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SCYNEXIS Announces Initiation of New Phase 3b Study (VANQUISH) to Evaluate Oral Ibrexafungerp as a Treatment for Complicated Vulvovaginal Candidiasis (VVC) in Patients Who Failed to Respond to Treatment with Fluconazole

JERSEY CITY, N.J., June 23, 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 initiation and first patient enrolled in a new Phase 3b, open-label, multicenter study (VANQUISH) to evaluate the efficacy, safety and tolerability of oral ibrexafungerp as a treatment for complicated vulvovaginal candidiasis (VVC) in patients who have failed treatment with fluconazole, based on mycological and clinical outcomes.

The VANQUISH study will enroll approximately 150 difficult-to-treat complicated VVC patients who will receive 600 mg of oral ibrexafungerp for one, three or seven consecutive days determined by their underlying complicating condition including immunocompromised state. Complicated patients include patients with recurrent VVC, those with VVC caused by non-*albicans Candida* species and those with diabetes, immunocompromising conditions (e.g., HIV), or immunosuppressive therapy (e.g., corticosteroids).

“After seeing the strong positive results of patients in the CANDLE Sub-study who had failed fluconazole and the refractory or relapsed VVC cases in our ongoing FURI study, we decided to conduct additional research to explore the efficacy of ibrexafungerp specifically in patients with the most challenging yeast infection cases that have not responded to azole treatments,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “This is another step in our efforts to advance this important non-azole antifungal treatment for VVC that provides an alternative for women with severe, difficult-to-treat fungal infections. Once completed, we believe the results of this study could further demonstrate ibrexafungerp’s ability to treat multiple types of complicated cases.”

Of the 14 patients in the Phase 3 open-label, single-arm FURI study (NCT03059992) 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.

In the nested sub-study of the CANDLE Phase 3 trial, 24 patients who failed to respond to the initial three-day regimen of fluconazole received a one-day open-label treatment course of ibrexafungerp (300 mg BID), and 71% successfully achieved a significant reduction or elimination of signs and symptoms. In both studies, ibrexafungerp was generally safe and

well-tolerated with findings consistent with the existing approved label.

“There is a significant need of treatment alternatives for patients with complicated VVC, including those with underlying conditions such as immunosuppression,” said Nkechi Azie, M.D., Vice President of Clinical Development and Medical Affairs. “The VANQUISH study will allow us to evaluate various dose regimens of ibrexafungerp in women with complicated VVC who have failed fluconazole therapy, to deepen the scientific data on additional dosing options of ibrexafungerp in these challenging complicated VVC scenarios. We thank our advisors and investigators for the strong interest shown in participating in this study, which highlights the need and the opportunity for ibrexafungerp to play a key role in the treatment of women suffering for these burdensome conditions.”

For more information on VANQUISH, please visit ClinicalTrials.gov (NCT05399641).

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) 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, 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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