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SCYNEXIS Receives FDA Qualified Infectious Disease Product (QIDP) and Fast Track Designations for SCY-247

The QIDP designation will ensure at least 10 years of market exclusivity for SCY-247 following approval

Recent articles highlight the growing threat from a rapidly spreading, multi-drug resistant, Candida auris fungal infection

JERSEY CITY, N.J., Jan. 21, 2026 (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 granted the Company Qualified Infectious Disease Product (QIDP) and Fast Track Designations for its second-generation triterpenoid antifungal therapy, SCY-247.

"Receiving FDA's QIDP and Fast Track designations for SCY-247 reflects the potential of SCY-247 to address the serious unmet need posed by life-threatening resistant fungal infections," said David Angulo, M.D., President and Chief Executive Officer of SCYNEXIS. "Last year we presented results from multiple preclinical efficacy models consistently showing the potent antifungal activity of SCY-247 against a broad array of fungal pathogens, including some of the most difficult to treat such as *Candida auris* and echinocandin-resistant *C. glabrata*, as well as data supporting extensive tissue distribution. We also disclosed positive Phase 1 SAD/MAD data that not only demonstrated SCY-247's promising safety and favorable pharmacokinetic properties, but also showed that the drug could achieve target exposures for invasive fungal disease at doses lower than our first generation fungerp. The data generated to date strongly positions SCY-247 as a unique candidate to address the clear need for novel, safe and potent antifungal agents able to address the rising threat of antifungal resistance."

In 2026, the Company expects to initiate a Phase 1 study of SCY-247 with the IV formulation as well as a Phase 2 study with the oral formulation in invasive candidiasis (IC). SCYNEXIS also aims to release proof-of -concept data for the oral formulation of SCY-247 in IC in 2026. Considering the differentiated attributes of SCY-247 and its potential role to counter health security threats posed by antifungal resistance development, we will also continue exploring potential non-dilutive funding opportunities to further support this program.

Scientific and media publications continue to highlight the need for novel antifungal solutions to address the growing public health threat resulting from the emergence of multi-drug resistant fungal pathogens such as *Candida auris*. In December 2025, a collaborative multi-institution scientific publication reported that *Candida auris* is spreading across the globe,

and gaining in virulence (link to their article here). The Independent published an article this month highlighting the growing public health threat in the United States from a rapidly spreading “superbug” strain of *Candida auris*. The article notes how individuals with compromised immune systems are particularly vulnerable to this strain of fungal infection, which does not respond to currently approved antifungal therapies. A link to the article can be found here.

With its broad spectrum of activity, the Company believes that SCY-247 has the potential to address this growing public health threat, due to its demonstrated activity against most drug-resistant fungi, including multi-drug-resistant *Candida auris* and azole-resistant *Aspergillus* spp.

For a drug product to be designated a QIDP, the sponsor is required to demonstrate that the drug is an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections. Subject to the specified statutory limitations, a drug that is designated as a QIDP and is approved for the use for which the QIDP designation was granted will receive a 5-year extension to any exclusivity for which the application qualifies upon approval.[1]

A drug that receives *Fast Track* designation is eligible for some or all of the following:[2]

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for *Accelerated Approval and Priority Review,* if relevant criteria are met
- *Rolling Review*, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA

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) has approved BREXAFEMME® (ibrexafungerp tablets) for the treatment of vulvovaginal candidiasis (VVC) and for reduction in the incidence of recurrent VVC. Additional antifungal assets from this novel class are currently in clinical, pre-clinical and discovery phases, 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: The Company’s expectation to initiate a Phase 1 study of SCY-247 with the IV formulation as well as a Phase 2 study with

the oral formulation in invasive candidiasis (IC), the Company's aim to release proof-of-concept data for the oral formulation of SCY-247 in IC in 2026, and the potential for SCY-247 to address fungal threats. 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 12, 2025, 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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[1] Source: https://www.fda.gov/media/148480/download
[2] Source: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

Source: Scynexis