

# SCYNEXIS Announces Positive Results from the Second Interim Analysis of Ongoing Phase 3 FURI Study, Demonstrating Oral Ibrexafungerp's Ability to Treat Severe Fungal Infections in the Hospital Setting

**Consistent with the first interim analysis, results confirm clinical antifungal activity of oral ibrexafungerp in patients with difficult-to-treat, severe, mucocutaneous and invasive fungal infections, including those caused by resistant strains**

**Hospital-based dose regimen of oral ibrexafungerp (750mg/day for up to 90 days) was generally safe and well-tolerated**

**Results reinforce the potential of oral ibrexafungerp as a much-needed alternative to existing fungal therapies and long-term IV treatment, and support a potential future submission under the LPAD regulatory pathway**

**Conference call to be held January 8, 2020 at 8:15 a.m. ET**

JERSEY CITY, N.J., Jan. 8, 2020 /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 its second interim efficacy analysis of the ongoing Phase 3 open-label FURI study. The study is 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 current standards of care, or require a non-azole oral step-down therapy for treatment of azole-resistant *Candida* species. Ibrexafungerp is the first representative of a novel antifungal family, the 'fungers', being developed for oral and intravenous (IV) usage to treat multiple serious fungal infections, including ones that have shown resistance or have not responded to existing therapies.

A Data Review Committee (DRC) of independent experts assessed the efficacy of oral ibrexafungerp in a second cohort of 21 treated patients from the FURI study. Together with the initial 20 patients [reported in January 2019](#), the dataset consists of 41 patients analyzed to date. Efficacy was consistent across both interim analyses, as oral ibrexafungerp showed clinical benefits in 83% of patients (34 out of 41), with 23 patients achieving a complete or partial response and 11 patients a stable disease response. Of the 41 treated patients, only six did not respond to ibrexafungerp treatment and one patient was considered indeterminate.

| Global Response              | 1st DRC Interim Analysis (n=20) | 2nd DRC Interim Analysis (n=21) | Aggregate Analysis (n=41) |
|------------------------------|---------------------------------|---------------------------------|---------------------------|
| Complete or Partial Response | 11                              | 12                              | 23 (56%)                  |
| Stable Disease               | 6                               | 5                               | 11 (27%)                  |
| <b>Total</b>                 | <b>17</b>                       | <b>17</b>                       | <b>34 (83%)</b>           |
| No Response                  | 2                               | 4                               | 6 (15%)                   |
| Indeterminate                | 1                               | 0                               | 1 (2%)                    |

These positive results support the continued patient enrollment in the FURI study and build toward a future New Drug Application (NDA) submission and potential approval under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD).

"These interim results, combined with the positive Phase 3 data from our vulvovaginal candidiasis (VVC) program, confirm the potential for ibrexafungerp to be a transformative antifungal agent across a variety of indications, addressing needs in both the in-patient and out-patient markets," said Marco Taglietti, MD., President and Chief Executive Officer of SCYNEXIS. "We believe that ibrexafungerp combines the best attributes of existing antifungal classes, such as oral administration, broad spectrum activity including against resistant pathogens, and a favorable safety profile, enabling us to maximize its full potential across several indications to benefit patients in need,

physicians who treat them, and the investment community that has supported our programs."

The 41 patients in the aggregate analysis suffered from a variety of severe conditions, including candidemia, intra-abdominal abscesses, esophageal candidiasis, oropharyngeal candidiasis, and bone infections. *Candida glabrata* and *Candida krusei*, two highly resistant organisms, were reported in approximately 70% of the cases. Ibrexafungerp treatment ranged from five to 90 days, with a mean duration of 37.1 days.

This second interim analysis was limited to patients who had completed treatment by the end of October 2019, and many patients are still on therapy and have not yet reached the point of clinical assessment. The FURI study protocol was recently amended to also include patients with aspergillosis, coccidioidomycosis, histoplasmosis, blastomycosis and other emerging, difficult-to-treat fungal infections. The maximum allowed treatment duration was also extended from 90 days to up to six months as needed for chronic conditions, based on favorable preclinical toxicology studies.

Oral ibrexafungerp was generally safe and well-tolerated, with gastrointestinal issues cited as the most common treatment-related adverse events. One patient with an ongoing fungal infection died while on study drug due to an underlying condition. The death was considered not drug-related and there were no safety signals warranting changes to the study.

"The positive results from this second interim analysis are fully consistent with the positive outcomes observed in the first interim analysis," said David Angulo, MD., Chief Medical Officer of SCYNEXIS. "Patients enrolled in the FURI study typically suffer from complex underlying medical conditions, aggravated by a severe fungal infection. We are pleased to see many responding favorably to treatment with ibrexafungerp and are optimistic it will be a much-needed alternative for patients suffering from difficult-to-treat, severe fungal infections, particularly given the limited treatment options available and the increase in drug-resistance. We anticipate meeting with the FDA to discuss these preliminary data and our salvage therapy program."

"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 their analysis of the cases."

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

#### **Conference Call Details**

SCYNEXIS management will hold a conference call today at 8:15 a.m. ET to discuss the positive results from the FURI study to date.

Dial-in Number: 844-309-3707

Conference ID: 7382405

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, the 'fungers'. 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 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 vulvovaginal candidiasis (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 SoC antifungal treatment or require a non-azole oral step-down therapy for treatment of azole-resistant *Candida* species. These infections include: acute and chronic invasive candidiasis, *candidemia*, and severe mucocutaneous *Candida* infections, including esophagitis, oropharyngeal and chronic mucocutaneous candidiasis. The FURI study protocol was recently amended to also include patients with

aspergillosis, coccidioidomycosis, histoplasmosis, blastomycosis and other emerging, difficult-to-treat fungal infections.

Patients must also have documented evidence of failure of, intolerance to, or toxicity related to a currently approved 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 a 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 with subsequent doses of 750mg QD (once a day) for up to six months. Patients are assessed several times during treatment, with efficacy assessed at end of oral ibrexafungerp therapy. Study subjects are also followed for six weeks after end of treatment.

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; 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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