April 21, 2020

SCYNEXIS Announces Positive Top-Line Results from its Second Pivotal Phase 3 Study (VANISH-306) of Oral Ibrexafungerp for the Treatment of Vulvovaginal Candidiasis (Vaginal Yeast Infection)

- *Ibrexafungerp achieved highly statistically significant superiority over placebo for the primary and key secondary study endpoints*
- *Ibrexafungerp was generally safe and well-tolerated*
- *Positive results consistent with previously reported VANISH-303 study support anticipated NDA submission for the treatment of vulvovaginal candidiasis (VVC) in the second half of 2020*
- *Enrollment is ongoing in the CANDLE Phase 3 study of oral ibrexafungerp for the prevention of recurrent VVC, with supplemental NDA submission planned for the second half of 2021*
- *Conference call to be held April 21st, 2020 at 8:30 a.m. ET*

JERSEY CITY, N.J., April 21, 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 positive top-line results for its Phase 3 VANISH-306 study investigating the safety and efficacy of oral ibrexafungerp, a novel broad-spectrum antifungal, as a treatment for women with vulvovaginal candidiasis (VVC), also known as vaginal yeast infection. With these results, ibrexafungerp has now achieved superiority over placebo with a high degree of statistical significance on key study endpoints required for regulatory approval of the VVC indication in both VANISH pivotal trials, clearing the way for the NDA submission for the treatment of VVC in the second half of 2020.

“We are thrilled with the results from VANISH-306, which are consistent with the previously reported VANISH-303 study findings in supporting the efficacy and safety of oral ibrexafungerp as a novel treatment for women with vaginal yeast infections,” said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. “Both VANISH Phase 3 studies also confirmed ibrexafungerp’s sustained clinical effect at the Day-25 follow-up visit, consistent with findings from the Phase 2b DOVE study. In parallel, we continue to advance our CANDLE Phase 3 study testing oral ibrexafungerp for the prevention of recurrent vaginal yeast infections, for which there are no approved therapies, and expect top-line data in this indication in the second half of 2021.”

Marco Taglietti, M.D., Chief Executive Officer of SCYNEXIS added, “This marks the successful completion of our VANISH Phase 3 program, with planned NDA submission to the FDA later this year. If approved, ibrexafungerp would be the first and only oral, non-azole

treatment for vaginal yeast infections – a condition that affects three out of four women in their lifetime but has limited treatment options, with no new approved therapies in over 20 years. The positive results from our VANISH program give us confidence that ibrexafungerp has the potential to address vaginal yeast infections across a broad range of disease severity, and could be an ideal treatment option particularly for patients not currently satisfied with existing therapies."

VANISH-306 Efficacy Results:

- 63.3 percent of ibrexafungerp-treated patients met the primary endpoint of clinical cure at the Day-10 test-of-cure (TOC) visit, defined as the complete resolution of all vaginal signs and symptoms (S&S) following a single-day 600mg dose regimen consisting of two doses of 300mg administered 12 hours apart.
- 58.5 percent of ibrexafungerp-treated patients met the secondary endpoint of mycological eradication at TOC visit, defined as negative culture.
- 72.3 percent of ibrexafungerp-treated patients were categorized as clinically improved at TOC visit, defined as having total signs and symptoms of 0 or 1.
- 73.9 percent of ibrexafungerp-treated patients had complete symptom resolution at the Day-25 follow-up (FU) visit.

	VANISH-306 (mITT, n=188)	**VANISH-303 (mITT, n=188)**
	IBX 300mg BID (%)	IBX 300mg BID (%)
Primary Endpoint		
Clinical Cure (0 S&S) at TOC	63.3*	50.5**
Secondary Endpoints		
Mycological Eradication at TOC	58.5**	49.5**
Clinical Improvement (S&S ≤1) at TOC	72.3*	64.4**
Complete Symptom Resolution at Day-25 FU	73.9**	59.6*
* p value ≤ 0.01 ** p value ≤ 0.001		

Safety Results:

In VANISH-306, oral ibrexafungerp was generally safe and well tolerated. Severe and serious adverse events (AEs and SAEs) were rare and there were no drug-related SAEs. Similar to previous studies, the majority of Treatment-Emergent AEs (TEAEs) observed at a higher frequency in the ibrexafungerp group in VANISH-306 were gastrointestinal (GI) in nature, with the three most common GI events (diarrhea/loose stool, nausea and abdominal pain) occurring at rates of 9.4%, 8.4% and 2.7%, respectively. These events were predominantly regarded as mild, of short duration and did not lead to discontinuation, confirming the favorable tolerability profile of the single-day 600mg dose regimen of oral ibrexafungerp that was previously observed.

