May 10, 2022

SCYNEXIS Presents New Interim Positive Data of Ibrexafungerp for Refractory Vulvovaginal Candidiasis from Ongoing Phase 3 FURI Study at the American College of Obstetricians and Gynecologists (ACOG) Annual Clinical & Scientific Meeting

- Data show that of the FURI study patients with refractory or relapsed vulvovaginal candidiasis (VVC) treated with ibrexafungerp, 71.4% had successful clinical outcomes.
- Ibrexafungerp demonstrated positive results in difficult-to-treat VVC patients with severe fungal infections who were either intolerant to standard antifungal therapy or experienced refractory infections despite treatment.
- In the study, ibrexafungerp was generally safe and well-tolerated with findings consistent with the existing product label.

JERSEY CITY, N.J., May 10, 2022 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company pioneering innovative medicines to overcome and prevent difficult-to-treat and drug-resistant infections, announced the presentation of new positive outcomes in patients with refractory vulvovaginal candidiasis (VVC) treated with oral ibrexafungerp from the ongoing Phase 3 FURI study. The new interim analysis was presented during the American College of Obstetricians and Gynecologists (ACOG) Annual Clinical & Scientific Meeting held in San Diego on May 6-8, 2022.

“We are extremely encouraged by these data showing positive outcomes in VVC patients with severe refractory or relapsed infections,” said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. “We are committed to making advancements in the area of women’s health and believe these outcomes underscore the potential clinical utility of this novel agent in the treatment of a broad spectrum of VVC cases.”

Of the 14 patients in the FURI study with refractory or relapsed cases of VVC treated with ibrexafungerp, 10 (71.4%) had successful clinical outcomes as judged by an independent Data Review Committee. Patients with VVC received 750 mg of oral ibrexafungerp (375 mg twice a day) every 72 hours for a total of three dosing days (Day 1, Day 4 and Day 7).

The ongoing Phase 3 open-label, single-arm FURI study (NCT03059992) 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. In the study, ibrexafungerp was generally safe and well-tolerated with findings consistent with the existing BREXAFEMME® (ibrexafungerp tablets) label.

Earlier this year, SCYNEXIS also announced positive results from its global Phase 3 CANDLE study investigating the safety and efficacy of oral ibrexafungerp for prevention of recurrent vulvovaginal candidiasis (rVVC), also known as vaginal yeast infection. The Company plans to submit to the U.S. Food and Drug Administration (FDA) a supplemental New Drug Application (sNDA) in the first half of 2022 based on the CANDLE data and anticipates receiving approval for a label expansion by year-end.

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 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 ≥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. In addition, clinical investigation and development 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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