

October 15, 2018



# SCYNEXIS, Inc. Announces First Patient Dosed in Phase 3 Open-label Study Evaluating Oral Ibrexafungerp in *Candida auris* Infections (CARES)

**Ibrexafungerp's potent activity against multidrug-resistant fungal pathogen *Candida auris* confirmed in multiple pre-clinical studies**

**Ibrexafungerp may provide a therapeutic option for this emerging pathogen classified as a serious global health threat by the CDC**

JERSEY CITY, N.J., Oct. 15, 2018 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today announced the dosing of the first patient with a *Candida auris* infection, an emerging life-threatening and multidrug-resistant fungal pathogen, in a Phase 3 open-label study evaluating oral ibrexafungerp (formerly SCY-078) in patients with candidiasis caused by *C. auris* (the CARES Study). Ibrexafungerp, 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 CARES study is a multi-center (U.S. and India), open-label, single-arm study designed to evaluate the efficacy, safety and tolerability of oral ibrexafungerp in subjects with documented *C. auris* infections ([Clinicaltrials.gov NCT03363841](https://clinicaltrials.gov/ct2/show/study/NCT03363841)).

"The need for effective new therapies for *C. auris* infections is clear, as the mortality rate for those infected is up to 60% and many strains have been reported to be resistant to drugs from all commercially available antifungal classes," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "Ibrexafungerp has shown potent *in vitro* activity against *C. auris*, including in strains resistant to other antifungal agents, and we are committed to evaluating its potential to serve as a therapy for patients affected by this difficult-to-treat infection. We thank the investigators for their participation in the CARES study, and we look forward to advancing this important trial."

To date, SCYNEXIS has reported the results of multiple pre-clinical studies demonstrating the potent activity of ibrexafungerp against *C. auris*:

- [Centers for Disease Control \(CDC\) Study](#), reported in the *Antimicrobial Agents and Chemotherapy (AAC)* medical journal, evaluated the *in vitro* activity of ibrexafungerp against a collection of 100 *C. auris* isolates. Ibrexafungerp showed potent activity against all strains at concentrations similar to clinically relevant doses. Additionally, the

study showed that ibrexafungerp retained similar activity against both susceptible and multidrug-resistant strains, including echinocandin-resistant *C. auris* isolates.

- [Case Western Reserve University School of Medicine Study](#) reported in the AAC medical journal, characterized the activity of ibrexafungerp, demonstrating potent activity against all tested *C. auris* isolates. Additionally, results showed that ibrexafungerp reduced biofilms and biofilm metabolic activity, a notable feature as *C. auris* infections have been frequently associated with intravenous catheter use.

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

*Candida auris*, a fungal strain first reported in 2009, has been linked to invasive fungal infections in several 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 up to 60% and that some strains of this species of *Candida* have proven to be resistant to all three major classes of antifungal drugs, rendering treatment difficult. This type of broad resistance to approved antifungal agents has not been observed in other species of *Candida*. The most common type of infection caused by *C. auris* is in the bloodstream. The CDC is actively tracking *C. auris* infections globally and has issued an alert to all healthcare facilities classifying this new pathogen as a serious global health threat. The incidence of *C. auris* infections in the U.S. is rapidly growing; in just the past year, the number of confirmed cases reported by the CDC has more than doubled.

For more information about *C. auris*, visit: <https://www.cdc.gov/fungal/candida-auris/index.html>

### **About Ibrexafungerp (formerly SCY-078)**

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 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 QIDP and Fast Track designations for the formulations of ibrexafungerp 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. SCYNEXIS's lead product candidate, ibrexafungerp (formerly SCY-078), is a novel oral/IV 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 are "forward-looking statements" within the meaning of the Private Securities Litigation Reform

Act of 1995, including without limitation, statements regarding: expectations for the timing of initiation of, and dosing in, clinical trials; plans for review of FURI and CARES. 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; 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 and to manufacture product supplies. 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.

## **CONTACT:**

### **Investor Relations**

Natalie Wildenradt

Argot Partners

Tel: 212-600-1902

[natalie@argotpartners.com](mailto:natalie@argotpartners.com)

### **Media Relations**

George E. MacDougall

MacDougall Biomedical Communications

Tel: 781-235-3093

[george@macbiocom.com](mailto:george@macbiocom.com)

🔗 View original content: <http://www.prnewswire.com/news-releases/scynexis-inc-announces-first-patient-dosed-in-phase-3-open-label-study-evaluating-oral-ibrexafungerp-in-candida-auris-infections-cares-300730914.html>

SOURCE SCYNEXIS, Inc.