

# SCYNEXIS Completes Two Additional Clinical Studies Further Supporting the Favorable Safety Profile of SCY-078

SCY-078 demonstrates a low potential for certain drug-drug interactions – a relevant differentiator versus the azoles, the leading antifungal class – providing an opportunity for favorable labeling

Significant step forward to further de-risk the ongoing development program of SCY-078

JERSEY CITY, N.J., Oct. 25, 2016 (GLOBE NEWSWIRE) -- Drug development company <u>SCYNEXIS</u>, <u>Inc.</u> (Nasdaq:SCYX) today announced the completion of two additional Drug-Drug Interaction (DDI) studies, further demonstrating the favorable safety profile of SCY-078.

An important milestone in drug development is to understand the potential impact of how two or more drugs interact with each other. Patients with invasive fungal infections are typically immuno-compromised and are commonly treated for long periods of time with multiple concomitant drugs for their underlying conditions. The potential for DDIs in these patients results in labeling restrictions, as is the case for the azole class of antifungals, which is associated with a high degree of DDIs with many commonly prescribed drugs.

To date, SCY-078 has been evaluated in multiple *in vitro* studies and Phase 1 clinical trials to assess the potential for SCY-078 to cause DDIs and to interfere with CYP liver enzymes, that are responsible for the metabolism of most drugs.

- Based on in vitro studies conducted with a broad range of CYP enzymes, SCY-078 showed minimal interference with most enzymes, either as a direct inhibitor or inducer, including CYP3A enzymes, the most common pathway for the metabolism of many drugs. CYP2C8 enzyme was shown to be the enzyme with a higher risk of being inhibited by SCY-078;
- <u>DDI rosiglitazone clinical study to evaluate CYP2C8 inhibition</u> rosiglitazone, an antidiabetic medication, is very sensitive to inhibition of CYP2C8 and was used as an indicator of the maximum potential for clinical interaction with oral SCY-078. This study showed that SCY-078 had no effect on rosiglitazone blood levels when coadministered (i.e., no meaningful interaction was observed), indicating a low risk of clinical interactions with drugs metabolized via CYP enzymes;
- <u>DDI tacrolimus clinical study</u>: tacrolimus is an anti-rejection drug commonly used for bone marrow and solid organ transplants patients. Several antifungals, specifically the azoles, induce an increase of tacrolimus blood levels (typically from two- to four-fold), resulting in toxicity concerns which frequently limits the use of the antifungals, and can require major tacrolimus dose adjustments. In this study, oral SCY-078 had no effect on the maximum tacrolimus blood levels (no change in C<sub>max</sub>) with only a minor effect

on tacrolimus' AUC. These results suggest a low risk of clinical interactions and support the ability of co-administration of both drugs.

"These results provide further evidence of the favorable safety profile of SCY-078 and suggest that SCY-078 has low risk for causing clinically relevant drug interactions," said Dr. David Angulo, Chief Medical Officer of SCYNEXIS. "Given the importance of drug coadministration for these vulnerable patients and the high risk for DDIs associated with the azoles – the only orally available antifungal class— we believe these data confirm the potential for SCY-078 to become a much-needed, potent, safe, flexible, and easy to administer antifungal alternative for these life-threatening fungal infections. This is another step towards completing our registration package and enabling a broad patient population to be included in our upcoming registration trials."

### **About SCY-078**

SCY-078 is an oral and IV glucan synthase inhibitor in Phase 2 clinical development for the treatment for fungal infections caused by *Candida* and *Aspergillus* species. SCY-078 is a semi-synthetic triterpene derivative of the natural product enfumafungin—a structurally distinct class of glucan synthase inhibitor. SCY-078 combines the broad spectrum antifungal activity of the Polyenes, the well-established safety profile of the Echinocandins and the flexibility of use (IV and oral formulations) of the Azoles. By belonging to a chemical class distinct from other antifungals, SCY-078 has shown *in vitro* and *in vivo* activity against multidrug resistant pathogens, including azole and echinocandin resistant strains. Positive results from a recently reported Phase 2 proof-of-concept study in a mucocutaneous *Candida* spp. infection (vulvovaginal candidiasis) provided evidence of the antifungal activity of orally administered SCY-078 in patients with *Candida* infections. The U.S. Food and Drug Administration (FDA) granted Fast Track, Qualified Infectious Disease Product (QIDP) and orphan drug designations (ODD) for the oral and IV formulations of SCY-078 for the indications of invasive *Candida* infections (including candidemia) and invasive *Aspergillus* infections.

## 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 serious and life-threatening invasive fungal infections. For more information, visit <a href="https://www.scynexis.com">www.scynexis.com</a>.

# **Forward Looking Statement**

Statements contained in this press release regarding the expected low risk of DDIs with SCY-078are "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: the risk that results in *in vitro* studies may not be repeated in clinical trials; and the risk that unexpected events or results may occur. These risks 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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