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SCYNEXIS delays initiation of new clinical studies using the IV formulation of SCY-078 at FDA's request

Ongoing and future clinical development using the oral formulation of SCY-078 are unaffected

JERSEY CITY, N.J., March 02, 2017 (GLOBE NEWSWIRE) -- Drug development company SCYNEXIS, Inc. (Nasdaq:SCYX) today announced that the United States Food and Drug Administration (FDA) has informed the Company to hold the initiation of any new clinical studies with the intravenous (IV) formulation of SCY-078 until the FDA completes a review of all available pre-clinical and clinical data of the IV formulation of SCY-078. Ongoing and future trials using the oral formulation of SCY-078 are unaffected by this regulatory action. A meeting with the FDA to discuss these data and to agree on subsequent clinical studies with the IV formulation of SCY-078 is scheduled for the second quarter of 2017.

The clinical hold decision was issued by the FDA following a review of three mild-to-moderate thrombotic events in healthy volunteers receiving the IV formulation of SCY-078 at the highest doses and highest concentrations in a Phase 1 study. The potential contribution of the IV formulation of SCY-078 to these events cannot be ruled out even though rates of thrombotic events due to intravenous catheters reported in the literature are comparable to those observed in the Phase 1 study.

SCYNEXIS is working closely with the FDA to review the data supporting the use of the IV formulation and dose regimen of SCY-078 selected by the Company for its upcoming clinical trials.

About SCYNEXIS
SCYNEXIS is a drug development 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, including but not limited to the statement, regarding the timing of the next meeting with the FDA to discuss the data and agree on subsequent studies, 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. These risks and uncertainties include, but are not limited, to: risks inherent in SCYNEXIS' ability to successfully develop SCY-078, including SCYNEXIS' ability to resolve the FDA's concerns to lift the clinical hold and obtain FDA 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 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 under the caption "Risk Factors" 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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