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SCYNEXIS Announces Positive Interim Data from Phase 3 FURI and CARES Studies Highlighting Oral Ibrexafungerp's Potency Against Severe Fungal Infections

- Data reinforce findings from previous analyses demonstrating oral ibrexafungerp's potential to combat difficult-to-treat and refractory fungal infections in the hospital setting.
- Ongoing FURI and CARES studies are a key component of the SCYNEXIS strategy to build ibrexafungerp into a broad antifungal franchise.
- SCYNEXIS is presenting the fourth interim analysis from FURI and the second interim analysis from CARES during the 32nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) being held in Lisbon, Portugal, April 23-26, 2022.

JERSEY CITY, N.J., April 22, 2022 (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 interim data from its ongoing Phase 3 FURI and CARES studies.

"These results further support ibrexafungerp's potential to treat complex fungal infections in the hospital setting," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "There is a significant need for a new antifungal therapy, particularly one that is active against *Candida* species frequently resistant to other antifungal agents, such as *Candida auris* and *Candida glabrata*. The data from more than 130 combined patients treated in our FURI and CARES studies further confirm that oral ibrexafungerp has a potential to play a significant role in treating patients with very challenging fungal diseases."

The ongoing Phase 3 open-label, single-arm FURI study is evaluating oral ibrexafungerp for the treatment of patients with severe fungal infections who are either intolerant to standard antifungal therapy or experience refractory fungal infections despite treatment. The CARES study, also an ongoing Phase 3 open-label, single-arm trial, is evaluating oral ibrexafungerp in patients with systemic infections caused by *C. auris*, an organism that is often multi-drug resistant, associated with high mortality and classified by the U.S. [Centers for Disease Control and Prevention \(CDC\) as an "Urgent Threat" to public health](#).¹

The data summarized below includes the results of study patients who had completed their treatment as of October 2021 and have been reviewed by a Data Review Committee (DRC), including 47 cases from the most recent review.

	FURI	CARES	Aggregate
	N=113 (%)	N=18 (%)	(FURI+CARES)
Global Response			N=131 (%)

Complete or Partial response or Clinical Improvement	66 (58.4)	14 (77.8)	80 (61.1)
Stable Disease	27 (23.9)	2 (11.1)	29 (22.1)
Total	93 (82.3)	16 (88.9)	109 (83.2)
No Response*	14 (12.4)	1 (5.6)	15 (11.5)
Indeterminate	6 (5.3)	1 (5.6)	7 (5.3)

**Includes two subjects who died while on treatment, due to their underlying (non-fungal) conditions.*

Of the 131 FURI and CARES study cases analyzed to date, 61.1% achieved a complete or partial response, or clinical improvement; 22.1% achieved stable disease, which is a favorable outcome in patients with severe progressive fungal infections; 11.5% were considered no response, which includes two patients who died of an underlying condition unrelated to the treatment; and 5.3% were considered indeterminate.

“We are extremely pleased to share these new positive interim analyses from our ongoing FURI and CARES studies, which continue to demonstrate the ability of ibrexafungerp to be a powerful tool in the fight against a broad range of serious and potentially deadly infectious diseases,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “This research is a key part of our efforts to build a broad antifungal franchise to help treat millions of patients struggling with severe fungal infections.”

The fourth interim analyses included 39 new cases from FURI and eight new cases from CARES who completed treatment during the 12 months since the prior interim analyses. Results were consistent with previously reported data and support continued patient enrollment in both studies.

SCYNEXIS will present additional details from these interim analyses at the 32nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) being held in Lisbon, Portugal, April 23-26, 2022.

About Ibrexafungerp

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an 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 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 granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the oral and IV 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. The European Medicines Agency (EMA) has granted ibrexafungerp Orphan Medicinal Product designation for the indication of IC. 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. SCYNEXIS scientists are developing the company's lead asset, ibrexafungerp (formerly known as SCY-078), as a broad-spectrum, systemic antifungal for multiple fungal indications in both the community and hospital settings. SCYNEXIS has initiated the launch of its first commercial product in the U.S., BREXAFEMME® (ibrexafungerp tablets). The U.S. Food and Drug Administration (FDA) approved BREXAFEMME on June 1, 2021. In addition, late-stage clinical development and investigation of oral ibrexafungerp for the prevention of recurrent vulvovaginal candidiasis (VVC) and the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. For more information, visit www.scynexis.com.

Forward-Looking Statements

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: oral ibrexafungerp's potential use by physicians and patients to treat fungal infections in multiple healthcare settings. 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' ability to successfully develop and obtain FDA approval for ibrexafungerp for additional indications, including the IV formulation of ibrexafungerp; unexpected delays may occur in the timing of acceptance by the FDA of an NDA submission; the expected costs of studies and when they might begin or be concluded; SCYNEXIS' need for additional capital resources; and SCYNEXIS' reliance on third parties to conduct SCYNEXIS' clinical studies and commercialize its products. These and other risks are described more fully in SCYNEXIS' filings with the Securities and Exchange Commission, including without limitation, its most recent Annual Report on Form 10-K, including under the caption "Risk Factors," and in 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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¹ U.S. Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States 2019. Revised December 2019. <https://www.cdc.gov/drugresistance/biggest-threats.html>. Accessed April 2022.



Source: Scynexis