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SCYNEXIS Announces Interim Results from Phase 2 Study of Oral SCY-078 in Patients with Invasive Candidiasis

Oral Dose of SCY-078 That Achieves Target Exposure Identified

SCY-078 Safe and Well-Tolerated

Antifungal Clinical Activity of SCY-078 Further Confirmed

JERSEY CITY, N.J., Aug. 01, 2016 (GLOBE NEWSWIRE) -- Drug development company SCYNEXIS, Inc. (Nasdaq:SCYX) today announced the results of an interim analysis of its Phase 2 study evaluating the pharmacokinetics (PK), safety, and tolerability of its novel and structurally distinct glucan synthase inhibitor, SCY-078, as an oral step-down treatment in patients initially treated with intravenous (IV) echinocandin therapy for invasive *Candida* infections. A once daily oral dose of 750mg of SCY-078 was identified as the dose that achieves the target exposure with favorable safety and tolerability in patients with invasive candidiasis.

“We are pleased that this study met all primary objectives. We identified a safe and well tolerated dose that achieves our target exposure in invasive candidiasis patients. Additionally, we observed antifungal activity, confirming the clinically meaningful efficacy previously shown in our recent proof-of-concept Phase 2 study in vulvovaginal candidiasis,” said Marco Taglietti, M.D., President and Chief Executive Officer at SCYNEXIS. “With the project further de-risked, we look forward to initiating subsequent studies of SCY-078, a new class of antifungal, as an IV/oral step-down therapy in patients with refractory invasive fungal infections by the end of 2016 and with invasive candidiasis in the first quarter of 2017.”

The main primary study objective was the identification of the oral dose of SCY-078 that would achieve the target exposure in at least 80% of patients. The interim population PK model predicts that the dose of 750mg will successfully achieve the target exposure at steady state in more than 80% of the population.

SCY-078 was safe and well tolerated, achieving the additional primary study objective. The frequency of adverse events (AEs) was similar among all treatment groups. The most commonly reported AEs in the study were gastrointestinal (GI) such as diarrhea, abdominal pain, nausea and vomiting. Two of the seven patients treated with 750mg of SCY-078 reported GI events (29%), compared to three of the seven patients treated with fluconazole (43%). All GI events were mild or moderate and none resulted in discontinuation.

Efficacy, a secondary endpoint in the study, was assessed at the end of antifungal therapy by determining the global response defined as the resolution of signs and symptoms attributable to the *Candida* infection and mycological eradication. Favorable global response rates were similar among all treatment groups. Of the seven patients randomized to the

SCY-078 750mg treatment group, six achieved a favorable global response (86%), compared to five out of seven in the fluconazole group (71%) and five out of seven in the SCY-078 500mg group (71%).

About the Study

In this Phase 2 multicenter, multinational, randomized, open-label study (clinicaltrials.gov identifier: NCT02244606) following three to ten days of IV echinocandin therapy, a total of 27 patients with invasive candidiasis were enrolled and 22 were randomized to receive either SCY-078 500mg QD with a 1,000mg loading dose (7 patients), SCY-078 750mg QD with a 1,250mg loading dose (7 patients) or standard of care (7 patients receiving fluconazole 400mg QD with a 800mg loading dose and 1 patient receiving micafungin IV 100mg QD because of a fluconazole-resistant isolate) for up to 28 days. Data in the interim analysis includes assessments conducted in the 22 randomized patients (ITT population) up to the end of treatment visit.

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 derivative of the natural product enfumafungin—a structurally distinct class of glucan synthase inhibitor. SCY-078 combines the well-established activity of glucan synthase inhibitors (similar to echinocandins) with the flexibility of having intravenous (IV) and oral formulations (similar to azoles). By belonging to a chemical class distinct from other antifungals, SCY-078 has shown *in vitro* and *in vivo* activity against multi-drug 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 (acute 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 indication of invasive candidiasis (including candidemia). The FDA also granted Fast Track and QIDP designations of SCY-078 for the indication of invasive aspergillosis.

About Invasive Candidiasis

Invasive candidiasis is a serious, often life-threatening infection caused by *Candida* species that typically affects a highly vulnerable population such as immunocompromised patients or patients under intensive care in hospital settings. We estimate that the U.S. annual incidence is approximately 98,000 cases with high mortality rates (i.e., 20-40%) despite currently available antifungal agents. Furthermore, the limited number of antifungal drug classes, consisting of azoles, echinocandins and polyenes, and their widespread use, has led to increased numbers of *candida* infections with drug-resistant strains. The Centers for Disease Control and Prevention (CDC) has listed fluconazole-resistant *Candida* as a serious public health threat requiring prompt and sustained action.

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. 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 subsequent development activities of SCY-078 and the potential benefits of SCY-078 for treatment of fungal infections. 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 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. 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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