November 9, 2021

SCYNEXIS Announces Successful Completion of Phase 1 Trial Evaluating Intravenous (IV) Formulation of Ibrexafungerp

Safety and tolerability of new liposomal IV formulation confirmed to reach target exposure in single ascending dose (SAD) and multiple ascending dose (MAD) study

JERSEY CITY, N.J., Nov. 09, 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 the successful completion of a Phase 1 clinical study to evaluate the safety, tolerability and pharmacokinetics of a liposomal intravenous (IV) formulation of ibrexafungerp in healthy subjects.

“The data from this study support the safety of the liposomal IV formulation of ibrexafungerp, allowing us to progress its development,” said David Angulo, M.D., Chief Medical Officer, SCYNEXIS. “Having the flexibility to easily switch between IV and oral formulations, when needed, will enable physicians to maximize the potential benefits from this innovative antifungal in a broad range of clinical settings often involved in the management of invasive fungal diseases, including intensive care units, hospital wards and outpatient services.”

The randomized double-blind, placebo-controlled trial, designed as a single ascending dose (SAD) and multiple ascending dose (MAD) study, was conducted in 64 healthy volunteers with treatment durations of up to seven days. The liposomal IV formulation of ibrexafungerp was generally well tolerated with no serious adverse events reported. The most common adverse events were mostly mild (few moderate) reactions at the infusion site. The dosing was successfully progressed until the target exposure was achieved (i.e., exposure associated with efficacy from animal models).

“The breakthrough achievement of this milestone moves SCYNEXIS closer to our vision of providing potentially life-saving antifungal treatments for use in multiple heath care settings,” said Marco Taglietti, M.D., President and Chief Executive Officer, SCYNEXIS. “Severe fungal infections can be extremely dangerous, especially for patients with compromised immune systems. This IV formulation could complement our late-stage oral ibrexafungerp clinical development programs and provide an important treatment option with a broad-spectrum antifungal activity for patients battling these serious infections.”

SCYNEXIS is currently evaluating strategic options to best optimize the new IV formulation development. Details will be shared in the near future, once finalized.

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. 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 liposomal IV formulation of ibrexafungerp, its potential use by physicians and patients in multiple healthcare settings. 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 IV formulation of ibrexafungerp; unexpected delays may occur in the timing of acceptance by the FDA of an NDA submission; the expected costs of studies and when they might begin or be concluded; 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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Source: Scynexis