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# **SCYNEXIS Announces Positive Interim Results from Phase 3 Open-Label FURI Study, Showing Oral Ibrexafungerp's Ability to Treat Refractory Fungal Infections and to Provide an Alternative to Long-Term IV Therapies**

**Analysis of first 20 patients confirms clinical antifungal activity of oral ibrexafungerp in patients with difficult-to-treat mucocutaneous and invasive fungal infections**

**Positive findings support expanding the use of oral ibrexafungerp in the FURI study to build toward a future regulatory submission**

JERSEY CITY, N.J., Jan. 30, 2019 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today announced positive results from the first interim efficacy analysis of the ongoing FURI study.

FURI is a Phase 3 open-label study evaluating oral ibrexafungerp as a salvage treatment in patients with difficult-to-treat mucocutaneous and invasive fungal infections that are refractory to or intolerant of currently available standards of care. An independent expert panel (Data Review Committee) assessed the efficacy of ibrexafungerp in the first 20 treated patients. Oral ibrexafungerp showed clinical benefits in 17 out of 20 patients, with 11 patients achieving a complete or partial response and six patients a stable disease response. Only two patients did not respond to ibrexafungerp treatment and the outcome for one patient was considered indeterminate. Along with demonstrating the ability to treat fungal infections in vulnerable patients who failed other therapies, these preliminary results support continued patient enrollment in the FURI study to build toward a future New Drug Application (NDA) submission and potential approval through the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD).

"The positive results of this first interim analysis met all of our goals," said Dr. Marco Taglietti, Chief Executive Officer of SCYNEXIS. "First, we fulfilled our ethical responsibility to justify the testing of oral ibrexafungerp in this patient population. Second, we showed that ibrexafungerp, administered orally, is effective in treating mucocutaneous and invasive fungal infections that do not respond to other therapies, including those administered intravenously. Third, we generated further evidence validating our vision of

ibrexafungerp as a transformative antifungal agent able to address significant unmet needs in both outpatient and hospital settings in a variety of indications."

The 20 patients evaluated in this interim analysis suffered from a variety of severe conditions, including esophageal candidiasis, intra-abdominal abscesses, and oropharyngeal candidiasis, with the most common fungal species being *Candida glabrata* and *Candida krusei*, two highly resistant organisms. Ibrexafungerp treatment ranged from seven to 90 days, with a mean duration of 36.4 days.

Oral ibrexafungerp was well-tolerated, with the most common treatment-related adverse events being gastrointestinal. There were no deaths due to progressive fungal disease and no safety signals warranting changes in the study.

"These preliminary results of oral ibrexafungerp in this salvage therapy setting are very promising," said Professor Oliver Cornely, M.D., Director of Clinical Trials Centre University of Cologne, Germany. "At my center, we have enrolled five patients in the FURI study, and I am thrilled that the positive responses observed in our patients are consistent with those observed by other investigators. Having an alternative new treatment to add to our current, limited armamentarium of antifungals, especially an oral option, is critical for those patients with resistant, difficult-to-treat or refractory fungal infections. Additionally, an oral option provides the flexibility and convenience of outpatient maintenance treatment. I am glad to see the progress in the development of oral ibrexafungerp and am looking forward to continuing my contribution to the program."

"The positive results of this interim analysis reassure us of oral ibrexafungerp's clinical benefits in this difficult-to-treat patient population, warranting continued enrollment in the FURI study," said Dr. David Angulo, Chief Medical Officer of SCYNEXIS. "As a physician, it was very gratifying to see patients with no adequate options respond to ibrexafungerp. Many of the patients enrolled in the FURI study are complex clinical cases with multiple underlying medical conditions, such as the following two cases:

- A 71-year-old male presented with a perforated duodenal ulcer and a retroperitoneal abscess showing positive culture for *C. krusei*, a notoriously difficult-to-treat and often multidrug-resistant fungal pathogen. After 19 days of unsuccessful intravenous therapy with an echinocandin (micafungin), the patient was enrolled in the FURI study. Treatment with oral ibrexafungerp for 17 days fully resolved the infection.
- A 63-year-old male with a 10-year history of painful esophageal constriction and recurrent esophageal candidiasis required a percutaneous gastroenterostomy feeding tube due to the inability of the patient to swallow and eat. Multiple courses of antifungals were unsuccessful in treating this fluconazole-resistant *C. glabrata* infection, and the patient was enrolled in the FURI study with severe esophagitis at baseline. After 54 days of oral ibrexafungerp treatment, the infection fully resolved. The patient remained asymptomatic during the follow-up period and the feeding tube was able to be removed.

"On behalf of SCYNEXIS," continued Dr. Angulo, "I would like to thank the patients and investigators for their participation in the FURI study and the independent Data Review Committee for assessing this first group of 20 patients."

SCYNEXIS plans to provide additional details and patient cases of this interim analysis at an upcoming scientific meeting.

### **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, and has granted Orphan Drug Designation for the IC and IA indications. Ibrexafungerp is formerly known as SCY-078.

### **About the FURI Study**

The FURI study is a multicenter, open label, non-comparator, single arm study to evaluate the safety and efficacy of ibrexafungerp in patients > 18 years of age with a documented invasive and/or severe mucocutaneous fungal disease that has been intolerant or refractory (rIFI) to standard of care (SoC) antifungal treatment.

Patients are also considered for enrollment if they have an eligible fungal disease and, in the judgement of the investigator, cannot receive approved oral antifungal options (e.g., susceptibility of the organism or risk for drug-drug interactions) and continued IV antifungal therapy is not desirable or feasible due to clinical or logistical circumstances.

Enrolled patients receive an initial loading dose of 750mg BID (twice a day) of oral ibrexafungerp during the first two days of treatment and subsequent oral doses of 750mg QD (once a day) for up to 90 days. Patients are evaluated several times during treatment, with treatment efficacy assessed at the end of ibrexafungerp therapy. Subjects are then followed for another six weeks.

More information about the FURI study can be found at <https://clinicaltrials.gov/ct2/show/NCT03059992>.

### **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. The Company'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* 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. 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; whether the positive results from the FURI trial to date will continue to be achieved as the study continues; uncertainties about the regulatory standards for approval through LPAD; 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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