

## SCYNEXIS Achieves New Development Milestones Reinforcing the Versatility of SCY-078 in Treating Serious Fungal Infections

- Regimen of intravenous (IV) formulation of SCY-078 successfully identified and characterized to support subsequent studies –
- Long-term toxicology studies completed, confirming favorable safety profile of oral SCY-078 –

JERSEY CITY, N.J., Dec. 13, 2016 (GLOBE NEWSWIRE) -- Drug development company <u>SCYNEXIS</u>, <u>Inc</u>. (Nasdaq:SCYX), a pharmaceutical company developing novel anti-infectives to address unmet therapeutic needs, today announced two new development milestones for SCY-078, a novel antifungal agent.

The SCY-078 Phase 1 intravenous (IV) Program consists of single-ascending and multiple-ascending dose studies to test different IV formulations and doses in healthy volunteers followed by oral regimens. Based on the available safety and pharmacokinetics (PK) data from this program, we have identified an IV formulation and dose regimen that, pending discussions with the FDA, we plan to test in the upcoming clinical trials of SCY-078.

Additionally, the SCY-078 toxicology program was expanded to include three-month oral dose studies in two species (rats and dogs). Consistent with findings from prior non-clinical toxicology studies of shorter durations, these longer-term toxicity studies confirmed the favorable safety profile of oral SCY-078. These results would allow flexible treatment regimens of SCY-078 for up to three months in our next stages of clinical development, which is particularly relevant for patients with invasive aspergillosis or refractory fungal infections.

"These latest successful milestones in our SCY-078 development program reflect its versatility in dosing and long-term tolerability for treating a variety of fungal infections. The benefits of both IV and oral formulations would allow SCY-078 to be used as a treatment against invasive fungal infections in multiple settings and indications," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "We are advancing SCY-078 to the next stages of development, with all key elements now in place: (i) both oral and IV formulations available; (ii) *in vitro* and *in vivo* data showing broad spectrum antifungal activity, including activity against azole- and echinocandin-resistant strains; (iii) promising clinical activity observed in two recently completed Phase 2 studies; and (iv) a well-characterized safety and tolerability profile in toxicology studies and in more than 300 patients and subjects exposed to SCY-078."

## **About SCY-078**

SCY-078 is an oral and IV glucan synthase inhibitor in Phase 2 clinical development for the treatment of fungal infections caused by *Candida* and *Aspergillus* species. SCY-078 is a triterpene, 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. 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 indications of invasive candidiasis (including candidemia) and invasive aspergillosis.

## About SCYNEXIS, Inc.

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 several fungal infections, including serious and life-threatening invasive fungal infections. For more information, visit <a href="https://www.scynexis.com">www.scynexis.com</a>.

## **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: SCYNEXIS's plan to test the IV formulation in upcoming clinical trials of SCY-078, including a Phase 2 study in patients with invasive candidiasis; that SCYNEXIS is advancing SCY-078 to the next stages of development; its plans to initiate studies evaluating SCY-078 in patients with refractory invasive fungal infections in the fourth quarter of 2016, and in patients with invasive candidiasis in early 2017; and the expected benefits of the use of both the IV and oral formulations of SCY-078. 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 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. 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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Source: SCYNEXIS, Inc.