



HALLUX ANNOUNCES START OF Phase 2 CLINICAL TRIAL

Laguna Hills, Calif., November 8, 2016. Hallux Incorporated, a pharmaceutical company focused on developing a novel subungual treatment for onychomycosis (toenail fungus), announced the initiation of their Phase 2 clinical trial.

The trial will enroll approximately thirty patients and follow them for 48 weeks. Principal investigator, Dr. Lewis Freed, DPM will be conducting the clinical trial at the OrthoArizona East Valley Foot and Ankle Clinic in Mesa, AZ using Hallux's proprietary terbinafine micro-insert dosage form. The goal of this study will be to demonstrate the safety, efficacy, and tolerability in patients with distal lateral subungual onychomycosis.

“In this phase of our clinical program, we intend to demonstrate the viability of our innovative, subungual method of delivering onychomycosis treatment directly to the site of infection” said Mark Taylor, Hallux Chief Executive Officer. “35 million Americans are reported to have onychomycosis and the market remains underserved with existing systemic and topical products. In the study, we will insert our proprietary, biodegradable terbinafine micro-insert (HTS-519), directly to the infected areas of the nail bed and plate. We believe this novel approach offers the promise of being able to achieve high cure rates, safely and conveniently.

Dr. Freed added, “Results from the initial evaluations were encouraging. I am excited about the potential of this targeted, localized drug delivery technique and the ability to leverage the power of terbinafine without the concerns of systemic therapy.”

About Onychomycosis

Onychomycosis is a fungal infection of the nail bed and plate caused predominately by dermatophyte fungi. The infection typically begins as a small white or yellow spot beneath the nail causing nail discoloration, thickening and splitting of the nail and detachment of the nail plate from the nail bed. The damage to the nails can result in pain and difficulty walking, wearing shoes and social embarrassment due to the unsightly appearance of the nails. Untreated onychomycosis may lead to other serious complications for diabetics and other immune compromised patients and patients with poor circulation.

Topical products have difficulty penetrating the nail plate and reaching the nail bed at sufficient concentrations while drug interactions and safety concerns have limited oral treatments for onychomycosis. About 35 million people in the U.S. have onychomycosis but treatments have been limited and the infection undertreated with 85% of patients not treated.



About Hallux

Hallux is a clinical-stage pharmaceutical company focused on developing a new dosage form and route of administration for treating onychomycosis (toenail fungus). Hallux's goal is to provide high effectiveness and safety for chronic onychomycosis patients. The company's targeted therapy HTS-519 is a quick in-office procedure that delivers high concentrations of terbinafine hydrochloride directly and selectively to the site of the infection with minimal exposure of the body to the drug. You can contact Hallux at www.HalluxInc.com.

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