

March 2, 2021



# SCYNEXIS Announces Positive Results from Interim Analyses of Ongoing Phase 3 Studies (FURI and CARES), Demonstrating Oral Ibrexafungerp's Ability to Treat Severe Fungal Infections in the Hospital Setting

- *Consistent with prior two interim analyses, FURI results confirm positive clinical activity of oral ibrexafungerp in patients with difficult-to-treat, severe, mucocutaneous and invasive fungal infections, including those caused by resistant strains*
- *1<sup>st</sup> Interim analysis of CARES study shows strong clinical activity of oral ibrexafungerp in patients with *Candida auris*, a high-mortality infection classified by CDC as an Urgent Threat to public health*
- *Results support continued enrollment in both studies, with potential future submissions under the LPAD regulatory pathway*
- *Conference call to be held March 2nd, 2021 at 8:30 a.m. ET*

JERSEY CITY, N.J., March 02, 2021 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: [SCYX](#)), a biotechnology company pioneering innovative medicines to overcome and prevent difficult-to-treat and drug-resistant infections, today announced positive results from the third interim efficacy analysis of the ongoing open-label Phase 3 FURI study and the first interim analysis of the ongoing open-label Phase 3 CARES study.

The global, open-label Phase 3 FURI study is designed to evaluate oral ibrexafungerp as a salvage treatment for patients with a variety of difficult-to-treat mucocutaneous and invasive fungal infections that are refractory to, intolerant of current standards of care, or require a non-azole oral step-down therapy for the treatment of azole-resistant species. The global, open-label Phase 3 CARES study is focused on hospitalized patients with invasive candidiasis caused by the emerging *Candida auris*, an organism that is often multi-drug resistant, associated with high mortality and classified by the [Centers for Disease Control and Prevention \(CDC\) as an Urgent Threat to public health](#). Furthermore, *Candida auris* has been shown to easily spread through contact in healthcare facilities, causing difficult-to-control outbreaks. Increased *C. auris* cases globally have been associated with higher rates of hospitalization due to the COVID pandemic.

Each study is intended to support a potential future NDA submission through the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD).

A Data Review Committee (DRC) of independent experts assessed the efficacy of oral ibrexafungerp in a third cohort of 33 patients from the FURI study and 10 patients from the CARES study. The third interim analysis of the FURI study showed that antifungal activity was consistently positive across all interim analyses with oral ibrexafungerp showing clinical benefit in 30 out of 33 patients, and no patient with progression of disease. On an aggregate basis, oral ibrexafungerp showed clinical benefits in 86.5% of patients (64 out of 74), with 46 patients achieving a complete or partial response and 18 patients achieving a stable disease response. Of the 74 treated patients, only five did not respond to ibrexafungerp treatment, one patient died of an underlying condition unrelated to the treatment and four patients were considered indeterminate.

Analysis of the CARES study found that 80% (8 out of 10) patients with invasive candidiasis and candidemia, due to *C. auris*, experienced a complete response, and one patient died of an underlying condition unrelated to the treatment and one patient was considered indeterminate.

<b>Global Response</b>	<b>Aggregate (FURI) n=74 (%)</b>	<b>CARES n=10 (%)</b>	<b>Aggregate (FURI+CARES) n=84 (%)</b>
Complete or Partial response	46 (62)	8 (80)	54 (64)
Stable Disease	18 (24)	0 (0)	18 (21)
<b>Total</b>	<b>64 (87)</b>	<b>8 (80)</b>	<b>72 (86)</b>
No Response	6 (8)	1 (10)	7 (8)
Indeterminate	4 (5)	1 (10)	5 (6)

These positive results support the continued patient enrollment in the FURI and CARES studies.

Oral ibrexafungerp exhibited a positive safety profile and was well-tolerated, with gastrointestinal issues cited as the most common treatment-related adverse events. There were no safety signals warranting changes to the studies.

“The consistently positive results from these analyses demonstrate the potential of oral ibrexafungerp to provide a flexible treatment option for combating serious life-threatening fungal infections, including those caused by the frequently drug-resistant *Candida auris*,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “The need for new anti-infectives capable of fighting the most resistant pathogens has never been more urgent as we confront the ongoing COVID-19 global pandemic. Ibrexafungerp is a versatile antifungal agent with potential to be a transformative therapy for multiple indications in both the hospital and community settings. It is currently under regulatory review for the treatment of vaginal yeast infections and, if approved, could be the first new antifungal class in more than two decades.”

David Angulo, M.D., Chief Medical Officer of SCYNEXIS, added, “The strong results observed across the FURI and CARES trials are highly consistent with what has been previously reported despite the diversity of medical conditions and organisms being treated. We believe these results are indicative of ibrexafungerp’s broad-spectrum activity, which could provide a new valuable treatment option for patients suffering from a range of severe

and often life-threatening fungal infections. We believe ibrexafungerp is the first investigational agent with reported clinical data in patients with *C. auris* infections and, given the historical difficulty of treating this pathogen, the results are particularly promising. We look forward to evaluating additional data as these trials continue to enroll patients.”

"I would like to thank the patients and investigators for their participation in both studies and the independent Data Review Committee for their analysis of the cases," concluded Dr. Angulo.

SCYNEXIS plans to provide additional details and patient cases from these interim analyses at an upcoming scientific meeting.

### **Conference Call Details**

SCYNEXIS management will hold a conference call today at 8:30 a.m. ET to discuss the positive results from these studies to date.

Dial-in Number: 877-705-6003

Conference ID: 13717020

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 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 under regulatory review for the treatment of vaginal yeast infection, also known as vulvovaginal candidiasis (VVC), and in late-stage development for multiple indications, including life-threatening fungal infections caused primarily by *Candida* (including *C. auris*) and *Aspergillus* species in hospitalized patients. 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 accepted a New Drug Application for ibrexafungerp for the treatment of VVC and granted a Prescription Drug User Fee Act (PDUFA) action date of June 1, 2021. It also granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the IV and oral formulations of ibrexafungerp for the indications of invasive candidiasis (IC) (including candidemia) and invasive aspergillosis (IA), 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 pioneering innovative medicines to help millions of patients worldwide overcome and prevent difficult-to-treat infections that are becoming increasingly drug-resistant. Our lead candidate, ibrexafungerp (formerly known as SCY-078), a broad-spectrum, IV/oral antifungal agent representing a novel therapeutic class, is under regulatory review for vaginal yeast infection and in late-

stage development for multiple life-threatening fungal infections in hospitalized patients. The SCYNEXIS team has deep expertise in anti-infective drug development and marketing, which can be leveraged to advance ibrexafungerp from clinical development to commercialization. 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 but not limited to statements regarding SCYNEXIS's expectations of the potential benefit of ibrexafungerp. 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 obtain regulatory approval to commence dosing of ibrexafungerp; SCYNEXIS's need for additional capital resources; 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 and Form 10-Q 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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