Novel OTC Drug Formulations That Stimulate Clearance of Drug-Resistant Topical Infections

Technology Readiness Level 5: Validated in Relevant Environment

Lead 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.

- Onychomycosis is a common fungal infection of the nail seen most in podiatry practices. This type of topical infection is often resistant to clearance, posing medical, aesthetic, and emotional concerns to patients and caregivers. Current topical treatments have poor efficacy. Oral antifungal medications are available but are poorly efficacious and can exhibit hepatotoxicity in some individuals. The present invention addresses the need of a definitive treatment to clear such fungal nail infections.
- Plantar warts caused by HPV infections are particularly prevalent in athletes and also commonly seen in podiatry practices. While there are a variety of topical over-the-counter (OTC) and in-office treatments available, many warts are difficult to clear or recur soon after their apparent clearance. The present invention addresses the need of a definitive topical drug approach to clear stubborn treatment-resistant warts.
- *Staphylococcus aureus* bacterial infections (Staph infections) occur commonly on the skin of many individuals. While typically benign they can spread quickly in some patients. Drug-resistant Staph infections that occur in some cases can be dangerous, leading to amputations, and may even become deadly in rare cases (e.g. MRSA infection). Topical or systemic antibiotics are available to treat Staph infections, but clearing drug-resistant Staph infections remain a major unmet challenge.

Opportunity

LIMR scientists created a new approach to eradicate topical infections by weakening the local microbial ecology and tissue microenvironment needed to support the pathogenicity of the primary infection. Specifically, they have developed OTC formulations of safe and effective antimicrobial and antifungal drugs that improve their ability to clear recalcitrant topical infections such as warts, onychomycosis, and Staph infections.

Drug-resistant topical infections can benefit from a local supportive microbiome in which the infectious agent takes hold. Some infections also benefit from an immunosuppressed tissue microenvironment. Accordingly, LIMR's OTC approach treats not only the causative infectious agent but also (1) the local supportive microbiome for the infectious agent, and (2) the local supportive tissue microenvironment. These parts of the supportive ecology of for the infectious agent enables a pathogenic infection to take hold. microbe to dig in to the local tissue or nail.

Unique Attributes

The unique attributes of LIMR's anti-infective technology are two-fold. First, it attacks not only the causative infectious agent but also the local 'micro-malbiome' (MMB) which is comprised of a pathogenic microbial environment needed to support the infectious agent. Second, the LIMR technology also relieves local immune suppression that is created by either the infectious agent, the MMB, or both. In relieving this immune suppression, LIMR's technology helps change the local inflammatory attitude in the individual toward the MMB. Together, these two new attacks leverage the anti-infective attack, rendering the latter far more effective than simple anti-infective drugs alone. In summary, by defeating the pathogenic ecology at an infection site, LIMR's OTC formulations are better situated to eradicate skin and nail infections that are often difficult to clear.

Clinical Applications

Clinical proof of concept has been demonstrated for plantar warts. The concept to jointly treat the MMB and inflammatory microenvironment along with the causative infection offers a generalized strategy for any topical infection, including various skin-borne viral, bacterial, or fungal infections or nail-borne fungal infections. These technologies also offer a novel strategy to address aggressive drug-resistant infections such as MRSA, or topical parasite infections, by relieving local immune suppression created by the infectious agent to evade host immunity.

Stage of Development

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These formulations are ready for preparation and sales as they are composed of agents already approved in the OTC market and/or are categorized by the US FDA as generally regarded as safe (GRAS).

Intellectual Property

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