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SCYNEXIS, Inc. Receives FDA Fast Track Designation for Oral Formulation of SCY-078 for the Treatment of Patients With Invasive Fungal Infections

RESEARCH TRIANGLE PARK, N.C., Jan. 9, 2015 (GLOBE NEWSWIRE) -- Drug discovery and development company SCYNEXIS, Inc. (Nasdaq:SCYX) today announced that the U.S. Food & Drug Administration (FDA) has granted Fast Track designation for the oral formulation of SCY-078, the Company's novel antifungal product in development for the treatment of invasive *Candidiasis*, including *Candidemia* and invasive *Aspergillosis*. SCYNEXIS is currently screening patients for a Phase 2 study of the oral formulation of SCY-078 and expects to enroll the first patient in the first quarter of 2015.

"This Fast Track designation, coupled with our prior receipt of QIDP designation, allows for an accelerated path to approval and underscores the FDA's understanding of the critical need for new and varied treatments for life-threatening invasive fungal infections," said Yves J. Ribeill, Ph.D., President and Chief Executive Officer of SCYNEXIS. "We now have multiple trial sites open and we look forward to reporting complete data in the first half of 2016."

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 an unmet medical need. 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. 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.

About SCY-078

SCY-078 (formerly MK-3118) is an oral glucan synthase inhibitor being developed for the treatment of invasive fungal infections including *Candidemia* and invasive *Aspergillosis*. SCY-078 is a semi-synthetic derivative of the natural product enfumafungin—a structurally distinct class of glucan synthase inhibitors. Glucan synthase inhibitors have been very effective in treating invasive fungal infections in a hospital setting, but are currently only available in intravenous formulations. The FDA designated SCY-078 as a Qualified Infectious Disease Product (QIDP) for oral use for the indications of invasive *Candidiasis*, including *Candidemia*, and invasive *Aspergillosis*. SCYNEXIS is developing both oral and intravenous formulations of SCY-078.

About Invasive Fungal Infections

Invasive fungal infections (IFI) are serious, often life-threatening infections caused by a variety of fungal species. The most common invasive fungal infections stem from *Candidiasis* and *Aspergillosis*, responsible for approximately 85 percent 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 SCYNEXIS

SCYNEXIS is a pharmaceutical company committed to the discovery, 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 intravenous (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. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. 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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