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SCYNEXIS Resumes Patient Dosing in Phase 3 MARIO Study

- First new patient dosed in Phase 3 MARIO study following the lifting of the FDA clinical hold
- Resumption of dosing in this study triggers a $10M milestone payment from GSK plus an additional $20M milestone due in six months; as previously disclosed GSK disputes these milestone payments, and SCYNEXIS vigorously disagrees with their position

JERSEY CITY, N.J., May 28, 2025 (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 that patient dosing has resumed in the Phase 3 MARIO study, which is an innovative study to investigate oral ibrexafungerp as a potential step-down antifungal therapy following IV echinocandin for invasive candidiasis, a life-threatening infection. The study had been on hold due to concerns about potential cross-contamination in light of draft U.S. Food and Drug Administration (FDA) guidance regarding manufacturing a non-antibiotic beta-lactam (ezetimibe) at the same site as ibrexafungerp. The study has resumed following the manufacture of new clinical supplies at another site and the lifting of the clinical hold by the FDA. If the study is successful and approval for this indication is granted by the FDA, it will give healthcare providers the opportunity to step-down their patients to a non-azole oral therapy that retains the Mechanism of Action (glucan synthase inhibition) of the IV-only echinocandins, which are the gold standard for treatment of invasive *Candida* infections. SCYNEXIS's position is that the dosing of this first new patient triggers a $10 million payment from partner GSK, with another $20 million payment to be triggered by the six-month anniversary of dosing. As previously disclosed, there is a disagreement between SCYNEXIS and GSK regarding the resumption of the MARIO Study and GSK's responsibility for paying these milestones. SCYNEXIS is working to resolve the disagreement.

"We are pleased to announce the dosing of the first new patient in the Phase 3 MARIO study following the lifting of the clinical hold by the FDA in April," said David Angulo, M.D., President and Chief Executive Officer. "The rapid resumption of patient enrollment, just a few days after the investigational sites were re-activated in the study, reflects the eagerness of the scientific community to have new treatment options for this life-threatening infection."

SCYNEXIS is thankful to the investigators participating in this trial for their support and patience during the clinical hold period, and for their continued commitment to the successful completion of this important study, which has already enrolled approximately 25% of the projected patients.

"I'm happy to see this important study restarted, and glad that we have been able to contribute by enrolling a new patient," said Barbara D. Alexander, MD, MHS, FIDSA Professor of Medicine and Pathology at Duke University and the Director of the

Transplant Infectious Diseases Service. “We need additional treatment options for patients with invasive fungal diseases, and we are looking forward to the completion of this study evaluating oral ibrexafungerp in this area of significant unmet need.”

“There is substantial need for new treatments for invasive candidiasis, particularly for *Candida* strains resistant to the currently approved antifungals,” added Dr. Luis Ostrosky-Zeichner, MD, Professor of Medicine and Epidemiology and Chief at the Division of Infectious Diseases of the McGovern Medical School (UTHealth Houston). “Ibrexafungerp could play an important role in improving the outcome of patients with these life-threating infections, and I am glad to see this important study reinitiated in our institution.”

About Triterpenoid Antifungals

Triterpenoid antifungals (also known as “fungerps”) are a novel class of structurally distinct glucan synthase inhibitors that combine the well-established activity of glucan synthase inhibitors with the potential flexibility of having oral and intravenous (IV) formulations. They have demonstrated broad-spectrum antifungal activity against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. Ibrexafungerp is the first representative of this novel class of antifungal agents. Ibrexafungerp, formerly known as SCY-078, is currently approved in the U.S. for the treatment of vulvovaginal candidiasis and is in late-stage development for invasive candidiasis. The next generation fungerp, SCY-247, is currently in the late stages of a Phase 1 clinical study.

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 is developing the company’s proprietary antifungal platform “fungerps.” Ibrexafungerp, the first representative of this novel class, has been licensed to GSK. The U.S. Food and Drug Administration (FDA) approved BREXAFEMME® (ibrexafungerp tablets) in June 2021, for its first indication in vulvovaginal candidiasis (VVC), followed by a second indication in November 2022, for reduction in the incidence of recurrent VVC. Late-stage clinical investigation of ibrexafungerp for the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. Additional antifungal assets from this novel class are currently in clinical, pre-clinical and discovery phases, including the compound SCY-247. For more information, visit www.scynexis.com.

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