

# SCYNEXIS Inc. Presents New Clinical and Non-Clinical Data Confirming the Potential of SCY-078 as a Novel Treatment for Lifethreatening Fungal Infections

- SCY-078 shown to be the first glucan synthase inhibitor with high oral bioavailability in humans
- Fungicidal activity of SCY-078 demonstrated against multiple Candida species, including difficult-to-treat strains
- SCY-078 progressing to next stages of clinical development in invasive candidiasis with both intravenous (IV) and oral formulations

Data Unveiled in Podium Presentations at ASM Microbe 2016

JERSEY CITY, N.J., June 20, 2016 (GLOBE NEWSWIRE) -- Drug development company SCYNEXIS, Inc. (Nasdaq:SCYX) presented today an interim sub-analysis of Phase 1 studies, which demonstrated that the oral bioavailability of SCY-078, its novel antifungal glucan synthesis inhibitor, allows to readily achieve the target blood exposure required to fight an Invasive *Candida* infection. Additionally, in a preclinical study, SCY-078 showed rapid *in vitro* fungicidal activity against multiple *Candida* species. Both data sets were presented in podium presentations at ASM Microbe 2016 in Boston from June 16 through 20, 2016.

In the Phase 1 studies presented, healthy subjects received either an oral (24 subjects) or IV (14 subjects) dose of SCY-078 citrate salt.

- The geometric mean half-lives after oral and IV administration were over 20 hours, supporting a once-a-day dosing.
- The estimated volume of distribution at steady-state (Vd<sub>ss</sub>) was 8.3 L/kg, indicating high tissue distribution and SCY-078's potential to reach multiple sites of infection.
- The absolute oral bioavailability, defined as the ratio of the dose-normalized AUC0-∞ values for the oral to IV doses, was high (~ 35%), indicating SCY-078's ability to reach target exposure (15 µM•h), when administered orally.

The *in vitro* time-kill experiments presented provided confirmation of the fungicidal activity (i.e., ability to kill the fungi) of SCY-078 not only against *Candida albicans* but also against other more difficult to treat *Candida* species including *glabrata, parapsilosis, tropicalis and krusei*. Having fungicidal activity is considered advantageous in treating invasive *Candida* infections in immunocompromised patients. As previously reported in the literature, our study also confirmed that the activity of fluconazole and voriconazole was not fungicidal but simply fungistatic against *Candida*.

"The confirmation of significant oral bioavailability and fungicidal activity against *Candida*, coupled with the positive clinical results from our recently released Phase 2 proof-of-concept study of orally administered SCY-078 in a mucocutaneous *Candida* infection (vulvovaginal candidiasis), further supports our current plans to advance the development of SCY-078 in invasive candidiasis," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "It has been a couple of decades since the first compound of a new class of antifungal agents has reached Phase 2 of development, and the data presented in this congress is a confirmation of the key attributes that define SCY-078 as a unique and clearly differentiated, first-in-class compound, potentially making SCY-078 an agent of choice in the treatment of life-threatening invasive candidiasis including those caused by multi-drug resistant *Candida* strains."

#### **About SCY-078**

SCY-078 is a glucan synthase inhibitor in Phase 2 clinical development as an IV and oral treatment for fungal infections caused by *Candida* and *Aspergillus* species. SCY-078 is a semi-synthetic derivative of the natural product enfumafungin—a structurally distinct class of glucan synthase inhibitor. SCY-078 combines the well-established activity of glucan synthase inhibitors (similar to echinocandins) with the flexibility of having intravenous (IV) and oral formulations (similar to azoles). By belonging to a chemical class distinct from other antifungals, SCY-078 has shown *in vitro* and *in vivo* activity against multi-drug resistant pathogens, including azole and echinocandin resistant strains. SCY-078 is currently in Phase 2 of development. Positive results from a recently reported Phase 2 proof-of-concept study in acute VVC provided evidence of the antifungal activity of orally administered SCY-078 in patients with *Candida* infections. The U.S. Food and Drug Administration (FDA) granted Fast Track, Qualified Infectious Disease Product (QIDP) and orphan drug designations (ODD) for the oral and IV formulations of SCY-078 for the indication of invasive candidiasis (including candidemia). The FDA also granted Fast Track and QIDP designations of SCY-078 for the indication of invasive aspergillosis.

### **About SCYNEXIS**

SCYNEXIS is a pharmaceutical company committed to the development and commercialization of novel anti-infectives to address significant unmet therapeutic needs. We are developing our lead product candidate, SCY-078, as an oral and IV drug for the treatment of serious and life-threatening invasive fungal infections. For more information, visit www.scynexis.com.

## **Forward Looking Statement**

Statements contained in this press release regarding matters that are expected to occur in the future are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, any statements related to subsequent development activities of SCY-078 and the potential benefits of SCY-078 for treatment of fungal infections. 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, risks inherent in SCYNEXIS' ability to successfully develop SCY-078, including SCYNEXIS' ability to obtain FDA 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. 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 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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Source: SCYNEXIS, Inc.