ghannoum, PhD

**Date and Time:** Sunday, June 23, 11:00 am - 1:00 pm

**Poster Presentation #:** AAR-634

**Session:** P583-AAR03

This study tested the *in vitro* activity of ibrexafungerp against *C. glabrata* clinical isolates (18 wild-type and 22 echinocandin-resistant strains), as well as the *in vivo* activity against wild-

type and echinocandin-resistant *C. glabrata* strains. The ibrexafungerp MIC range against 40 *C. glabrata* clinical isolates was 0.5-4.0 µg/mL, with an MIC<sub>90</sub> of 1.0 µg/mL. Time-kill studies showed that ibrexafungerp, at concentrations of 0.25 to 1 µg/mL, produced a 4 to 6 log reduction in growth of the susceptible strain at 24- and 48-hour time points. Mice infected with *C. glabrata* and treated with ibrexafungerp at doses ≤ 30 mg/kg showed significant reductions in kidney fungal burden for both a susceptible strain ( $P \leq 0.01$ ) and an echinocandin-resistant strain ( $P \leq 0.03$ ). *In vivo* and *in vitro* assays suggest that ibrexafungerp has promise for the treatment of invasive candidiasis caused by wild-type and echinocandin-resistant *C. glabrata*.

**Title:** [Efficacy of Ibrexafungerp \(Formerly SCY-078\) in a Murine Therapeutic Model of \*Pneumocystis\* Pneumonia](#)

**Presenter:** Stephen Barat, PhD

**Date and Time:** Sunday, June 23, 11:00 am - 1:00 pm

**Poster Presentation #:** AAR-636

**Session:** P583-AAR03

This poster will highlight results from an *in vivo* study designed to evaluate the therapeutic activity of oral ibrexafungerp against *Pneumocystis* pneumonia (PCP), a significant risk for immunocompromised patients. Oral ibrexafungerp was evaluated at two dose levels (15mg/kg or 30mg/kg, twice daily), compared to trimethoprim/sulfamethoxazole (50/250mg/kg three times weekly), the current standard of care, and vehicle control. At each dose level, oral ibrexafungerp demonstrated activity against *Pneumocystis*, as determined by a reduction in organism burden and improved survival, supporting future clinical studies of ibrexafungerp for both treatment of PCP and prophylactic use as a single oral agent in immunocompromised patients.

**Title:** [Interim Analysis of a Phase 3 Open-Label Study to Evaluate the Efficacy and Safety of Oral Ibrexafungerp \(Formerly SCY-078\) in Patients with Refractory or Intolerant Fungal Diseases \(FURI\)](#)

**Presenter:** Luis Ostrosky-Zeichner, MD

**Date and Time:** Sunday, June 23, 11:00 am- 1:00 pm

**Poster Presentation #:** CIV-166

**Session:** P550-CIV01

This poster will present results from the first interim analysis of 20 patients with various *Candida* infections from the FURI study, an open-label trial of oral ibrexafungerp in patients with refractory fungal infections. In this analysis, 11 patients (55%) achieved complete or partial response, six patients (30%) maintained stable disease, two patients (10%) experienced progression of disease and one case was considered indeterminate. Of particular interest, the patients enrolled in the FURI study predominantly had non-*albicans* *Candida* spp. infections, which are more resistant and difficult to treat with current marketed antifungal agents, reflecting the need for new antifungal therapies.

The ASM Microbe 2019 presentations will be available on the SCYNEXIS website following the event.

## 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](http://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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