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SCYNEXIS Receives Designation as a Small and Medium Enterprise by the European Medicines Agency

JERSEY CITY, N.J., April 19, 2016 (GLOBE NEWSWIRE) -- Drug development company SCYNEXIS, Inc. (Nasdaq:SCYX) announced today that the Company has been granted Small and Medium Sized Enterprise (SME) status by the European Medicines Agency (EMA).

The SME designation was created by the EMA to bolster innovation and support smaller-sized companies with the goal to promote the development of new medicines in the European Union. Through the SME program, companies are eligible to receive financial incentives, regulatory fee reductions and waivers, and European Union funding through national and regional level programs. SME-status companies are also able to seek scientific advice, protocol assistance and other information and training from dedicated EMA personnel during the clinical development process, up through submission of a European marketing authorization application. Companies with SME status have the opportunity to discuss such topics as clinical endpoints, trial statistics and drug comparators with the EMA during the clinical development process, with the goal of accelerating the clinical development program and regulatory approval process.

“We are pleased to receive SME status from the EMA and believe our company will greatly benefit from the financial incentives and the support offered through this special designation,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “We believe that the assistance this program provides will support the expansion of the SCY-078 development program in the Europe Union, and will strengthen our efforts to bring what is potentially the first in a new class of antifungal drugs to a global patient population.”

“This designation is a testament to our commitment for a global clinical development program – especially in the European Union,” said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. “We look forward to continuing to strengthen and expand our relationships with medical centers, physicians and key opinion leaders in Europe.”

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 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 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 SCY-078's potential as an anti-fungal therapy and any benefits SCYNEXIS may receive in connection with its designation as a SME. 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 or EMA 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 related to SCYNEXIS 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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