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## **SCYNEXIS Presents Data at ACOG 2019 Further Supporting a Future NDA Submission of Oral Ibrexafungerp for Vulvovaginal Candidiasis (VVC)**

**Complete regulatory embryo-fetal toxicology package shows no adverse fetal effects caused by ibrexafungerp**

**Confirmed antifungal activity of ibrexafungerp against a variety of *Candida* strains resistant to fluconazole**

**Favorable embryo-fetal safety profile and sustained activity, including against resistant strains, are significant differentiators versus fluconazole, the current standard of care in VVC**

JERSEY CITY, N.J., May 6, 2019 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today announced data demonstrating the potential of ibrexafungerp as an agent to address VVC. The data, which were presented at the 2019 American College of Obstetrics and Gynecology Annual Clinical and Scientific Meeting (ACOG), further support the company's plan to submit a New Drug Application (NDA) for VVC in the second half of 2020.

"The data presented at ACOG 2019 adds to a growing body of evidence demonstrating the favorable safety profile and the antifungal activity of ibrexafungerp against difficult-to-treat and often drug-resistant *Candida* infections," said Stephen A. Barat, PhD, Vice President of Pre-Clinical Research and Early Development at SCYNEXIS. "We are particularly pleased with the positive results observed in our complete reproductive and developmental toxicology package, which allow us to move closer to our planned NDA submission for VVC in the second half of 2020. Reproductive and developmental studies (fertility and early embryonic, embryo-fetal, peri- and post-natal) provide evidence that ibrexafungerp does not cause fetal or reproductive harm. These findings are extremely meaningful for the VVC patient population, often of child-bearing age, and can differentiate oral ibrexafungerp against fluconazole, which has a warning for potential risks of spontaneous abortion and congenital abnormalities in its prescribing information."

Details of the presentations are as follows:

**Poster Title:** Ibrexafungerp, a Novel Oral Antifungal, Demonstrates No Reproductive or Developmental Harm in Preclinical Models

A full developmental and reproductive toxicity package for ibrexafungerp was recently concluded, as required for approval and labeling of prescription medications. These preclinical studies included investigation of the effects of ibrexafungerp on a) fertility and libido of adult male and female animals during treatment; b) conception, implantation and development of embryos; c) development of fetuses, parturition, survival and lactation; d) the development of offspring from birth through sexual maturation; and e) the ability of those offspring to mate and conceive a second-generation post exposure. The studies indicate that ibrexafungerp does not result in reproductive harm to adult animals nor does it result in developmental harm to offspring.

**Presentation Title:** *In Vitro* Activity of Ibrexafungerp (SCY-078) Against *Candida* spp. (including Fluconazole-resistant Isolates)

*In vitro* MIC data for ibrexafungerp against multiple *Candida* spp. were compiled from seven independent studies. The combined studies included 242 isolates with fluconazole resistance (FLU-R) and 532 wild-type (WT) isolates of *C. albicans*, *C. glabrata*, *C. tropicalis* and *C. parapsilosis*. The MIC<sub>50</sub> values for ibrexafungerp against the WT isolates ranged from 0.008 to 0.5 ug/mL. Similar results were obtained against FLU-R strains, for which ibrexafungerp MIC<sub>50</sub> values ranged from 0.06 to 0.5 ug/mL. Overall, ibrexafungerp was active (MIC within two dilutions of WT) against 240/242 (99%) of the FLU-R isolates tested in these studies.

**Poster Title:** A Phase 2b, Dose-Finding Study Evaluating Oral Ibrexafungerp vs Fluconazole in Vulvovaginal Candidiasis (DOVE)

In a randomized, double-blind, double-dummy Phase 2b study, subjects received either one of five oral ibrexafungerp dose regimens (750mg-QD 1 day, 300mg-BID 1 day, 450mg-BID 1 day, 150mg-BID for 3 days, and 300-BID for 3 days) or an active comparator dose of oral fluconazole (FLU) (150mg single dose). Subjects were then evaluated for clinical cure and mycological eradication at Day-10 and Day-25. Subjects receiving the ibrexafungerp dose of 300mg BID for one day (600mg-dose), showed the best combination of clinical response and tolerability. At Day-10, clinical cure, defined as complete resolution of all signs and symptoms, was observed in 14 of 27 (52%) subjects in the ibrexafungerp 600mg-dose arm and 14 of 24 (58%) subjects in the FLU arm. At Day-25, the rate of clinical cure in the ibrexafungerp 600mg-dose arm reached 70% compared to 50% in the FLU arm. At Day-10 and Day-25, the mycological eradication rates were 63% and 48% for the ibrexafungerp 600mg-dose arm and 63% and 38% for the FLU arm. The most common AEs were mild nausea and diarrhea.

### 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](http://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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