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

JERSEY CITY, N.J., May 13, 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 and structurally distinct glucan synthase inhibitor, SCY-078, for the treatment of invasive *Candida* infections, including candidemia.

The orphan drug designation of SCY-078 provides seven years of market exclusivity. The Company was previously granted Qualified Infectious Disease Product (QIDP) designation, which provides an additional five years of exclusivity. Together, these designations provide SCYNEXIS with a potential twelve years of market exclusivity in the U.S. following FDA approval.

"We are pleased with FDA's decision to grant SCY-078 orphan drug designation which speaks to the urgent need for a new class of antifungal agents to treat this rare and life-threatening condition, particularly as resistance to current treatments continues to rise," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "This latest achievement is another key milestone for SCYNEXIS and we look forward to announcing top line data from our two ongoing Phase 2 studies of SCY-078's oral formulation for the treatment of vulvovaginal candidiasis (VVC) and invasive candidiasis in June and July 2016, respectively."

In the U.S., under the Orphan Drug Act, the FDA's Office of Orphan Products Development grants orphan drug status to a drug intended to treat a rare disease or condition, which is generally a disease that affects fewer than 200,000 individuals in the country. In addition to the potential extended 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 and an exemption from FDA application fees.

About Invasive Candidiasis

Invasive candidiasis is a serious, often life-threatening infection caused by *Candida* species that typically affects a highly vulnerable population such as immunocompromised patients or patients under intensive care in hospital settings. We estimate that the U.S. annual incidence is approximately 98,000 cases with high mortality rates (i.e., 20-40%) despite the currently available antifungal agents. Furthermore, the limited number of antifungal drug classes, consisting of azoles, echinocandins and polyenes, and their widespread use, has led to increased numbers of *candida* infections with drug-resistant strains. The Centers for Disease Control and Prevention (CDC), has listed fluconazole-resistant *Candida* as a

serious public health threat requiring prompt and sustained action.

About SCY-078

SCY-078 is an oral glucan synthase inhibitor in Phase 2 development for the treatment of 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 inhibitors. SCY-078 combines the well-established activity of glucan synthase inhibitors with the flexibility of use of azole with both oral and IV formulations. By belonging to a chemical class distinct from other antifungals, SCY-078 has shown *in vitro* activity against multi-drug resistant pathogens, including azole and echinocandin resistant strains. SCY-078 is currently in Phase 2 development with the oral formulations in two indications: invasive candidiasis and vulvovaginal candidiasis. SCY-078 has received both Fast Track and QIDP designations from FDA for the oral and intravenous (IV) formulations 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 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 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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