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SCYNEXIS Reports Completion of Chronic Nonclinical Toxicology Studies Supporting Long-Term Administration of Ibrexafungerp

Ibrexafungerp's favorable toxicology and embryofetal toxicity profile provide further differentiation from currently available antifungal treatments

Results support long-term dosing of oral ibrexafungerp, a key step for future development of potential new indications such as prophylaxis use and treatment of chronic fungal infections

Nonclinical toxicology package completed; Company is on track to submit first NDA in 2020

JERSEY CITY, N.J., May 30, 2019 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today announced that the company has completed the nonclinical toxicology evaluations that are required by regulatory authorities, including the U.S. Food and Drug Administration (FDA), to support long-term administration in human clinical trials. The toxicology studies were conducted in rodent and non-rodent species for six and nine months, respectively. SCYNEXIS remains on track to submit its first New Drug Application (NDA) to the FDA in 2020.

"The favorable results of these long-term toxicology studies reinforce the safety profile of ibrexafungerp, allowing for patients enrolled in clinical trials to receive oral ibrexafungerp for an extended period of time, and enabling its potential development as a prophylactic agent and as a treatment for chronic fungal infections," said Marco Taglietti, M.D., President and Chief Executive Officer at SCYNEXIS. "A substantial unmet medical need remains for potent antifungal agents that can be safely administered long-term to address difficult-to-treat fungal infections."

Many fungal infections, including chronic pulmonary aspergillosis, bone fungal infection, chronic disseminated candidiasis, chronic mucocutaneous candidiasis and prophylaxis, require long-term antifungal therapy. Regulatory guidelines recommend that drugs intended for long-term use be tested for their safety in rodent and non-rodent species for six and nine months, respectively, in order to identify toxicities that may not have been seen in shorter-term studies but may arise after long-term exposure. Oral ibrexafungerp, administered chronically in these long-term toxicology studies, was not associated with any new safety findings. These results, together with [the reproductive and developmental toxicity studies recently reported](#), complete the core nonclinical toxicology package necessary to support our first NDA planned for 2020.

"Our development program continues to demonstrate the versatile profile of ibrexafungerp, with this favorable nonclinical data on top of the recent positive clinical findings in a variety of difficult-to-treat fungal infections, including multidrug-resistant infections caused by *Candida auris*," said David Angulo, M.D., Chief Medical Officer at SCYNEXIS. "We believe that the availability of long-term administration, coupled with ibrexafungerp's fungicidal activity against *Candida*, high tissue penetration, low risk for drug-drug interactions and convenient oral administration, will provide significant advantages over currently available antifungal treatments in a variety of outpatient and hospital infections."

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. SCYNEXIS'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*, *Aspergillus* and *Pneumocystis* 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 successfully develop and 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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