The combined safety database of the VANISH and DOVE programs in VVC patients now includes more than 850 enrolled patients, with 575 treated with the one-day 600mg dose regimen of ibrexafungerp. The overall incidence of the most common GI events for ibrexafunergp-treated patients in the total database was 16.7% for diarrhea/loose stool,

11.8% for nausea and 4.5% for abdominal pain, supporting the favorable safety and tolerability profile of ibrexafungerp.

For more information about the VANISH-306 study go to: https://clinicaltrials.gov/ct2/show/NCT03987620.

Conference Call Details
SCYNEXIS management will hold a conference call today at 8:30 a.m. ET to discuss the positive results from the VANISH-306 Phase 3 study.

Dial-in Number: 877-705-6003 (Local); 201-493-6725 (International)
Conference ID: 13702597
Webcast Link

The slide and audio webcast can be accessed by visiting the Investors section of the Company's website at http://ir.scynexis.com. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the Company's website for 30 days.

About the VANISH Program

The VANISH program was designed following the 2016 "Vulvovaginal Candidiasis: Developing Drugs for Treatment, Guidance for Industry" by the FDA. The program is comprised of two Phase 3, randomized, double-blind, placebo-controlled, multi-center studies designed to demonstrate superiority of oral ibrexafungerp versus placebo. For each study, patients with an acute episode of VVC with a signs and symptoms (S&S) score of four or greater on a scale of zero (no S&S) to 18 (maximum severity) are randomized to ibrexafungerp (two doses of 300mg 12 hours apart for one day) or placebo in a 2:1 ratio. Similar to the design of the Phase 2b DOVE study, primary efficacy analyses were conducted in the modified-intent-to-treat (mITT) population, comprised of patients with culture confirmed *Candida* spp. infection at baseline who received at least one dose of study treatment. The primary endpoint of each trial is clinical cure rate, defined as the complete resolution of all signs and symptoms (S&S) at the Test-of-Cure (TOC) visit (Day 10). Secondary endpoints include mycological eradication at TOC and complete symptom resolution at the follow-up (FU) visit (Day 25). The VANISH-303 study was conducted in U.S. centers and the VANISH-306 study enrolled patients from sites in the U.S. and Europe. The Company plans to submit a New Drug Application (NDA) to the U.S. Food Drug Administration (FDA) for the treatment of VVC in the second half of 2020 based on the consistently positive results from the VANISH trials.

About Vulvovaginal Candidiasis (VVC)

VVC, commonly known as a vaginal yeast infection due to *Candida*, is the second most common cause of vaginitis. Although these infections are frequently caused by *Candida albicans*, fluconazole-resistant *Candida* strains, such as *Candida glabrata*, have been reported to become increasingly more common. VVC can be associated with substantial morbidity, including significant genital discomfort, reduced sexual pleasure, psychological distress and loss of productivity. Typical VVC symptoms include pruritus, vaginal soreness, irritation, excoriation of vaginal mucosa and abnormal vaginal discharge. An estimated 70-75% of women worldwide will have at least one episode of VVC in their lifetime, and 40-50% of them will experience two or more episodes. Approximately 6-8% of women with VVC

suffer from recurrent disease, defined as experiencing at least three episodes within a 12-month period.

Current treatments for VVC include several topical azole antifungals (clotrimazole, miconazole, and others) and fluconazole, the only orally-administered antifungal currently approved for the treatment of VVC in the U.S. Fluconazole reported a 55% therapeutic cure rate in its label, which now also includes warnings of potential for fetal harm, illustrating the need for new oral alternatives. The needs of women with moderate-to-severe VVC, recurrent VVC, VVC caused by fluconazole-resistant *Candida* spp. or VVC during child-bearing age are not fully addressed by oral fluconazole or topical products. In addition, there are no oral alternatives for VVC patients who do not respond to or do not tolerate fluconazole, and there are no FDA-approved products for the prevention of recurrent VVC.

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, the 'fungerps'. This agent combines the well-established activity of glucan synthase inhibitors with the potential flexibility of having oral and 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 vulvovaginal candidiasis (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 pioneering innovative medicines to help millions of patients worldwide overcome and prevent difficult-to-treat infections that are becoming increasingly drug-resistant. Our lead candidate, ibrexafungerp (formerly known as SCY-078), is a broad-spectrum, IV/oral antifungal agent representing a novel therapeutic class, in late stage development for multiple indications, ranging from vaginal yeast infections to life-threatening fungal infections in hospitalized patients. The SCYNEXIS team has deep expertise in anti-infective drug development and marketing, which can be leveraged to advance ibrexafungerp from clinical development to commercialization. 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; the expected costs of studies and when they might begin or be concluded; the effects that the COVID-19 pandemic may have on SCYNEXIS, its supply chain and clinical trials, and SCYNEXIS's

reliance on third parties to conduct SCYNEXIS's clinical studies. 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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