December 15, 2021

European Medicines Agency Grants Orphan Medicinal Product Designation for SCYNEXIS' Innovative Antifungal Ibrexafungerp for the Indication of Invasive Candidiasis

- Orphan medicinal product designation will provide at least 10 years of market exclusivity in the EU for ibrexafungerp for invasive candidiasis.
- SCYNEXIS recently was awarded a new patent in the U.S. and obtained allowance of an additional European patent application, expanding lifecycle protection to 2038.

JERSEY CITY, N.J., Dec. 15, 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 that the European Medicines Agency (EMA) has granted orphan medicinal product designation to ibrexafungerp for the indication of invasive candidiasis (IC).

“Our vision for ibrexafungerp is to build a global antifungal franchise for community and hospital infections by leveraging the versatility and potency of our unique systemic antifungal agent to benefit patients,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “Ibrexafungerp benefits from lengthy regulatory and patent exclusivities in the U.S. and around the world. The 10 years of market exclusivity in the EU based on orphan medicinal product designation builds on those exclusivities as we work to expand the approved indications for our groundbreaking therapy to help patients around the world fight these serious and sometimes deadly fungal infections.”

David Angulo, M.D., Chief Medical Officer of SCYNEXIS added, "EMA's granting of orphan product designation for invasive candidiasis underscores the unmet need and the agency's assessment of the potential for ibrexafungerp to provide a significant treatment benefit to patients suffering from this life-threatening disease. This orphan designation is timely, as we recently announced the initiation of a global, Phase 3 study of ibrexafungerp as a much-needed oral step-down therapy for the treatment of invasive candidiasis.”

Announced in December, the MARIO global Phase 3 multi-center, randomized, double-blind study of two treatment regimens will evaluate oral ibrexafungerp as a step-down treatment in patients suffering from invasive candidiasis compared to oral fluconazole.

Additionally, SCYNEXIS recently was awarded a new patent in the U.S. and obtained allowance of an additional European patent application, expanding lifecycle protection for ibrexafungerp.

- In September, the U.S. Patent and Trademark Office issued SCYNEXIS a patent covering the combination of ibrexafungerp and azole therapy for the treatment of invasive aspergillosis, providing protection in the U.S. until 2038.

- Last month, the European Patent Office allowed a SCYNEXIS patent application for the liposomal intravenous (IV) formulation of ibrexafungerp, which recently completed a successful Phase 1 study, providing protection until 2038.

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 medicinal product designation for the indication of IC. Ibrexafungerp is formerly known as SCY-078.

About SCYNEXIS

SCNEXIS, 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 (rVVC) 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: the expected benefits and protections provided by the patents on, and regulatory designations of, ibrexafungerp; and the expected benefits 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 patent protections, including that third parties may challenge the validity of such patents and designations, 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.

CONTACT:
Investor Relations
Irina Koffler
Managing Director
LifeSci Advisors, LLC
646-970-4681
ikoffler@lifesciadvisors.com

Media Relations
Gloria Gasaatura
LifeSci Communications
646-970-4688
ggasaatura@lifescicomms.com

SCYNEXIS

Source: Scynexis