December 6, 2021

SCYNEXIS Announces Agreement with FDA on Innovative Strategy for Approval of Oral Ibrexafungerp for Treatment of Invasive Candidiasis

- SCYNEXIS is initiating a global Phase 3 study to evaluate oral ibrexafungerp as a step-down treatment for invasive candidiasis (IC), including candidemia.
- Study provides an expeditious path toward approval of ibrexafungerp as the first non-azole oral therapy for invasive candidiasis.
- Approximately 35,000 cases of IC in the U.S. per year are caused by*Candida* species resistant to azoles, for which ibrexafungerp could provide a much-needed oral alternative.
- SCYNEXIS will provide an overview of the strategy and answer questions about the clinical development programs during a Hospital Pipeline Update webcast today at 10 a.m. ET.

JERSEY CITY, N.J., Dec. 06, 2021 (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 initiation of a global Phase 3 study to evaluate the efficacy, safety and tolerability of oral ibrexafungerp as a step-down therapy for patients with invasive candidiasis and/or candidemia following intravenous (IV) echinocandin therapy in the hospital compared to currently-available outpatient therapies.

“We believe that ibrexafungerp, with its activity against fluconazole-resistant strains, is perfectly suited to provide a much-needed alternative as a step-down oral treatment for invasive candidiasis to allow patients to leave the hospital and continue treatment with a potent fungicidal therapy,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “Through our collaborative dialogue with the FDA, we have agreed to an innovative study design that provides an expeditious path to gain regulatory approval of ibrexafungerp for a hospital-based indication.”

The global Phase 3 multi-center, prospective, randomized, double-blind study of two treatment regimens will evaluate oral ibrexafungerp as a step-down treatment in patients suffering from invasive candidiasis (IC) compared to oral fluconazole. Eligible hospital patients with IC will receive treatment with IV echinocandin and will then be switched to either oral ibrexafungerp or oral fluconazole once step-down criteria are met. Approximately 220 patients will be enrolled and randomized in the study.

The primary objective of the study is to determine whether treatment of IC with IV

echinocandins followed by oral ibrexafungerp is as effective as treatment with IV echinocandins followed by oral fluconazole, the current standard of care. The primary end point of the study will be all-cause mortality at 30 days after initiation of antifungal therapy.

There will also be an open label arm to evaluate oral ibrexafungerp compared to the best available therapy in patients with azole-resistant infections. Approximately 35,000 cases of IC in the U.S. per year are caused by *Candida* species that are resistant to azoles,[1] for which ibrexafungerp could provide a much-needed oral alternative.

“Invasive fungal infections are extremely challenging, and there is a significant need for antifungals that can support long-term step-down treatment strategies,” said David Angulo, M.D., Chief Medical Officer of SCYNEXIS. “The development program of ibrexafungerp is designed to take advantage of key attributes of the drug, including its oral bioavailability, potent fungicidal activity against *Candida* species, including most species resistant to other antifungal agents such as azoles and echinocandins, and high tissue distribution which permits it to reach deep-seated infections. There is a very exciting opportunity for oral administration, which is key to optimizing patient care during a prolonged treatment period for invasive fungal diseases that may last from weeks to months.”

Hospital Pipeline Update Webcast

SCYNEXIS will host a Hospital Pipeline Update webcast at 10 a.m. ET today, December 6, to discuss an overview of the Company’s updated pipeline and product development strategies, including plans to expand the labeling of ibrexafungerp in the hospital setting. Advance registration via this link is required for the webcast.

About Ibrexafungerp

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an antifungal agent and the first representative of a novel class of structurally-distinct glucan synthase inhibitors, triterpenoids. This agent combines the well-established activity of glucan synthase inhibitors with the potential flexibility of having oral and intravenous (IV) formulations. Ibrexafungerp is in late-stage development for multiple indications, including life-threatening fungal infections caused primarily by *Candida* (including *C. auris*) and *Aspergillus* species in hospitalized patients. It has demonstrated broad-spectrum antifungal activity, *in vitro* and *in vivo*, against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. The U.S. Food and Drug Administration (FDA) approved BREXAFEMME® (ibrexafungerp tablets) on June 1, 2021. The FDA also granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the IV and oral formulations of ibrexafungerp for the indications of invasive candidiasis (IC) (including candidemia) and invasive aspergillosis (IA) and has granted Orphan Drug Designation for the IC and IA indications. The European Medicines Agency has also granted orphan product designation for the indication of IC. Ibrexafungerp is formerly known as SCY-078.

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. SCYNEXIS scientists are developing the company’s lead asset, ibrexafungerp (formerly known as SCY-078), as a

broad-spectrum, systemic antifungal for multiple fungal indications in both the community and hospital settings. SCYNEXIS has initiated the launch of its first commercial product in the U.S., BREXAFEMME® (ibrexafungerp tablets). The U.S. Food and Drug Administration (FDA) approved BREXAFEMME on June 1, 2021. In addition, late-stage clinical investigation of oral ibrexafungerp for the prevention of recurrent vulvovaginal candidiasis (VVC) and the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. For more information, visit www.scynexis.com.

Forward-Looking Statements

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: progressing development of the oral and liposomal IV formulation of ibrexafungerp, its potential use by physicians and patients in multiple healthcare settings including as a step-down therapy, and our ability to successfully complete clinical trials in an expeditious manner if at all. 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 and obtain FDA approval for ibrexafungerp for additional indications, including the oral formulation of ibrexafungerp as a step-down treatment for IC; unexpected delays in the timing of our clinical trials; the expected costs of studies and when they might begin or be concluded; whether ibrexafungerp will successfully achieve its clinical end points; SCYNEXIS' need for additional capital resources; and SCYNEXIS' reliance on third parties to conduct SCYNEXIS' clinical studies and commercialize its products. 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 and Quarterly Report on Form 10-Q, including in each case under the caption "Risk Factors," and in 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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1. U.S. Centers for Disease Control and Prevention (CDC) 2019 report

Source: Scynexis