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SCYNEXIS Announces FDA Acceptance and Priority Review of New Drug Application for Oral Ibrexafungerp for the Treatment of Vaginal Yeast Infections

- *6-month Priority Review granted for ibrexafungerp with PDUFA target action date set for June 1, 2021*
- *FDA indicated that it is not currently planning to hold an advisory committee meeting for the application*
- *SCYNEXIS is continuing preparations for a U.S. commercial launch of ibrexafungerp in 2nd half 2021*

JERSEY CITY, N.J., Dec. 07, 2020 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: [SCYX](#)), a biotechnology company pioneering innovative medicines to overcome and prevent difficult-to-treat and drug-resistant infections, today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the SCYNEXIS's New Drug Application (NDA) for ibrexafungerp for the treatment of vulvovaginal candidiasis (VVC), also known as vaginal yeast infections. The FDA has granted this application Priority Review, a designation which is granted to applications for potential drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment of serious conditions when compared to standard applications.

Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of June 1, 2021. Additionally, the FDA has communicated that it is not currently planning to hold an advisory committee meeting to discuss the application.

The NDA is supported by positive results from two Phase 3, randomized, double-blind, placebo-controlled, multi-center studies (VANISH-303 and VANISH-306), in which oral ibrexafungerp demonstrated statistically superior efficacy and a favorable tolerability profile in women with VVC.

"The acceptance of this NDA marks a major milestone toward our goal of bringing to market the first new class of antifungals in over 20 years and the first new oral treatment in more than 25 years to the millions of women suffering from vaginal yeast infections," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "As the first oral, non-azole treatment for this particularly symptomatic condition, we believe ibrexafungerp has the potential to change the antifungal treatment landscape."

Ibrexafungerp benefits from both Qualified Infectious Disease Product (QIDP) and Fast Track designations granted by the FDA for the treatment of VVC and prevention of recurrent

VVC. Under QIDP designation, ibrexafungerp will receive five years of market exclusivity in addition to the five years of exclusivity as a new chemical entity.

Dr. Taglietti added, “We expect to benefit from almost 15 years of market exclusivity, which includes 10 years of regulatory exclusivity as a QIDP product and composition-of-matter patent protection until 2035. We believe this time on the market will allow us to establish ibrexafungerp as a major antifungal franchise and a key treatment option across several indications, which may help the brand attain blockbuster status.”

“In VVC alone we believe ibrexafungerp has the potential to achieve significant sales in the U.S., given the large market and the limited treatment options,” said Jim Maffezzoli, Vice President of Marketing and Sales. “With over 16 million prescriptions written each year and only one oral product to treat this condition, we believe our novel antifungal treatment has significant potential to address the needs of women and healthcare providers who are not satisfied with the standard of care. Based on ibrexafungerp’s unique collection of attributes, including its differentiated mechanism of action, we are confident that, if approved, ibrexafungerp can capture a meaningful percentage of the VVC addressable market with the potential for label expansion in the hospital setting.”

About Vulvovaginal Candidiasis (VVC)

VVC, commonly known as a vaginal yeast infection due to *Candida*, is the second most common cause of vaginitis. Although these infections are frequently caused by *Candida albicans*, fluconazole-resistant *Candida* strains, such as *Candida glabrata*, have been reported to become increasingly more common. VVC can be associated with substantial morbidity, including significant genital discomfort, reduced sexual pleasure, psychological distress and loss of productivity. Typical VVC symptoms include pruritus, vaginal soreness, irritation, excoriation of vaginal mucosa and abnormal vaginal discharge. An estimated 70-75% of women worldwide will have at least one episode of VVC in their lifetime, and 40-50% of them will experience two or more episodes. Approximately 6-8% of women with VVC suffer from recurrent disease, defined as experiencing at least three episodes within a 12-month period.

Current treatments for VVC include several topical azole antifungals (clotrimazole, miconazole, and others) and fluconazole, the only orally-administered antifungal currently approved for the treatment of VVC in the U.S. Fluconazole reported a 55% therapeutic cure rate in its label, which now also includes warnings of potential for fetal harm, illustrating the need for new oral alternatives. The needs of women with moderate-to-severe VVC, recurrent VVC, VVC caused by fluconazole-resistant *Candida* spp. or VVC during child-bearing age are not fully addressed by oral fluconazole or topical products. In addition, there are no oral alternatives for VVC patients who do not respond to or do not tolerate fluconazole, and there are no FDA-approved products for the prevention of recurrent VVC.

About SCYNEXIS

SCYNEXIS, Inc. (NASDAQ: SCYX) is a biotechnology company pioneering innovative medicines to help millions of patients worldwide overcome and prevent difficult-to-treat infections that are becoming increasingly drug-resistant. Our lead candidate, ibrexafungerp (formerly known as SCY-078), is a broad-spectrum, IV/oral antifungal agent representing a novel therapeutic class. It is currently under review by the FDA as a treatment for vaginal yeast infections and in late-stage development for multiple life-threatening fungal infections

in hospitalized patients. The SCYNEXIS team has deep expertise in anti-infective drug development and marketing, which can be leveraged to advance ibrexafungerp from clinical development to commercialization. For more information, visit www.scynexis.com.

Forward Looking Statement

Statements contained in this press release regarding expected future events or results are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to statements regarding SCYNEXIS's expectations that ibrexafungerp has the potential to change the antifungal treatment landscape, that it will benefit from 15 years of market exclusivity, that this time on the market will allow it to establish ibrexafungerp as a major antifungal franchise and a key treatment option across several indications, the market potential for ibrexafungerp in VVC alone, and the treatment potential of ibrexafungerp. 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 the regulatory process to obtain FDA approval for ibrexafungerp; SCYNEXIS's need for additional capital resources; and risks inherent in the commercialization of products, if approved. These and other risks are described more fully in SCYNEXIS's filings with the Securities and Exchange Commission, including without limitation, its most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q 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. In addition, statements SCYNEXIS's beliefs and opinions on the relevant subject are based on information currently available to SCYNEXIS and, while SCYNEXIS believes that information provides a reasonable basis for these statements, that information may be limited or incomplete. These statements should not be read to indicate that SCYNEXIS has conducted an exhaustive inquiry into or review of, all relevant information.

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