SB208, a nitric oxide-releasing topical drug candidate, is in development for the treatment of fungal infections of the skin and nails, such as tinea pedis and onychomycosis.

The active ingredient in the silicone-based gel of SB208 is NIT-1000, a polyanionic macromolecule that stores nitric oxide in the polymer matrix and has demonstrated in-vivo topical and fungal activity in-vitro.

- Causative agents for both diseases are primarily the dermatophytes T. rubrum, T. mentagrophytes and T. tonsurans.
- Recent studies suggest that the nail plate, interdigital space and surrounding cutaneous tissue may serve as an overlooked reservoir of dermatophytes, perpetuating reinfection and co-infection of onychomycosis and tinea pedis.
- T. pedis occurs in at least 33% of onychomycosis patients and studies have demonstrated enhanced efficacy when T. pedis and onychomycosis are treated concurrently.

Phase 2 – Tinea Pedis (NI-AF201) Study Overview

- Subjects were randomized 1:1:1:1 SB208 Gel (2%, 4% or 16%) or vehicle treatment arms.
- A single dose of SB208 comprised 50 mg of NIT-1000 topical solution loaded in a polydimethylsiloxane-based gel co-administered with 250 mg of an Aqueous Hydrogen Peroxide, that upon aspiration of the foot and interdigital spaces, releases nitric oxide as a fungal agent.
- Treatment was stratified by baseline positive fungal culture.
- Endpoint assessments were 1) negative fungal culture; 2) mycological cure; and, 3) clinical cure.

Antimicrobial Activity of Nitric Oxide in Superficial Fungal Infections

Nitric oxide exerts its fungicidal activity against a broad spectrum of fungal species, including T. rubrum, through inactivation of cellular enzymes, disruption of cellular respiration, and lipid peroxidation.

As a gas, nitric oxide readily penetrates the nail plate reaching the site of infection.

Conclusions

- SB208 4% and 16% demonstrated a treatment effect (p<0.05) in mycological cure which warrants further development in additional efficacy clinical trials.
- All TEAEs were mild and considered not related to study medication.
- No serious adverse events were reported and no subjects discontinued due to AEs.
- SB208 provides antifungal activity from an alternative class of compounds than allylamines and azoles for T. pedis alone, but when utilised in co-infection settings in patients with onychomycosis, provides a new treatment option with a single topical product.
- SB208 product profile demonstrates potential advantages over allylamines and azoles.

Efficacy and Safety of SB208, an Investigational Topical Nitric Oxide-Releasing Gel, in a Phase 2 Study of Subjects with Interdigital Tinea Pedis

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Efficacy Results

- Negative Fungal Culture
- Mycological Cure
- Clinical Cure

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