



## SCYNEXIS Provides Corporate and SCY-078 Pipeline Update

January 4, 2018

### **Path Forward Established for IV Program of SCY-078, with Clinical Trials to Initiate in the Third Quarter of 2018 with an Improved IV Formulation** **Clinical Development of Oral Formulation of SCY-078 Continues to Progress as Planned in Multiple Indications Approvable with an Oral Agent** **2018 Strategy Designed to Maximize Therapeutic Versatility of SCY-078 as a Treatment for Serious Fungal Infections** **Company to Host a Conference Call Today at 5:00pm ET**

JERSEY CITY, N.J., Jan. 4, 2018 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative anti-infective therapies for difficult-to-treat and often life-threatening infections, today provided a corporate update, including recent pipeline developments and anticipated milestones in 2018, for its lead antifungal candidate, SCY-078. SCY-078 is the first representative of a novel oral and intravenous (IV) triterpenoid antifungal family in clinical and pre-clinical development for the treatment of several serious fungal infections, including invasive candidiasis, invasive aspergillosis, refractory invasive fungal infections and vulvovaginal candidiasis (VVC).

"In 2017, we made significant progress in advancing the clinical development of SCY-078 in indications addressable and approvable with an orally-administered antifungal therapy," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "In addition, we advanced the IV program of SCY-078 to address the clinical hold placed by the U.S. Food and Drug Administration (FDA) following thrombotic events observed in a Phase 1 study. We plan to restart clinical trials with IV SCY-078 in the third quarter of 2018, using a liposomal IV formulation that has shown an improved tolerability profile in pre-clinical assessments compared with the cyclodextrin-based IV formulation used in the earlier study."

Dr. Taglietti continued: "We are excited about our strategic plans for 2018, when we envision SCY-078 advancing in multiple Phase 2 and Phase 3 trials to maximize the broad potential clinical utility of SCY-078 in addressing unmet medical needs in VVC, invasive candidiasis, invasive aspergillosis and refractory invasive fungal infections."

#### **Path Forward Established for IV Program of SCY-078, with Clinical Trials to Initiate in the Third Quarter of 2018 with an Improved IV Formulation**

As previously disclosed in March 2017, the FDA required SCYNEXIS to hold the initiation of any new clinical studies of the IV formulation of SCY-078 following the review of three mild-to-moderate inflammation-related thrombotic events in healthy volunteers receiving the IV formulation at the highest dose level in a Phase 1 study. That study used a cyclodextrin-based IV formulation.

- **Broad Pre-clinical Program Executed to Address the Clinical Hold.** Based on subsequent interactions with the FDA, SCYNEXIS completed a broad range of pre-clinical activities designed to identify the underlying cause of the thrombotic events and to evaluate the optimal administration regimen for the cyclodextrin-based IV formulation of SCY-078. In parallel, SCYNEXIS continued its pursuit of alternative IV formulations.
  - **No Intrinsic Pro-Coagulant Effect of the SCY-078 Compound.** Several pre-clinical studies showed that SCY-078 does not affect blood coagulation by itself, providing supporting evidence that the thrombotic events associated with the administration of the cyclodextrin-based IV formulation were triggered by vascular endothelium inflammation at the site of infusion.
  - **Accelerated Development of a Liposomal IV Formulation of SCY-078.** During 2017, SCYNEXIS accelerated the development of a new formulation based on liposomal technology. This technology has been successfully used to improve systemic tolerability of other commercially available IV formulations.
  - **Favorable Profile of the Liposomal IV Formulation of SCY-078.** SCYNEXIS compared the cyclodextrin-based IV formulation head-to-head against the liposomal IV formulation of SCY-078 in pre-clinical evaluations, and the liposomal formulation showed a superior profile for infusion-related tolerability and vascular inflammation.
- **Pre-clinical Activities Ongoing to Enable Planned Human Studies of the Liposomal IV Formulation of SCY-078.** Based on these initial pre-clinical studies, SCYNEXIS believes that the liposomal IV formulation may offer significant clinical benefits over the cyclodextrin-based IV formulation and, therefore, decided to focus its efforts on the advancement of the liposomal IV formulation of SCY-078. This decision was discussed with the FDA and a path forward was established. Additional pre-clinical studies are ongoing, and SCYNEXIS intends to initiate a Phase 1 study in healthy volunteers in the third quarter of 2018, pending FDA's review.
- **Phase 2b Study in Invasive Candidiasis.** Upon successful completion of the Phase 1 study in healthy volunteers, SCYNEXIS plans to initiate a Phase 2b study of SCY-078 in invasive candidiasis with the liposomal IV formulation in the fourth quarter of 2018.

#### **Clinical Development of Oral Formulation of SCY-078 Continues to Progress as Planned in Multiple Indications Approvable with an Oral Agent**

SCYNEXIS is pursuing several programs where the oral formulation of SCY-078 has the potential to be a suitable treatment for indications with significant unmet medical needs and considerable commercial potential.

- **VVC – Most Advanced Stage of Clinical Development, Targeting Both Acute and Recurrent Infections.**
  - **Rapid Recruitment in the Phase 2 Dose-finding DOVE Study.** In August 2017, SCYNEXIS initiated dosing in the Phase 2 study, designed to evaluate the safety and efficacy of the oral formulation of SCY-078 vs. oral fluconazole, the standard of care, for the treatment of VVC. Robust enrollment in the trial has been maintained, and SCYNEXIS continues to expect top-line results in mid-2018. In a previously conducted, proof-of-concept, Phase 2a study in VVC patients, SCY-078 showed high clinical cure and low recurrence rates.

