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SCYNEXIS, Inc. Receives Orphan Drug Designation for SCY-078 for the Treatment of Invasive Aspergillus Infections

First non-azole, orally and IV bioavailable antifungal agent with orphan drug designation for both invasive Aspergillus infections and invasive Candida infections

JERSEY CITY, N.J., Aug. 24, 2016 (GLOBE NEWSWIRE) -- Drug development company SCYNEXIS, Inc. (Nasdaq:SCYX) today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to the Company's novel triterpenoid broad-spectrum antifungal agent, SCY-078, for the treatment of invasive *Aspergillus* infections.

The orphan drug designation of SCY-078 provides seven years of market exclusivity in the U.S. following FDA approval of an NDA for the orphan designated indication. This is the second U.S. orphan designation received for SCY-078. Earlier this year, the Company announced that SCY-078 received orphan drug designation for the treatment of invasive *Candida* infections, including candidemia. The Company was previously granted Qualified Infectious Disease Product (QIDP) designation for both the IV and oral formulations of SCY-078, which provides an additional five years of exclusivity. Together, these designations provide SCYNEXIS with a potential 12 years of market exclusivity in the U.S. upon FDA approval.

"The FDA's decision to grant SCY-078 orphan drug designation for invasive *Aspergillus* infections is another important milestone in the development of our lead compound recognizing the broad antifungal spectrum of this novel antifungal agent. We believe SCY-078 has the potential to be a unique treatment option for patients with acute and chronic fungal infections caused by *Aspergillus*," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "SCY-078 has clinically-relevant attributes such as high tissue penetration and distribution, reduced risk for drug-drug interactions, activity against azole-resistant pathogens and versatile administration with both oral and IV formulations. If approved, SCY-078 would currently be the only alternative to azoles to treat invasive *Aspergillus* infections (including azole-resistant strains), with the flexibility of both oral and IV formulations."

In the U.S., under the Orphan Drug Act, the FDA's Office of Orphan Products Development grants orphan drug designation to products intended to treat rare diseases or conditions, which are defined by the FDA as those affecting fewer than 200,000 people in the U.S.. In addition to the potential U.S. market exclusivity in the specified indication, if SCYNEXIS complies with certain FDA requirements, the designation provides several benefits and incentives, including tax credits related to qualified clinical trial expenses, eligibility for

orphan drug grants, and an exemption from FDA application fees.

About Invasive *Aspergillus* Infections

Invasive aspergillosis is a serious fungal infection caused by *Aspergillus* species that usually affects people who have weakened immune systems, such as people who have had an organ transplant or a stem cell transplant. Invasive aspergillosis most commonly affects the lungs, but it can also spread to other parts of the body. There are approximately 46,000 cases of invasive aspergillosis reported in the U.S. annually, with a mortality rate as high as 50%. Current standard of treatment is 8 to 12 weeks of azoles usually started as IV treatment for one to two weeks followed by oral step-down treatment for several weeks.

About SCY-078

SCY-078 is an oral and IV glucan synthase inhibitor in Phase 2 clinical development for the treatment for fungal infections caused by *Candida* and *Aspergillus* species. SCY-078 is a semi-synthetic triterpene 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. Positive results from a recently reported Phase 2 proof-of-concept study in a mucocutaneous *Candida* spp. infection (acute vulvovaginal candidiasis) 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 indications of invasive *Candida* infections (including candidemia) and invasive *Aspergillus* infections.

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 serious and life-threatening invasive fungal infections. For more information, visit www.scynexis.com.

Forward Looking Statement

Statements contained in this press release regarding the expected benefits of SCY-078, the expected timing of results from clinical trials and expected benefits of orphan drug designation of SCY-078 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 due to a number of factors, including: regulatory risks; the risk that results in prior trials may not be repeated in subsequent trials; and the risk that unexpected events may occur that may delay the reporting of results from clinical trials. These risks 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 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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