FDA Approves IND for Hallux Subungual Gel 42%

A New Approach Enabling Physicians to Treat Toenail Fungus at the Point-of-Care

Hallux Inc.

LAGUNA HILLS, CA, UNITED STATES, January 14, 2026 /EINPresswire.com/ -- Hallux Inc., a clinical stage pharmaceutical company focused on nail disease and common disorders of the lower extremities, today announced that it has received FDA approval to proceed with a Phase 2b clinical trial investigating lead product Hallux Subungual Gel 42% (HSG 42) in the topical treatment of toenail onychomycosis, including conditions compromised by dermatophytoma. The 56 week, vehicle controlled study evaluates the efficacy, safety and tolerability of HSG 42 administered in once monthly single doses directly onto the mycotic nail bed over 48 weeks. The primary efficacy endpoint is complete cure. Secondary endpoints include mycological cure and clinical cure. The 134 subject study, to be conducted in 12 clinical sites, will stratify subjects presenting with dermatophytoma, a common yet underdiagnosed subtype of onychomycosis characterized by fungal masses encapsulated in biofilm.

> HSG 42 is highly differentiated. It is the first subungual-topical treatment for toenail fungus administered by physicians in-clinic.”
>
> *Mark Taylor*

Hallux CEO Mark Taylor said, “My deep appreciation goes to the small and dedicated Hallux team that ran the rigorous 47 subject, multicenter phase 2a pilot that was followed by a productive Type B meeting with the agency and the filing of this new IND enabling HSG 42 to proceed into its first well controlled study." HSG 42 is highly differentiated. It is the first subungual-topical treatment for toenail fungus administered by physicians in-clinic. It is the first antifungal agent to be evaluated against dermatophytoma in a controlled study. Pending statistically significant clinical outcomes, it could be the first terbinafine topical approved by the FDA for onychomycosis.

About Hallux Inc.

Hallux is a clinical stage pharmaceutical company determined to bring to market a novel subungual-topical form of terbinafine that is applied by physicians to treat nail fungus at the point-of-care. Hallux’s goal is to provide chronic sufferers of onychomycosis with a highly effective topical therapy that is quick, safe and administered by physician that kills fungi and reliably facilitates the regrowth of disease-free nail.

Mark Taylor
Hallux Inc.
+1 949-637-4656
Mark@Halluxinc.com
Visit us on social media:
LinkedIn

This press release can be viewed online at: https://www.einpresswire.com/article/882955267

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.
© 1995-2026 Newsmatics Inc. All Right Reserved.