

SCYNEXIS Presented Preclinical Data on Second Generation Fungerp SCY-247 against Mucormycosis at the 11th Advances Against Aspergillosis and Mucormycosis Conference

- *In vivo* data demonstrated response rate for oral SCY-247 similar to current standard of care, intravenous Liposomal Amphotericin B, for the treatment of mucormycosis
- Combination of SCY-247 and Liposomal Amphotericin B showed significant enhancement in survival and reduction in fungal burden in lung and brain tissue compared to monotherapies

JERSEY CITY, N.J., Jan. 29, 2024 (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 presentation of preclinical efficacy data on its second generation fungerp candidate SCY-247.

Dr. Ashraf Ibrahim, PhD, FAAM, FECCM, Professor of Medicine in the Division of Infectious Diseases at the David Geffen School of Medicine at UCLA and an investigator at the Lundquist Institute at Harbor-UCLA Medical Center, presented a poster entitled, "SCY-247, a novel second-generation IV/oral triterpenoid antifungal, is efficacious in the neutropenic mouse model of pulmonary mucormycosis," at the 11th Advances Against Aspergillosis and Mucormycosis (AAAM) Conference in Milan, Italy from January 25 – 27. Mucormycosis is a life-threatening fungal infection with an associated mortality that ranges from 46% to 96%⁴, most commonly affecting immunocompromised patients including those with leukemia, patients undergoing bone marrow transplants, and patients affected by severe COVID or uncontrolled diabetes mellitus.

In this highly lethal mouse model of mucormycosis, SCY-247 showed very promising *in vivo* efficacy. Orally administered SCY-247 resulted in 40% and 50% survival at 21 days post infection for the intermediate (32 mg/kg) and high doses (48 mg/kg), respectively, compared to 0% survival in the placebo group ($p = 0.011$ and 0.007 , respectively). This is comparable to the 40% survival observed in the control group treated with 10 mg/kg of intravenous standard of care of liposomal amphotericin B (LAMB) ($p = 0.008$ vs. placebo). Even more encouraging was a 90% survival observed in the group receiving combination therapy of SCY-247 32 mg/kg plus LAMB 10 mg/kg ($p < 0.0001$ vs. placebo and $p < 0.05$ vs. monotherapy). The positive survival data correlated with a statistically significant fungal burden reduction in both lung and brain tissue with SCY-247 32 mg/kg dose ($p = 0.0288$ and 0.0355 vs. placebo, respectively) and 48 mg/kg dose ($p = 0.0015$ and 0.0052 vs. placebo, respectively) as well as with the active control LAMB ($p = 0.0005$ vs. placebo for both lung and brain tissues). The combination treatment of SCY-247 plus LAMB demonstrated the

greatest reduction in fungal burden and was highly statistically significant in both lung and brain tissue (both $p < 0.0001$ vs. placebo).

“The potent antifungal efficacy of SCY-247 in a murine model of pulmonary mucormycosis alone and in combination with liposomal amphotericin B provides an important preclinical rationale for further development of this new therapeutic agent,” said Thomas J. Walsh, MD, FCCP, FAAM, FIDSA, Director of the Center for Innovative Therapeutics and Diagnostics in Richmond, Virginia.

“The opportunity to significantly improve the lives of patients suffering from life-threatening fungal infections is a key driver for all of us at SCYNEXIS, and positive results like the ones presented at AAAM reinvigorate our commitment to providing innovative tools in the fight against deadly infections,” said David Angulo, M.D., President and Chief Executive Officer of SCYNEXIS. “These positive data continue to accumulate and define the unique properties of SCY-247, highlighting its potential to be differentiated from currently available antifungals. We continue to expeditiously advance the development of this promising antifungal with plans to be in a clinical stage by year end.”

The work reported here utilized the National Institute of Allergy and Infectious Diseases’ (NIAID’s) suite of preclinical services for *in vivo* testing (Contract No. HHSN272201700039/75N93022F00001).

About Mucormycosis

Mucormycosis is an often life-threatening fungal infection that typically affects the nose, sinuses, eyes, and brain and is characterized by tissue necrosis and rapid progression.¹ While multiple types of fungi can cause mucormycosis, *R. delemar* and *R. oryzae* are the most common, accounting for ~70% of cases.² Infections are most common in patients with compromised immune systems, including those with cancer, diabetes or those taking steroid medications.³ The overall mortality rate of mucormycosis ranges from 46% to 96%.⁴

About SCY-247

SCY-247 is a second-generation antifungal compound, from a novel class of structurally-distinct glucan synthase inhibitors, triterpenoids (fungicins), under development as therapeutic options for systemic fungal diseases. The triterpenoid class of antifungals represents the first new class of antifungal compounds since 2001. These agents combine the well-established activity of glucan synthase inhibitors with the potential flexibility of having oral and intravenous (IV) formulations. SCY-247 is in pre-IND development stage and has demonstrated broad-spectrum antifungal activity, *in vitro* and *in vivo*. SCYNEXIS anticipates that the U.S. Food and Drug Administration (FDA) may grant SCY-247 Qualified Infectious Disease Product (QIDP) and Fast Track designations for the IV and oral formulations of SCY-247.

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 is developing the

company's proprietary antifungal platform "fungerps". Ibrexafungerp, the first representative of this novel class, has been licensed to GSK. The U.S. Food and Drug Administration (FDA) approved BREXAFEMME® (ibrexafungerp tablets) in June 2021, for its first indication in vulvovaginal candidiasis (VVC), followed by a second indication in November 2022, for reduction in the incidence of recurrent VVC. Late-stage clinical investigation of ibrexafungerp for the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. Additional antifungal assets from this novel class are currently in pre-clinical and discovery phase, including the compound SCY-247. 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: SCYNEXIS's plans to begin a clinical study in SCY-247 by year end and SCY-247's potential to be differentiated from currently available antifungals. 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 regulatory and other costs in developing 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 filed on March 31, 2023, including under the caption "Risk Factors." 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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¹Hernández JL, Buckley CJ. Mucormycosis. [Updated 2023 Jun 12]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan

<https://pubmed.ncbi.nlm.nih.gov/31335084/>

² Ribes JA, Vanover-Sams CL, Baker DJ. Zygomycetes in human disease. Clin Microbiol Rev. 2000 Apr;13(2):236-301. doi: 10.1128/CMR.13.2.236. PMID: 10756000; PMCID: PMC100153. <https://pubmed.ncbi.nlm.nih.gov/10756000/>

³ Akshay R, Nguyen TH, Rising incidence of mucormycosis in patients with COVID-19: another challenge for India amidst the second wave? Lancet, 2021 June, [https://doi.org/10.1016/S2213-2600\(21\)00265-4](https://doi.org/10.1016/S2213-2600(21)00265-4)

⁴<https://www.cdc.gov/fungal/diseases/mucormycosis/statistics.html>



Source: Scynexis