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SCYNEXIS Presents Interim Analysis from FURI at Virtual IDWeek 2021 Showing Favorable Therapeutic Response in Severe Hospital-Based Fungal Infections Treated with Oral Ibrexafungerp

Subpopulation analysis of 74 patients from ongoing Phase 3 FURI study demonstrated similar efficacy against multiple serious fungal infections

JERSEY CITY, N.J., Sept. 29, 2021 (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 an oral presentation of analyses of interim data from its ongoing Phase 3 FURI study showing favorable clinical activity of oral ibrexafungerp in severe hospital-based fungal infections across multiple serious fungal infections. The compilation and disease subset analyses are being presented during IDWeek, taking place virtually September 29 – October 3, 2021.

“We are very pleased to share the results of these analyses to help provide greater understanding of ibrexafungerp and its potential to help patients suffering from a multitude of severe fungal infections, many of which have high mortality rates,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “Based on the accumulation of data to date and additional analysis of therapeutic response by disease area, results demonstrate that ibrexafungerp has similar efficacy across a broad spectrum of serious fungal diseases and in the future could be valuable in the treatment of patients who have failed or are intolerant to currently available therapies.”

Oral presentation details:

- **Oral Ibrexafungerp Outcomes by Fungal Disease in Patients from an Interim Analysis of a Phase 3 Open-label Study (FURI) –** Peter G. Pappas, M.D., University of Alabama at Birmingham (UAB)
  Oral Presentation – New Findings in Medical Mycology: O-25.
  Summary: Data from an interim analysis of the combined data of 74 patients from the Phase 3 FURI clinical study evaluating oral ibrexafungerp for the treatment of patients with refractory candidiasis, patients who were intolerant to the standard of care, or patients who were unable to receive an approved oral antifungal option (e.g., susceptibility of the organism) and a continued IV antifungal therapy was clinically undesirable or unfeasible, found that oral ibrexafungerp provided an overall favorable therapeutic response in patients with 13 distinct types of fungal infections. Of the 74 patients treated with oral ibrexafungerp 62.1% showed complete or partial response, 24.3% achieved stable disease, 6.8% showed progressive disease, and 5.4% were

indeterminate. One patient died due to an unrelated cause.

In the subset analysis by disease area, patients treated with ibrexafungerp who showed complete or partial response included those with: candidemia – 72.7% (8/11); intra-abdominal infections 58.3% (7/12) *Candida* infections of the bones and joints – 62.5% (5/8); and oropharyngeal candidiasis – 64.3% (9/14).

In addition, during IDWeek SCYNEXIS is presenting two posters that discuss sub-populations from FURI study with difficult-to-treat infections:

- **Oral Ibrexafungerp Outcomes in Patients with Oropharyngeal Candidiasis and Esophageal Candidiasis from an Interim Analysis of a Phase 3 Open-label Study (FURI) –** Jose A. Vazquez, M.D., FACP, FIDSA, Augusta University
  Poster Presentation – Medical Mycology: 992
  Summary – Esophageal candidiasis (EC) and oropharyngeal candidiasis (OPC) are infections that can be treated in the outpatient setting and are treated with oral azole therapy. When these patients fail oral azole therapy, they have limited intravenous treatment options and no oral options. The presentation highlights a sub-analysis of 24 patients (83.3% were refractory) from the Phase 3 FURI study with esophageal candidiasis (EC) or oropharyngeal candidiasis (OPC) treated with oral ibrexafungerp. Of these patients, 62.5% showed complete or partial response, 29.2% achieved stable disease and 16.7% showed progressive disease.

- **Outcomes of *Candida* Bone and Joint Infections in Eight Patients from a Phase 3 Open-label Study (FURI) –** John Walton Sanders III, MD, MPH, Wake Forest Baptist Health
  Poster Presentation – Medical Mycology: 983
  Summary – *Candida* bone and joint infections are difficult to treat requiring long courses of oral azole therapy (6-12 months). The presentation highlights a sub-analysis of eight patients with *Candida* bone and joint infections from the Phase 3 FURI study. The median days of ibrexafungerp therapy for this population was over 210.5 days. Of these patients, 62.5% showed complete or partial response, 12.5% achieved stable disease and 12.5% showed progressive disease. One patient was considered indeterminate.

Recorded presentations will be accessible to meeting attendees via the IDWeek Interactive Program Site.

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 standard of care (SoC) antifungal treatment.

Patients are also considered for enrollment if they have an eligible fungal disease and, in the judgment 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 an initial loading dose of 750mg BID (twice a day) of oral

ibrexafungerp during the first two days of treatment and subsequent oral doses of 750mg QD (once a day) for up to 90 days. Patients are evaluated several times during treatment, with treatment efficacy assessed at the end of ibrexafungerp therapy. Subjects are then followed for another six weeks. For more information on the Phase 3 FURI study, visit ClinicalTrials.gov (NCT03059992).

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 U.S. Food and Drug Administration (FDA) approved BREXAFEMME® (ibrexafungerp tablets) on June 1, 2021. The FDA also granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the IV and oral 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. 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 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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