

NanoBio Demonstrates New Topical Approach to Treating Nail Fungus that Circumvents Problems with Current Therapy

Data presented at annual ICAAC/IDSA meeting in Washington, D.C.

WASHINGTON, D.C. (October 27, 2008) — A novel therapy for nail fungus, NB-002, has demonstrated a new topical approach to healing nail fungus by penetrating skin pores and diffusing through the skin that surrounds the entire nail plate, according to a study conducted by NanoBio Corporation.

The data represent a unique approach to treating nail fungus (onychomycosis), which resists topical therapies because they cannot penetrate the nail and access the site of infection. The results were reported this morning at the 48th annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)/Infectious Diseases Society of America (IDSA) 46th annual meeting in Washington, D.C.

"In testing NB-002 on human cadaver skin, we have demonstrated that the lotion permeates and then laterally diffuses across tissue plains in the epidermis and the dermis to more than 1 centimeter away from the site of application," said Susan Ciotti, Ph.D., director of formulations and research and development, and presenting author of the data.

"The average great toenail measures 22 millimeters across, so we are able to deliver NB-002 across the entire span of an infected human large toenail, a huge advance in the treatment of onychomycosis," Ciotti said.

Because of its novel mode of penetration and diffusion, NB-002 is able to achieve 50 times the minimum drug concentration required to kill the fungus in the very center of the nail bed. Only 4 micrograms per gram of tissue are required for NB-002 to kill fungal infections.

Newer, more effective therapies for nail fungus are important because onychomycosis remains a large unmet medical need, according to the NanoBio scientists. Oral systemic medications are plagued by serious hepatic and cardiac toxicity concerns, while current topical medications are not effective because they are unable to penetrate to the site of infection.

"The safe and efficient delivery of NB-002 makes it an ideal candidate for the treatment of onychomycosis," Ciotti said. "And because there is no systemic absorption, NB-002 does not pose the risk of adverse events or drug interactions that systemic antifungal agents present."

NB-002 kills both active spores and developing hyphae, an additive effect that lessens the fungi's ability to survive in human tissue, said James R. Baker, Jr., M.D., founder and chairman of NanoBio Corp. Studies conducted in vitro demonstrate that NB-002 has robust antifungal activity against all organisms that cause nail fungus, including *Trichophyton rubrum*, *T. mentagrophytes*, *Epidermophyton floccosum*, *Microsporum canis* and *Candida*

albicans.

NanoBio scientists credit the topical lotion's safety and robust anti-infective activity to NB-002's novel technology platform. The lotion is composed of an oil-in-water emulsion and a commonly used antimicrobial surfactant that are mixed at high speeds to nanosize the particles and infuse them with high levels of potential energy. The resulting nanodroplets easily penetrate hair follicles and skin pores to reach the site of infection without damaging or irritating skin or mucous membranes. Upon contact with the pathogen, the highly charged particles release their energy to the pathogen's outer membranes, disrupting the fungus.

NB-002 is currently being studied in a randomized, double-blind, placebo-controlled, phase 2 trial in more than 400 subjects with onychomycosis. Final results are expected in the first quarter of 2009.

About NanoBio

NanoBio® Corp. is a privately held biopharmaceutical company focused on developing and commercializing anti-infective products and mucosal vaccines derived from its patented NanoStat™ technology platform. The company's lead clinical product candidates are treatments for herpes labialis (cold sores), onychomycosis (nail fungus), acne, cystic fibrosis and mucosal vaccines for influenza and hepatitis B. Company headquarters and laboratory facilities are located in Ann Arbor, Mich.

[Link to Poster Presentation M-2135, Mechanism of Skin Penetration and Distribution of a Novel Nanoemulsion](#)