

SCYNEXIS Presents Positive Interim Data of Oral Ibrexafungerp for Severe Fungal Infections from Ongoing Phase 3 FURI Study During IDWeek 2022

- Cumulative interim analysis of outcomes by fungal disease type highlighted in a platform presentation demonstrates 82.3% positive clinical outcomes in patients treated with ibrexafungerp.
- All-cause mortality analysis shows 94.6% survival 30 days post-therapy in patients with invasive candidiasis or candidemia who were treated with ibrexafungerp.

JERSEY CITY, N.J., Oct. 24, 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 the presentation of cumulative interim outcomes and all-cause mortality data in patients with refractory candidiasis treated with oral ibrexafungerp from the ongoing Phase 3 FURI study. The analyses were presented during IDWeek 2022 held in Washington, D.C., October 19-23, 2022.

“We are pleased to present these aggregate data from previous interim analysis showing favorable outcomes in our ongoing FURI trial, which focuses on the potential of ibrexafungerp to help patients with challenging fungal infections,” said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. “These results reinforce our conviction that ibrexafungerp has the potential to benefit patients with severe fungal disease and limited treatment options, and they are supportive of our plans to pursue a salvage therapy indication for ibrexafungerp.”

FURI Outcomes by Fungal Disease Type

Ibrexafungerp demonstrated a favorable therapeutic response for the majority of patients with a variety of serious fungal infections who have failed or are intolerant to currently available treatments or for whom currently available oral antifungals are not adequate due to resistance and IV therapy is no longer feasible or desirable. The data presented includes 113 patients enrolled in the FURI study who had completed treatment through October 2021. Of these patients, the most common fungal disease was invasive candidiasis/candidemia (IC) in 56 (49.6%), followed by severe mucocutaneous candidiasis in 32 (28.3%), refractory vulvovaginal candidiasis (VVC) in 14 (12.3%), and invasive aspergillosis (IA) in 11 (9.7%).

Complete or partial response was reported in 62.5% of patients with IC with an additional 23.2% reporting stable disease. For patients with severe mucocutaneous candidiasis, 53.1% reported complete or partial response and 34.4% reported stable disease. Most subjects

with refractory VVC also responded favorably, with 71.4% achieving clinical improvement. Six of 11 patients with invasive aspergillosis achieved complete/partial response or stable disease.

All-Cause Mortality in Patients with Invasive Candidiasis

All-cause mortality outcomes through 30 days post completion of ibrexafungerp treatment was presented as a poster. Fifty-six of 113 FURI patients (49.6%) in this data set had a diagnosis of invasive candidiasis (41/56; 73.2%) or candidemia (15/56; 26.8%).

In this population with difficult to treat fungal infections with limited treatment options, the most common pathogens were *Candida glabrata*, *C. albicans*, *C. krusei* and other non-*albicans Candida* species. Overall survival at Day 30 was 94.6% (3 deaths out of 56 patients).

Ibrexafungerp Pipeline Update

In addition, Nkechi Azie, M.D., Vice President, Clinical Development and Medical Affairs at SCYNEXIS, presented an ibrexafungerp pipeline update during the New Antimicrobials and ID Diagnostics in the Pipeline – Fungal session at the conference.

“We are pleased to have had the opportunity to present an overview of our ibrexafungerp program and ongoing trials,” Dr. Azie said. “We are proud of our continued clinical progress as we remain committed to bringing our innovative, potent antifungal to market as a potential option for patients with difficult to treat fungal infections.”

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 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.

INDICATION

BREXAFEMME is a triterpenoid antifungal indicated for the treatment of adult and postmenarchal pediatric females with vulvovaginal candidiasis (VVC).

DOSAGE AND ADMINISTRATION

The recommended dosage of BREXAFEMME is 300 mg (two tablets of 150 mg) twice a day

for one day, for a total treatment dosage of 600 mg. BREXAFEMME may be taken with or without food.

IMPORTANT SAFETY INFORMATION

BREXAFEMME is contraindicated during pregnancy and in patients with a history of hypersensitivity to ibrexafungerp

BREXAFEMME administration during pregnancy may cause fetal harm based on animal studies. Prior to initiating treatment, verify pregnancy status in females of reproductive potential and advise them to use effective contraception during treatment

When administering BREXAFEMME with strong CYP3A inhibitors, the dose of BREXAFEMME should be reduced to 150 mg twice a day for one day. Administration of BREXAFEMME with strong CYP3A inducers should be avoided

Most common adverse reactions observed in clinical trials (incidence $\geq 2\%$) were diarrhea, nausea, abdominal pain, dizziness, and vomiting

To report SUSPECTED ADVERSE REACTIONS, contact SCYNEXIS, Inc. at 1-888-982-SCYX (1-888-982-7299) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information, visit www.brexafemme.com. Please click [here](#) for Prescribing Information.

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. SCYNEXIS filed a supplemental New Drug Application (sNDA) to expand BREXAFEMME's labelling to include the prevention of recurrent vulvovaginal candidiasis, and the FDA assigned a target PDUFA action date of November 30, 2022, for this additional indication. In addition, late-stage clinical investigation of oral ibrexafungerp for the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. For more information, visit www.scynexis.com.

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