



# Novel OTC Treatments that Stimulate Immunity to Clear Drug-Resistant Topical Infections of the Skin and Nail

## Lead Lankenau Institute for Medical Research Investigators

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### Unmet Need

Topical infections in the body can often be cleared by common topical antibiotics or antifungal agents, but some of these infections can be extremely challenging. For example, certain Staph infections on the skin can become very aggressive, leading to amputations and even death due to the uncontrolled systemic expansion. Antibiotic resistance is the most fearsome element, where new approaches for control and eradication are badly needed. While other infections are benign and pose no serious medical risk, like nonpathogenic skin infections or fungal nail (onychomycosis), they are common, especially in elderly individuals, and often resistant to eradication. In particular, toe nail onychomycosis is commonly seen in podiatry practices, where its resistance to clearance poses medical, aesthetic, and emotional concerns to patients and caregivers.

### Opportunity

LIMR scientists have developed a radically new approach to eradicate topical infections by weakening the local ecology of the infection that supports it. Specifically, they have developed topical over-the-counter (OTC) formulations of safe and effective agents that are capable of clearing recalcitrant topical infections such as onychomycosis, Staph, or plantar wart. Their new approach treats the infection ecology, which includes not only the causative microbe itself but also (1) a local supportive microbiome for the pathogenic microbe, and (2) a local supportive tissue microenvironment for this pathogenic ecology. In particular, the immune microenvironment subverted by this ecology enables the pathogenic microbe to dig in. This ecology is what the LIMR anti-infective strategy targets. Their approach is conceptually similar to successes achieved in other medical disciplines, e.g., oncology, where restoration of a local immune response by itself can be sufficient to eradicate the pathogenic state.

### Unique Attributes

The unique attribute of this anti-infective technology is the combination approach it takes to eradicate infection. By focusing not just on the causative microbe(s), which is the traditional approach, LIMR's technology also seeks to correct the local 'micro-malbiome' or MMB which sets the local ecology in which the causative microbe takes hold. Further, the technology also applies a simple approach to restore a proper inflammatory attitude toward the MMB, which together act to limit the ability of effectiveness of simple topical antimicrobials.

In summary, by defeating the ecology of the infection which helps support its pathogenicity, LIMR's OTC formulations are better situated to eradicate skin and nail infections that are difficult to clear.

## **Clinical Applications**

These technologies have broad application in the OTC marketplace, having already achieved proof of concept to eradicate plantar warts that are difficult to clear. LIMR's concept to jointly treat the MMB and inflammatory microenvironment with the causative microbe offers a generalized strategy for any topical infection, including various skin bacterial or fungal infections or nail fungal infections.

Additionally, these technologies offer a novel adjuvant strategy to address aggressive infections such as MRSA, which can be disfiguring or deadly, or topical parasite infections, by relieving local immune suppression created by the parasite to evade host immunity.

## **Stage of Development**

These formulations are ready for preparation and sale, as they are composed of agents already available in the U.S. OTC and / or generally regarded as safe (GRAS categorization) by the U.S. FDA.

## **Intellectual Property**

A PCT patent on the technology has been filed.

## **References and Publications**

None as yet.

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