- **Initiation of Phase 3 Program Planned for the Fourth Quarter of 2018.** SCYNEXIS anticipates that the dose regimen selected from the DOVE study will be subsequently evaluated in Phase 3 studies following an End-of-Phase 2 meeting with the FDA. SCYNEXIS expects to initiate the Phase 3 clinical program in the fourth quarter of 2018.
- **Refractory Invasive Fungal Infections – Potential for Streamlined Development Pathway.**
  - **Enrollment Ongoing in the FURI Study for the Treatment of Patients with a Wide Range of *Candida* spp. Infections with Limited or No Treatment Options.** Sixteen sites in the U.S and Europe are now active in this open-label study, and enrollment is progressing as planned.
  - **CARES Study Opened for Enrollment for the Treatment of Patients with *Candida auris* Infections.** Systemic infections caused by *C. auris*, a pathogen that is often multidrug-resistant, are associated with high mortality. The CARES study is designed to provide rapid access to oral SCY-078 for patients with this life-threatening and difficult-to-treat infection. This emergency protocol allows for expeditious site initiation upon request from investigators.
  - **Both FURI and CARES Studies Designed as Pivotal Trials to Support a Potential Approval.** The open-label design of these studies allows for evaluation of the data on an interim basis to further inform subsequent regulatory steps of the development program.
- **Invasive Aspergillosis – SCY-078 in Combination with Standard of Care May Represent a Significant Opportunity to Improve Outcomes for this High-Mortality Infection.**
  - **Favorable Profile of SCY-078.** SCYNEXIS believes that SCY-078's broad activity against *Aspergillus* spp., including azole-resistant strains, along with its minimal drug-drug interactions, high tissue penetration into the lungs and oral formulation allowing for long-term administration, make it an ideal candidate for use as combination therapy to provide improved outcomes vs. standard of care.
  - **Promising *In Vitro* and *In Vivo* Data with Combination Use of SCY-078 and Standard of Care vs. *Aspergillus* spp.** In recent pre-clinical studies, the combination of SCY-078 with other antifungal agents resulted in significantly better outcomes when compared to treatment with single agents.
  - **Plan to initiate Phase 2 Study in the Third Quarter of 2018.** This initial study in patients with invasive aspergillosis is planned as a randomized, double-blind trial with the objective of assessing the safety and efficacy of oral SCY-078 in combination with azole therapy, the standard of care for this indication. SCYNEXIS is finalizing the study design and expects to start this clinical study in the third quarter of 2018.

#### 2018 Key Upcoming Milestones

- Complete enrollment and announce top-line study results of the Phase 2b study of oral SCY-078 as a treatment for VVC in mid-2018.
- Initiate the Phase 1 clinical trial to evaluate the safety and tolerability of the liposomal IV formulation of SCY-078 in healthy volunteers in the third quarter of 2018.
- Initiate a Phase 2 study of oral SCY-078 in combination with current standard of care as a treatment for invasive aspergillosis in the third quarter of 2018.
- Upon successful completion of the Phase 1 study, initiate a Phase 2b clinical trial designed to evaluate IV/oral SCY-078 for the treatment of invasive candidiasis. SCYNEXIS expects to initiate this study in the fourth quarter of 2018.
- Initiate the Phase 3 program for VVC in the fourth quarter of 2018.
- Continue to advance enrollment in both the FURI and CARES studies, both in the U.S. and globally, with preliminary data review planned for the fourth quarter of 2018.

#### Conference Call Details

SCYNEXIS will host a conference call today at 5:00pm Eastern Time to provide a general corporate and SCY-078 pipeline update, as well as to present its plans for 2018. The call can be accessed by dialing 844-309-3707 or 661-378-9467 prior to the start of the call and referencing conference ID: 2897769. The conference call will also be webcast live over the Internet and can be accessed on the "Investors" section of the SCYNEXIS website, [www.scynexis.com](http://www.scynexis.com).

#### About SCY-078

**SCY-078** is an investigational antifungal agent that is a semi-synthetic derivative of the natural product enfumafungin. SCY-078 is 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 IV and oral formulations. SCY-078 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 of antifungal activity, *in vitro* and *in vivo*, against multi-drug resistant pathogens, including azole- and echinocandin-resistant strains. The FDA granted Fast Track, Qualified Infectious Disease Product and Orphan Drug Designations for the formulations of SCY-078 for the indications of invasive candidiasis (including candidemia) and invasive aspergillosis.

#### About SCYNEXIS

SCYNEXIS, Inc. ([NASDAQ:SCYX](http://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 delivering innovative anti-infective therapies. The [SCYNEXIS team](#) has extensive experience in the life sciences industry, discovering and developing more than 30 innovative medicines over a broad range of therapeutic areas. The Company's lead product candidate, **SCY-078**, is a novel IV/oral antifungal agent in Phase 2 clinical and pre-clinical development for the treatment of several 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 maybe, "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' ability to successfully develop SCY-078, including SCYNEXIS' ability to resolve the FDA's concerns regarding the IV formulation of SCY-078 on a timely basis, if at all, and obtain FDA's approval for SCY-078; the expected costs of studies and when they might begin or be concluded; and SCYNEXIS' reliance on third parties to conduct SCYNEXIS' clinical studies. These and other risks are described more fully in SCYNEXIS' 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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