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SCYNEXIS, Inc. Receives FDA Fast Track and QIDP Designations for Intravenous Formulation of SCY-078 for the Treatment of Patients with Invasive Fungal Infections

JERSEY CITY, N.J., Jan. 28, 2016 (GLOBE NEWSWIRE) -- Drug development company SCYNEXIS, Inc. (Nasdaq:SCYX) today announced that the U.S. Food and Drug Administration (FDA) has granted both Fast Track and Qualified Infectious Disease Product (QIDP) designations for the intravenous (IV) formulation of SCY-078, SCYNEXIS' novel antifungal product, for the indications of invasive candidiasis (including candidemia) and invasive aspergillosis. SCYNEXIS is currently conducting a Phase 1 study of the IV formulation of SCY-078 to evaluate the safety, tolerability and pharmacokinetics of single-rising doses. The FDA granted QIDP and Fast Track designations for the oral formulation of SCY-078 for both the treatment of invasive candidiasis and invasive aspergillosis in 2014. The oral formulation is currently in Phase 2 development for both invasive candidiasis and vulvovaginal candidiasis.

"In the 2016 revision of its clinical guidelines for the management of candidiasis, the Infectious Diseases Society of America (IDSA) strongly recommends the use of echinocandins as initial therapy for invasive candidiasis. These recommendations are based on better overall outcomes observed with echinocandins — the only glucan synthase inhibitors currently available — when compared to azoles," said Dr. Peter Pappas, Principal Investigator of the Mycoses Study Group and Professor of Infectious Diseases at the University of Alabama School of Medicine. "SCY-078, a glucan synthase inhibitor, holds significant potential to become a first-line treatment alternative for this life-threatening condition. We view the FDA's granting of Fast Track and QIDP designations as validation of the potential value of SCY-078 as a promising new antifungal agent."

"SCY-078, the first representative of a novel class of glucan synthase inhibitors, goes beyond the two main classes of antifungal agents currently used for fungal infections by combining the best attributes of azoles and echinocandins," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "SCY-078 allows for both oral and IV administrations, like an azole, and is designed to block an established target in clinically relevant infectious fungi such as *Candida* and *Aspergillus*, like an echinocandin, including multi-drug resistant strains. Holding QIDP and Fast Track designations for both formulations further fosters our plans for expedited development of this innovative product in multiple indications addressing well-recognized medical and market needs."

The FDA's Fast Track Drug Development Program is a process designed to facilitate the development and expeditious review of drugs to treat serious conditions and fill unmet medical needs. This designation allows for companies to interact with the FDA review team frequently to discuss critical development issues such as study design, required safety data

necessary to support approval, and structure and content of a New Drug Application (NDA). Additionally, should the FDA determine that a Fast Track product may be effective after their preliminary evaluation of clinical data submitted by a sponsor, the FDA may also consider reviewing portions of a marketing application before the sponsor submits the complete application, known as a “rolling” NDA.

The QIDP designation, provided under the 2012 U.S. Generating Antibiotic Incentives Now (GAIN) Act, allows SCYNEXIS to have priority review, eligibility for Fast Track status, and an additional five years of market exclusivity in the U.S. for SCY-078.

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. The FDA designated SCY-078 as a QIDP for both oral and IV use for the indications of invasive candidiasis, including candidemia, and invasive aspergillosis.

About Invasive Fungal Infections
Invasive fungal infections (IFI) are serious, often life-threatening infections caused by a variety of fungal species. *Candida* and *Aspergillus* species are the fungi responsible for approximately 85% of all invasive fungal infections in the U.S. and Europe. The incidence of invasive fungal infections has increased significantly over the past two decades, as the populations of patients at risk have continued to rise. Morbidity and mortality remain high despite the currently available antifungal agents. Because there are limited treatment options, and they are used widely, there has been an increase in the number of infections due to drug-resistant strains.

About Vulvovaginal Candidiasis (VVC)
VVC, commonly known as a "yeast infection," is usually caused by *Candida albicans* and typical symptoms include pruritus, vaginal soreness, irritation and abnormal vaginal discharge. An estimated 75% of women will have at least one episode of VVC during their lifetime and 40%-45% will experience two or more episodes. As many as 8% of these patients suffer from recurrent VVC, defined as experiencing at least four episodes a year. Current treatments for VVC include topical antifungals and the use of prescription oral antifungals such fluconazole, which has a therapeutic cure rate of 55% as reported in the label. There are no products currently approved for the treatment recurrent VVC.

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 in humans. 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 SCYNEXIS's clinical product development plans, clinical product development timelines, and potential commercialization of any product under development. 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 SCYNEXIS's ability to successfully develop SCY-078, including SCYNEXIS's ability to obtain FDA approval for SCY-078, the expected costs of studies and when they might begin or be concluded, and SCYNEXIS's reliance on third parties to conduct SCYNEXIS's clinical studies. Risks are described more fully in SCYNEXIS's filings with the Securities and Exchange Commission, including without limitation its most recent Quarterly Report on Form 10-Q 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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