

# **SCYNEXIS Expands FURI Protocol to a Broader Range of Refractory Serious Fungal Infections, Building on Ibrexafungerp's Positive Data and Favorable Toxicology Profile Observed to Date**

**Use of oral ibrexafungerp expanded to patients with aspergillosis, coccidioidomycosis, histoplasmosis, blastomycosis and other emerging, difficult-to-treat fungal infections**

**Maximum allowed treatment duration increased to six months based on favorable preclinical chronic toxicology studies**

**Second independent committee's review and assessment of FURI patients that have currently completed treatment to be available in the first quarter of 2020**

JERSEY CITY, N.J., Oct. 24, 2019 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ:SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today announced an amendment to the protocol for the ongoing FURI study investigating the safety and efficacy of oral ibrexafungerp (formerly SCY-078) as a salvage treatment for patients with resistant or refractory severe fungal infections. Ibrexafungerp, 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, including many that have shown resistance to existing therapies.

Key amendments to the FURI study protocol include the following:

- Under the amended study design, patients with aspergillosis, coccidioidomycosis, histoplasmosis, blastomycosis and infections caused by other emerging fungi including yeasts and molds are now eligible for enrollment along with those suffering from *Candida* infections.
- Maximum allowed treatment duration with ibrexafungerp has been extended from 90 days to up to 180 days, as needed for chronic conditions.
- Ibrexafungerp will also be available as a combination therapy with standard of care (SoC) for selected subjects.

"The positive data overserved to date provide a valid rationale for expanding the use of oral ibrexafungerp to a broader set of patients with resistant, refractory and other difficult-to-treat fungal infections," said Dr. David Angulo, Chief Medical Officer of SCYNEXIS. "We are thrilled to provide physicians with the option to treat a wider range of fungal infections and the ability to administer ibrexafungerp for longer durations, which is crucial to fight certain conditions with very limited treatment options. We also believe the expansion of the FURI study increases the number of targets for potential regulatory submissions under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD). We continue to be encouraged by the level of interest and enrollment seen to date in our FURI study and plan to report on a second interim analysis of the data by an independent Data Review Committee in the first quarter of 2020."

### **About the FURI Study**

The FURI study is a multicenter, open label, non-comparator, single arm study to evaluate the safety and efficacy of oral 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 fungal 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 ibrexafungerp for up to 180 days at a dosing regimen that will depend on fungal disease. Patients are evaluated several times during treatment, with efficacy assessed at the end of ibrexafungerp therapy. Subjects are then followed for another six weeks. The study is planned to be conducted at approximately 40 sites globally and enrollment is expected to continue until ibrexafungerp's commercial availability. The Company expects to enroll approximately 200 subjects.

### **About Invasive Fungal Infections**

Fungal diseases caused by *Candida*, *Aspergillus*, *Pneumocystis*, dimorphic fungi, etc., represent a growing threat, particularly to patients with compromised immune systems. Invasive fungal diseases caused by *Candida* and *Aspergillus* species are of principal concern. *Candida* is the most common cause of health care-associated bloodstream infections in the United States. The overall mortality rate of invasive candidiasis remains over 30% despite therapy. *Candida auris* is an emerging *Candida* species that presents a serious global health threat. Healthcare facilities in several countries have reported that *C. auris* has caused severe illness in hospitalized patients. Some strains of *C. auris* are resistant to all three major classes of antifungal drugs. This type of multidrug resistance has not been seen before in other species of *Candida*. Also of concern, *C. auris* can persist on surfaces in healthcare environments and spread between patients in healthcare facilities, unlike most other *Candida* species. In addition, invasive aspergillosis has emerged worldwide as an important cause of nosocomial and community-acquired infection in a wide spectrum of immunocompromised patients. These include patients receiving cancer chemotherapy, hematopoietic stem cell transplantation and solid organ transplantation, and patients with advanced human immunodeficiency virus (HIV)-infection. The overall mortality rate of invasive aspergillosis remains high, particularly in the most profoundly immunocompromised patient populations.

### **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 *Candida 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 (including prevention of recurrent VVC) 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 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; 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.

## CONTACT:

### Investor Relations

Heather Savelle

Argot Partners

Tel: 212-600-1902

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


**Media Relations**

George E. MacDougall

MacDougall

Tel: 781-235-3093

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

 View original content: <http://www.prnewswire.com/news-releases/scynexis-expands-furi-protocol-to-a-broader-range-of-refractory-serious-fungal-infections-building-on-ibrexafungerps-positive-data-and-favorable-toxicology-profile-observed-to-date-300944397.html>

SOURCE SCYNEXIS, Inc.