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SCYNEXIS, Inc. Announces Positive Results in its Proof-of-Concept Phase 2 Study of SCY-078, the First Member of a Novel Class of Glucan Synthase Inhibitors

Confirmation of Clinically Relevant Antifungal Activity of SCY-078 in Patients with Candida Infections

Company to Host a Conference Call Today at 5:00pm ET to Discuss Results

JERSEY CITY, N.J., June 08, 2016 (GLOBE NEWSWIRE) -- Drug development company SCYNEXIS, Inc. (Nasdaq:SCYX) today announced top line results of its Phase 2 study of two dose regimens of oral SCY-078 versus the current standard of care, oral fluconazole, in patients with acute vulvovaginal candidiasis (VVC), also known as vaginal yeast infection.

“We are delighted with the positive results of this proof-of-concept study that was designed to provide evidence of the antifungal activity of orally administered SCY-078 in patients with *Candida* infections and to assess the potential clinical utility of this molecule in the VVC indication,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “These results are supportive of our planned development of SCY-078 as a novel antifungal class for the treatment of VVC as well as invasive candidiasis, a serious and difficult to treat fungal infection, as the same pathogens are involved in both diseases. We look forward to providing additional updates as our clinical programs advance.”

This Phase 2 study enrolled 96 patients with moderate to severe acute VVC. Both dose regimens of SCY-078 showed similar activity, and results from the Per-Protocol (PP) population were consistent with the Intent-to-Treat (ITT) population (patients who receive at least one dose of study medication). The efficacy analysis provides compelling evidence of the antifungal effect of SCY-078 that appears comparable to fluconazole in the treatment of VVC. Results seen with fluconazole in this trial were in-line with results published in fluconazole’s label.

Intent-to-Treat (ITT) Population

	Combined SCY-078 (n=64)	Fluconazole (n=32)
Clinical cure (1)	78.1 %	65.6 %
Mycological eradication (2)	70.3 %	68.8 %
Therapeutic cure (3)	56.3 %	56.3 %

1. Clinical cure is defined as resolution of signs and symptoms of infection without further antifungal treatment, specifically all signs and symptoms that had a score of 2 or 1 at baseline should be 0 and those with a score of 3 at baseline should be 0 or 1 at the

test of cure visit, in line with FDA draft guidelines.
2. Mycological eradication is defined as a negative culture for baseline yeast pathogen.
3. Therapeutic cure is defined as patients who achieve both clinical cure and mycological eradication at test of cure visit.

There were no severe or serious adverse events in any of the three treatment groups, and there were no discontinuations. While a considerably higher rate of gastrointestinal-related adverse events (diarrhea, nausea, vomiting and abdominal pain) were reported in the SCY-078 treatment arms as compared to the fluconazole arm, all events were mild to moderate in severity and transient in nature, with the majority of the events lasting one day or less after the initiation of SCY-078 dosing. There were no clinically relevant changes noted in vital signs, physical exam findings, chemistry, or hematology parameters. With antifungal activity now established, and as part of the Company's development plan going forward, a range of doses and treatment durations will be explored to identify the optimal therapeutic window for SCY-078 in VVC.

"New treatment options for patients with vulvovaginal candidiasis are needed, particularly for patients with recurrent episodes of VVC or those caused by azole-resistant *Candida* strains," said Dr. Jack Sobel, Professor of Medicine at Wayne State University's School of Medicine. "The evidence of clinical antifungal activity of SCY-078 observed in this proof-of-concept VVC study is an important step forward in the development of this novel compound, which holds promise for addressing current unmet needs in the treatment of recurrent VVC and invasive fungal infections."

Conference Call Details

SCYNEXIS will host a conference call today at 5:00pm Eastern Time to discuss the results and provide an update on the SCY-078 development program. The call can be accessed by dialing 844.309.3707 or 661.378.9467 prior to the start of the call and referencing conference ID: 27542113. The conference call will also be webcast live over the Internet and can be accessed on the "Investors" section of the SCYNEXIS website, www.scynexis.com.

About the Study

The Phase 2 study is a randomized, multicenter, active controlled, evaluator-blinded study of oral SCY-078 compared to oral fluconazole in adult female patients with acute vulvovaginal candidiasis (VVC). A total of 96 patients with an acute moderate to severe, symptomatic episode of VVC were randomized in a 1:1:1 ratio to receive either three daily doses or five daily doses of SCY-078 or oral fluconazole, at the labeled dose regimen of 150mg single dose. This was a pilot investigation and not powered to demonstrate a statistically significant difference in any of the parameters tested. Efficacy was evaluated based on the proportion of patients achieving clinical cure, mycological eradication and therapeutic cure (combination of both clinical cure and mycological eradication) at day 24 (+/-3) after initiation treatment, in line with draft guidelines from the FDA.

About SCY-078

SCY-078 is a glucan synthase inhibitor in Phase 2 development as an oral 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 inhibitors. 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. SCY-078 is currently in Phase 2 development with the oral formulations in two indications: invasive candidiasis and vulvovaginal candidiasis. The U.S. Food and Drug Administration (FDA) granted Fast Track, Qualified Infectious Disease Product (QIDP) and orphan drug designations 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 Vulvovaginal Candidiasis

VVC, commonly known as a "yeast infection," is usually caused by *Candida albicans* and typical symptoms include pruritus, vaginal soreness, irritation and abnormal vaginal discharge. An estimated 75% of women will have at least one episode of VVC during their lifetime and 40%-45% will experience two or more episodes. As many as 8% of these patients suffer from recurrent VVC, defined as experiencing at least four episodes a year. Current treatments for VVC include topical antifungals and the use of prescription oral antifungals such as fluconazole, which has a therapeutic cure rate of 55% as reported in the label. There are no products currently approved for the treatment recurrent VVC.

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. 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, the potential to limit adverse events in future studies and the potential benefits of SCY-078 for treatment of VVC. 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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