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# SCYNEXIS Announces Advancement of Ibrexafungerp's Intravenous Formulation to Clinical Stage and Provides Further Updates on its Clinical Studies in Patients with Life-Threatening Fungal Infections

- *Approval granted by health authority for the intravenous (IV) formulation of ibrexafungerp to enter Phase 1; dosing in healthy volunteers to start in the first quarter of 2021*
- *New interim analysis of the data from the Phase 3 studies of ibrexafungerp in refractory invasive fungal infections (FURI and CARES) expected in the first quarter of 2021; additional 43 patients will double the existing dataset of 41 cases already analyzed*
- *Analysis of the CARES study will provide the first clinical trial data of an investigational treatment against infections caused by *Candida auris*, a multidrug-resistant fungus deemed an urgent threat by the CDC*

JERSEY CITY, N.J., Dec. 10, 2020 (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 significant progress on the ibrexafungerp IV formulation and provided an update on its ongoing Phase 3 studies in the hospital setting.

## **(1) Liposomal IV formulation of ibrexafungerp entering Phase 1 study**

SCYNEXIS has successfully completed preclinical testing of its liposomal IV formulation of ibrexafungerp and is advancing the program into human trials in healthy volunteers. The first trial will be conducted as a Phase 1, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, and pharmacokinetics of the intravenous liposomal formulation of ibrexafungerp in healthy subjects. The study will be conducted in South Africa. SCYNEXIS has been granted approvals from the health authority and ethics committee, with dosing anticipated to start in the first quarter of 2021.

## **(2) New interim analysis of Phase 3 FURI and CARES open-label studies expected in the first quarter of 2021, doubling the existing dataset of patient cases**

SCYNEXIS has collected data for another 43 patients who have completed treatment in the FURI and CARES open-label studies, and a Data Review Committee (DRC) of

independent experts is assessing the efficacy of oral ibrexafungerp in this combined third interim analysis. The FURI study is evaluating oral ibrexafungerp as a salvage treatment in 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 treatment of azole-resistant species. The CARES study is focused on hospitalized patients with invasive candidiasis caused by the multidrug-resistant *Candida auris* organism, which is associated with high mortality. Similar to interim analyses of data previously reported, SCYNEXIS plans to report results on this new group of patients in the first quarter of 2021, bringing the total data set to 84 patients from FURI and CARES. Each study is designed to support a potential future NDA submission through the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD).

“As we prepare for our first commercial launch of oral ibrexafungerp in the community setting in 2021, we are also excited about advancing ibrexafungerp for patients with serious and life-threatening infections in the hospital setting,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “The analysis of our CARES study will provide the first clinical trial data of an investigational treatment against *Candida auris*, a multidrug-resistant fungus deemed an urgent threat by the CDC. When approved, ibrexafungerp would represent the first new antifungal class in over 20 years and, with the advancement of our IV formulation, ibrexafungerp could become the first new class offering the flexibility of both IV and oral formulations in over 40 years.”

## **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), is a broad-spectrum, IV/oral antifungal agent representing a novel therapeutic class, in late stage development for multiple indications, ranging from vaginal yeast infections to 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 expected timing of dosing of volunteers and patients and reporting of interim analyses. 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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