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SCYNEXIS Reports Successful Completion of Pre-NDA Meetings with the FDA Regarding Ibrexafungerp for the Treatment of Vulvovaginal Candidiasis

- *Following recent productive meetings, the Company remains on track to submit a New Drug Application (NDA) for the treatment of Vulvovaginal Candidiasis (VVC), also known as Vaginal Yeast Infection, in Q4 2020.*

JERSEY CITY, N.J., July 29, 2020 (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 successful completion of pre-NDA meetings with U.S. Food and Drug Administration (FDA) regarding ibrexafungerp for the treatment of VVC, a common fungal infection that affects millions of women in the U.S. every year.

The purpose of the meetings was to discuss and confirm the clinical, non-clinical and chemistry, manufacturing and controls (CMC) content and requirements for the Company's planned NDA submission and ensure that all elements of submission are met. Ahead of the meetings, SCYNEXIS submitted a pre-NDA briefing document to the FDA that outlined the Company's preliminary data package, including clinical safety and efficacy, non-clinical results, CMC and other regulatory elements. Based on FDA feedback, the Company believes its regulatory package will be sufficient to support a submission of ibrexafungerp for the treatment of VVC. The Company remains on track to submit its NDA in Q4 2020.

"We are extremely encouraged by our collaborative meetings with the Agency," said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. "This is an important milestone for us as we advance what could potentially be the first new antifungal class to be approved in over 20 years, and the only oral, non-azole treatment option for women suffering from vaginal yeast infections."

SCYNEXIS previously announced positive top-line results from its Phase 3, randomized, double-blind, placebo-controlled, multi-center studies (VANISH-303 and VANISH-306) investigating the safety and efficacy of oral ibrexafungerp as a treatment for women with VVC. In both studies, ibrexafungerp consistently showed statistical superiority over placebo for the key endpoints required to support the NDA filing for this indication. Additionally, ibrexafungerp had a favorable tolerability profile throughout its Phase 3 program in VVC. Enrollment is ongoing in the Phase 3 CANDLE study, investigating the safety and efficacy of oral ibrexafungerp for the prevention of recurrent VVC, for which there is no approved therapy in the U.S. Pending successful completion of this trial, SCYNEXIS anticipates top-line results and the submission of a supplemental NDA for this indication in the second half of 2021.

About Ibrexafungerp

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an investigational 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 currently in development for the treatment of fungal infections caused primarily by *Candida* (including *C. auris*) and *Aspergillus* species. It has demonstrated broad-spectrum antifungal activity, *in vitro* and *in vivo*, against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. The FDA has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the formulations of ibrexafungerp for the indications of invasive candidiasis (IC) (including candidemia), invasive aspergillosis (IA) and VVC, 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 committed to positively impacting the lives of patients suffering from difficult-to-treat and often life-threatening infections by developing innovative therapies. The SCYNEXIS team has extensive experience in the life sciences industry, having discovered and developed more than 30 innovative medicines over a broad range of therapeutic areas. The Company's lead product candidate, ibrexafungerp (formerly known as SCY-078), is a novel IV/oral antifungal agent in Phase 3 clinical and preclinical development for the treatment of multiple serious and life-threatening invasive fungal infections caused by *Candida* and *Aspergillus* species. For more information, visit www.scynexis.com.

Forward Looking Statement

Statements contained in this press release regarding expected future events or results are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, but are not limited, to: risks inherent in SCYNEXIS's ability to submit an NDA to the FDA as scheduled and to obtain FDA approval for ibrexafungerp. These and other risks are described more fully in SCYNEXIS's filings with the Securities and Exchange Commission, including without limitation, its most recent Annual Report on Form 10-K under the caption "Risk Factors" and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. SCYNEXIS undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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