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SCYNEXIS Presents Data Analyses Showing Ibrexafungerp's Potential to Fight Invasive Candidiasis and Candidemia, Including Infections Caused by Candida Auris, During the 32nd Annual European Congress of Clinical Microbiology & Infectious Diseases

- New interim analysis of the Phase 3 CARES study showed complete or partial response in 78% of the 18 patients treated with ibrexafungerp for infections caused by *Candida auris*, a potentially deadly and multidrug-resistent pathogen with an outbreak recently reported at a Detroit specialty hospital.[1]

- Interim data of the ongoing Phase 3 FURI and CARES studies of patients with invasive candidiasis and candidemia treated with ibrexafungerp is positive and consistent with previous analyses.

- Additional new *in vivo* data presented supports ibrexafungerp as a potential treatment for mucormycosis, a debilitating and sometimes deadly fungal infection that has seen an increase in cases globally during the COVID-19 pandemic.

JERSEY CITY, N.J., April 27, 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 several poster presentations highlighting details from interim analyses of data from its ongoing Phase 3 FURI and CARES studies investigating the potential of ibrexafungerp as a treatment for invasive candidiasis (IC) and candidemia, including infections caused by *Candida auris* (*C. auris*). The posters were presented at the 32nd Annual European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) held in Lisbon, Portugal April 23-26, 2022.

"We are excited to share these latest data with the medical community as we advance our hospital clinical programs in invasive candidiasis, including candidemia," said David Angulo, M.D. Chief Medical Officer of SCYNEXIS. "There is great unmet need for additional therapies to fight these infections, which can be quite serious, especially if the pathogen is resistant to current therapies, as can be the case with *C. auris*. We are proud to be a part of this important research."

C. auris, a contagious fungal infection that can quickly spread in patients in hospital wards or nursing home facilities, has been designated as an "urgent threat" by the CDC.[2] Invasive *C.*

auris infections have a high mortality rate – more than one in three patients can die.[3]

"Many *C. auris* strains are resistant to at least two classes of antifungals, which makes these interim research findings of ibrexafungerp's activity against this terrible pathogen so promising," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "The reported outbreak of *C. auris* at a specialty hospital in Detroit just last week underscores the urgency of finding new treatment options to battle this ongoing dangerous fungal public health threat."

Below are highlights of the posters presented:

- **Outcomes of Oral Ibrexafungerp in the Treatment of 18 Patients with *Candida auris* Infections, from the CARES Study**
  Presenter: R.S. Siebert (Pretoria, South Africa)
  Summary: SCYNEXIS presented results of an interim analysis of the CARES study of 18 enrolled patients with candidemia, lower urinary tract and intra-abdominal fungal infections caused by *Candida auris* (*C. auris*). In the analysis, 11 patients had received prior antifungal therapy for their infection. Following treatment with oral ibrexafungerp for a mean duration of 18 days, 78% of patients showed complete or partial response, 11% had stable disease, one patient died of other causes, and one outcome was indeterminate.

- **Oral Ibrexafungerp Outcomes in Patients with Invasive Candidiasis and Candidemia from the FURI and CARES Studies**
  Presenter: Oliver Cornely (Cologne, Germany)
  Summary: SCYNEXIS presented interim analyses with combined data of 49 patients, who completed treatment for invasive candidiasis and candidemia between 2018 and 2020, as part of the ongoing Phase 3 FURI (n=39) and CARES (n=10) studies. Aggregate data from the two studies showed that of the patients treated with ibrexafungerp, 68% had complete or partial response; 14% had stable disease; 6% showed disease progression; 8% were indeterminate; and 4% died from progression of an underlying disease.

- **Efficacy Assessment of Ibrexafungerp in the Neutropenic Mouse Model of Pulmonary Mucormycosis**
  Presenter: Ashraf Ibrahim (Torrance, Calif., United States)
  Summary: Preclinical data on ibrexafungerp from an investigational analysis were presented. The data were based on an *in vivo* mouse model of mucormycosis and support ibrexafungerp, a broad-spectrum antifungal, as an effective potential treatment for mucormycosis. The study found that when ibrexafungerp was combined with liposomal amphotericin B (LAMB) or posaconazole (POSA), synergistic benefits were observed with a statistically significant enhancement in median survival time and overall survival when compared to any one therapy alone ($P<0.05$). The study also found that ibrexafungerp monotherapy demonstrated *in vivo* efficacy in treating both *R. delemar* and *M. circinelloides* infections in mice, consistent with other antifungals currently used against mucormycosis.

SCYNEXIS scientific posters, including those presented at ECCMID, are available on the corporate website here.

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 investigation and 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 U.S. Food and Drug Administration (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 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.

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[1] USA Today. April 21, 2022. https://www.usatoday.com/story/news/nation/2022/04/21/candida-auris-detroit-hospital/7394202001/. Accessed April 2022.

[2] 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.
[3] U.S. Centers for Disease Control and Prevention. *Candida auris*: A Drug-resistant Germ That Spreads in Healthcare Facilities. Revised December 2018. https://www.cdc.gov/fungal/candida-auris/c-auris-drug-resistant.html. Accessed April 2022.

Source: Scynexis