FACT SHEET
Hallux, Inc.

HALLUX FOCUS AND MISSION

- Hallux is a clinical-stage pharmaceutical company focused on developing a new dosage form and route of administration for treating chronic onychomycosis (toenail fungus) patients.
- To date, treatments for toenail fungus have been either topical products that have difficulty reaching the site of infection, or oral products that have systemic safety issues.
- Our mission is to provide a highly effective and safe solution for patients with chronic onychomycosis who have had to live with this disease for years.

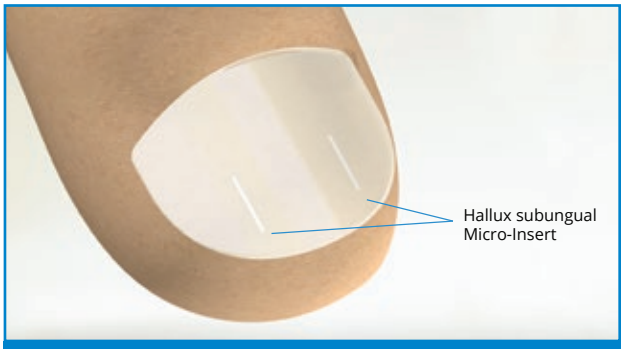
HALLUX ONYCHOMYCOSIS SOLUTION

The Only Local, Direct to the Nail Bed Approach to Killing Toenail Fungus

- Our treatment goal is focused on safely treating onychomycosis with a biodegradable Micro-Insert that is highly effective, without the systemic safety issues associated with oral medications.
- Our innovative subungual treatment approach delivers high, localized concentrations of terbinafine, a proven fungicidal (fungus-killing) drug, directly to the site of the infection.
- Delivering this proven fungicidal drug therapy to the nail bed enables high concentrations of terbinafine to reach the site of infection where it is needed instead of introducing it systemically where it can affect the liver and interact with other drugs the patients may be taking.
- The Hallux local and highly targeted drug therapy is accomplished by delivering the HTS-519 Micro-Insert directly to the nail bed. The Micro-Insert is placed at the site of infection and initially provides a highly concentrated burst of fungicidal drug followed by concentrations that remain well above the MFCs (minimum fungicidal concentrations) over time to kill the fungus.

Without the Risks Associated with Oral Medication

- At Hallux, our approach to treating onychomycosis is to safely deliver high concentrations of a powerful, fungus-killing drug directly to the nail bed.
- We accomplish this by killing the fungus without exposing the body and vital organ systems to oral medications.
- Our approach to treating onychomycosis directly and locally in the toenail bed eliminates the:
    - Need for oral medications
    - Risk of liver toxicity associated with oral medications
    - Potential for systemic side effects
    - Potential for harmful interactions with other systemic drugs



Hallux's Micro-Insert technology enables direct, subungual delivery of terbinafine at the site of the infection with higher concentrations at the nail bed.

DEVELOPMENT PATHWAY

- Phase 2A clinical trials for the HTS-519 Micro-Insert began in July 2016.
- The trial name is the Efficacy, Safety, and Tolerability of the HTS-519 Micro-Insert in Patients with Mild to Moderate Toenail Fungus of the Big Toenail.
- This initial study is slated to last for 48 weeks and is being conducted in the greater Phoenix, AZ area.
- Patient inclusion criteria includes:
    - Male or female, 18-74 years of age
    - Fungal toenail infection of one or both of the large toenails
    - The nail infection must be due to a dermatophyte—mixed dermatophyte or non-dermatophyte infections are excluded
    - Willingness to avoid or refrain from professional pedicures or application of any nail polish product or nail cosmetics to the toenails after the screening visit

MANAGEMENT TEAM

- The Management team at Hallux consists of experienced operators in pharmaceutical development and commercialization.
- The team includes:
    - Mark Taylor—Chief Executive Officer and Co-Founder/Director
    - Jay Birnbaum, PhD—Chief Scientific Officer and Co-Founder/Director
    - Hendrick Arend Kroon, MD, MBA—Executive Vice President and Chief Medical Officer
    - Feng-Yu Lee—Head of Quality Assurance and Compliance
    - Robert Orr—Head of Drug Product and CMC
    - Chris Dax—Head of Commercial Planning and Reimbursement
- Detailed management profiles can be found online at HalluxInc.com/leadership.

The Hallux Micro-Insert (drug/device delivery) is in clinical studies and not FDA approved in the United States.

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