

January 3, 2019



# **SCYNEXIS Provides Year-end Update and Outlines Plans for 2019**

**Initiated VANISH Phase 3 program of oral ibrexafungerp in acute VVC; top-line data expected in 1H 2020 with potential NDA filing in 2H 2020**

**Initiation of recurrent VVC Phase 3 trial planned for 1H 2019**

**Continued advancement of oral ibrexafungerp clinical development program in hospital-based invasive fungal infections**

**Received non-dilutive state incentive cash benefit of \$6.7 million; approximately \$51 million cash balance as of January 3, 2019, sufficient to ensure full funding of the VANISH Phase 3 VVC trials past top-line data**

JERSEY CITY, N.J., Jan. 3, 2019 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today provided a year-end update and 2019 development plans for ibrexafungerp, an investigational antifungal agent and the first representative of a novel class of structurally-distinct glucan synthase inhibitors, triterpenoids.

"In 2018, we achieved multiple meaningful clinical milestones, most notably reporting positive data from our Phase 2b DOVE study evaluating oral ibrexafungerp for the treatment of vulvovaginal candidiasis (VVC)," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "The identification of a clinically and mycologically effective, well-tolerated oral dose of ibrexafungerp was a critical step for the initiation of our global Phase 3 program. The outcome of this registration program could be transformative for the millions of women with VVC not satisfied with existing therapies and also for SCYNEXIS, as ibrexafungerp could represent the first new antifungal class approved since 2001."

Dr. Taglietti continued: "We are laser-focused on ensuring the efficient and timely completion of our VANISH Phase 3 trials to allow an NDA filing expected in the second half of 2020. We start 2019 with approximately \$51 million in cash, sufficient to ensure the full funding of the VANISH Phase 3 trials past top-line results. We will continue to operate thoughtfully to progress the development of ibrexafungerp across multiple indications and to opportunistically explore commercial partnerships and other non-dilutive forms of cash injections, like the recent \$6.7 million we received from the New Jersey Technology Business Tax Certificate Transfer (NOL) Program."

## **Ibrexafungerp Development Update:**

- **Initiated VVC Phase 3 registration program. SCYNEXIS remains on track to report top-line data in 1H 2020, with potential New Drug Application (NDA) filing in 2H 2020.**
  - The VANISH Phase 3 program comprises two Phase 3 trials (approximately 350 patients each) designed to evaluate the safety and efficacy of one-day oral ibrexafungerp versus placebo for the treatment of VVC. Pending successful completion of these two trials, SCYNEXIS plans to file an initial NDA for oral ibrexafungerp for the treatment of VVC in 2H 2020.
  - SCYNEXIS plans to initiate a third Phase 3 trial (approximately 350 patients) evaluating oral ibrexafungerp versus placebo in recurrent VVC in 1H 2019, an indication with no product currently approved.
  - The Phase 3 program builds on the positive top-line data reported from the Phase 2b DOVE study in July 2018, which showed that the one-day oral ibrexafungerp dose selected for Phase 3 clinical evaluation was well-tolerated, with strong overall clinical and mycological activity and improved sustained effect compared to fluconazole, the current standard of care for VVC.
  - If approved, ibrexafungerp would provide an oral option for millions of women not currently well-served by existing VVC therapies, most notably patients failing fluconazole or relapsing after treatment, with infections caused by fluconazole-resistant *Candida* spp., with difficult-to-treat symptoms, with recurrent VVC (for which no product is currently approved) and of child-bearing age concerned about fluconazole's reported embryo/fetal toxicities.
  
- **Continued advancement of oral ibrexafungerp clinical development in hospital-based invasive fungal infections.**
  - Site initiation activities continue to progress for the Phase 2 trial (SCYNERGIA) designed to evaluate the safety and efficacy of oral ibrexafungerp in combination with standard-of-care voriconazole in patients with invasive pulmonary aspergillosis. An animal model of pulmonary aspergillosis demonstrated improved outcomes and survival rates, supporting the potential superiority of ibrexafungerp in combination with azole therapy versus standard of care alone in this high-mortality indication.
  - The FURI study, evaluating oral ibrexafungerp for the treatment of patients with invasive fungal infections refractory or resistant to standard of care, is ongoing. A preliminary assessment by a Data Review Committee (DRC) of the first 20 completed patients was recently conducted, and SCYNEXIS anticipates reporting top-line findings by February 2019.
  - The CARES study, evaluating oral ibrexafungerp for the treatment of patients with *Candida auris* infections, is ongoing with several patients enrolled. *C. auris* is an emerging life-threatening and multidrug-resistant fungal pathogen, with a mortality rate of up to 60%. CARES is the first study assessing an investigational agent against this pathogen.
  - While oral ibrexafungerp is progressing as a potential valuable option to treat hospital-based invasive fungal infections, SCYNEXIS continues the

development of the intravenous liposomal formulation of ibrexafungerp and will provide further updates in the future.

### **Corporate Update:**

- SCYNEXIS is committed to identifying non-dilutive forms of cash injections. Through the Technology Business Tax Certificate Transfer (NOL) Program in the state of New Jersey, SCYNEXIS recently obtained \$6.7 million of non-dilutive funds.
- Considering SCYNEXIS's worldwide rights to ibrexafungerp and patent protection until 2035, SCYNEXIS continues to explore business development partnerships to maximize ibrexafungerp's commercial opportunity.
- As of January 3, 2019, SCYNEXIS has cash, cash equivalents and short-term investments of approximately \$51 million. SCYNEXIS expects this will be sufficient to ensure full funding of the VANISH Phase 3 VVC trials past top-line results, expected in 1H 2020.

### **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](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; the expected costs of studies and when they might begin or be concluded; 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.

**CONTACT:**

**Investor Relations**

Natalie Wildenradt

Argot Partners

Tel: 212-600-1902

[natalie@argotpartners.com](mailto:natalie@argotpartners.com)

**Media Relations**

George E. MacDougall

MacDougall Biomedical Communications

Tel: 781-235-3093

[george@macbiocom.com](mailto:george@macbiocom.com)

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