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Sfunga Therapeutics and Deerfield Management Announce Publication on Novel Antifungal SF001 in *Nature*

– SF001, with QIDP and FDA Fast Track designations,
in Phase 1 clinical development –

New York, NY — Nov. 8, 2023 — Sfunga Therapeutics (“Sfunga”), a biotechnology company, and Deerfield Management Company (“Deerfield”), a healthcare investment firm, today announced the publication of data on a novel antifungal molecule AM2-19 in the scientific journal *Nature*.¹ AM2-19 is a derivative of amphotericin (AmB), rationally designed to mitigate toxicities and optimize antifungal activity. AM2-19, formulated as the development candidate, SF001, received Qualified Infectious Disease Product (QIDP) and Fast Track designations from the U.S. Food and Drug Administration (FDA) in 2023, and is in Phase 1 clinical development.

Fungal infections cause more than 150 million severe, life-threatening infections that result in about 1.7 million deaths each year globally.² Invasive fungal infections (IFI) typically occur in people with compromised immune systems due to HIV/AIDS, cancer therapies and organ transplants. These infections also occur in people with severe lung disease, including that caused by influenza and SARS CoV-2. Despite this public threat, only four classes of antifungal medicines are available. Each class has known adverse effects with the potential to put patients’ safety and outcomes at risk. AmB is a naturally occurring small molecule, used since the 1950s as a treatment for people with IFI. The drug has a broad spectrum of activity, but AmB causes kidney impairment in about 80 percent of patients, limiting its use.³

“Patients with invasive fungal infections have few available antifungal treatment options that are effective and safe. Sfunga is working to improve patient outcomes by developing a therapy with all of the antifungal properties of AmB, but with much better safety and tolerability,” said Kieren Marr, M.D., M.B.A., FIDSA, Sfunga co-founder and Chief Medical Officer and adjunct professor of medicine and business at Johns Hopkins University. “We are optimistic about the continued clinical development of SF001, the lead compound of the Sfunga pipeline already in Phase 1 clinical development.”

Sfunga was formed in 2019 as a collaborative venture between Martin Burke M.D., Ph.D., senior author of the *Nature* paper and professor of chemistry at the University of Illinois at Urbana-Champaign, and Deerfield. Clinical development was initiated in 2023, under Marr’s direction. Sfunga has completed SF001’s first in human single-ascending dose study and is poised to begin a multiple-ascending dose study in 2024.

“The innovative development of SF001, published in *Nature* today, stems from leveraging highly valuable discoveries about the structure and function of AmB,” said James Flynn, Managing Partner, Deerfield Management and Cure® Founder. “Our collaboration to create Sfunga furthers Deerfield’s commitment to providing tailored funding, infrastructure, and support needed for successful commercial development of novel discoveries that advance health.”

With nearly three decades of experience in healthcare investment, Deerfield generally maintains a portfolio of more than 150 private and public investments across the life science, medical device, diagnostic, digital health and health service industries at all stages of evolution from start-up to mature company.

SF001: Rationally designed for optimal safety and efficacy

To develop AM2-19, Burke and his colleagues determined how AmB kills fungi and damages kidney cells using solid-state nuclear magnetic resonance imaging. They found that AmB’s mechanism for both actions involves creating an extracellular “sponge” that extracts critical sterol molecules from the membranes of cells. AmB binds to ergosterol in fungi and cholesterol in human kidney cells, ultimately contributing to cellular death.

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Additional high-resolution atomic-level analyses provided insights into the binding interactions between AmB and each sterol. The resulting information guided the investigators' development of AM2-19's structure and shape as a new molecule that could rapidly extract fungal ergosterol without harmful toxicity to human cells.

In laboratory studies, AM2-19 bound to ergosterol but not cholesterol, demonstrating decreased toxicities, with potent efficacy against pathogenic yeasts and moulds *in vitro* and in animal studies.

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Arun M, Soutar C, Zhang J, et al. Tuning sterol extraction kinetics yields a renal sparing polyene antifungal. *Nature*. 2023. doi: 10.1038/s41586-023-06710-4.

Fungal Infections Threaten Global Public Health

Fungi are organisms made of one cell, like yeasts, or many cells, such as moulds or mushrooms. Fungi naturally exist in the environment and the human body. The World Health Organization (WHO) designated 19 fungi as priority pathogens in 2022, naming four as critical and of the highest importance to public health: *Cryptococcus neoformans*, *Candida auris*, *Aspergillus fumigatus* and *Candida albicans*.⁴

WHO reports that fungal diseases are expanding in their incidence and geographic range globally because of climate change, increased international travel and trade, and the impact of the COVID-19 pandemic, among other factors. Also, both yeasts and moulds are increasingly reported to develop resistance to available antifungals, limiting treatment options and contributing to poor outcomes.

About Sfunga

Sfunga Therapeutics is a cutting-edge biotechnology company dedicated to transforming the treatment of life-threatening fungal infections using a novel approach rooted in structural chemistry. Sfunga was founded under the belief that mechanistic insights enable targeted optimizations of natural products. Today, Sfunga is advancing the first polyene antifungal rationally designed to mitigate toxicities and increase efficacy. For more information, please visit www.sfunga.com.

About Deerfield Management

Deerfield is an investment management firm committed to advancing healthcare through investment, information and philanthropy. The Firm works across the healthcare ecosystem to connect people, capital, ideas and technology in bold, collaborative and inclusive ways. For more information, visit www.deerfield.com.

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Endnotes

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- ¹ Arun M, Soutar C, Zhang J, et al. Tuning sterol extraction kinetics yields a renal sparing polyene antifungal. *Nature*. 2023. doi: 10.1038/s41586-023-06710-4.
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- ³ Noor A, Preuss CV. Amphotericin B. National Library of Medicine. *StatPearls*. January 2023. Updated March 24, 2023. <https://www.ncbi.nlm.nih.gov/books/NBK482327/>.
- ⁴ WHO fungal priority pathogens list to guide research, development and public health action. Geneva: World Health Organization; 2022. License: CC BY-NC-SA 3.0 IGO. <https://iris.who.int/bitstream/handle/10665/363682/9789240060241-eng.pdf?sequence=1>.