

NOVEL TOPICAL SMALL RNA MOLECULE AS TREATMENT FOR PSORIASIS (Tel Hashomer)**code:** TH 2012020**Novel Topical small RNA Molecule as Treatment for Psoriasis**

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Abstract

Psoriasis is a common, chronic, relapsing/remitting, [immune-mediated](#) systemic disease, characterized by red scaly skin lesions including patches, papules, and [plaques](#), which usually itch. They result in significant negative impact on the patient's quality of life. The skin lesions seen in psoriasis may vary in severity from minor, localized patches to covering the entire body.

Psoriasis is the most prevalent auto inflammatory disease worldwide. Over 7.5 million Americans and more than 125 million individuals worldwide are affected.

The Need

The main unmet need in the treatment of psoriasis, is for an agent that is as effective as the biologics, that is safe and effective when used topically in the treatment of mild to moderate cases of psoriasis. Although there is a well stocked R&D pipeline, with drug candidates that go some way in meeting these demands, a drug that meets this need still remains elusive, restricting the psoriasis drug market. However, the industry will achieve growth with the launch of novel interleukin inhibitors, like IL-22 with proven efficacy.

The Technology

Psoriasis, a chronic, debilitating skin disease that affects millions of people worldwide is our major research focus.

We have applied a mouse model for human psoriasis that accurately reproduces major facets of the disease, and allows the testing of the efficacy and safety of potential topical agents on human skin. Our approach facilitated the discovery of pathways that are involved in the pathogenesis of psoriasis and highlighted the importance of the specific compounds to control the skin lesions.

We have found that in the psoriatic lesion the expression of several small RNA molecules differs from the normal skin. Based on our findings **we discovered a novel composition based on small, specific, RNA molecules that is naturally expressed massively in normal skin while being missing in the psoriatic lesions**. We named this molecule SAL197.

We have unfolded the **SAL197** mechanism of action and its protective effect on psoriatic lesions, and this novel composition is the basis of our new topical drug for psoriasis.

We have developed and validated several modes of topical delivery to achieve efficacy in affected lesions.

Our product inhibits the expression of IL-22 and IL-17 receptors, which are directly involved in the formation of the psoriatic lesion.

The Product

A novel topical composition based on an active compound, SAL197 to treat skin lesions in individuals affected by psoriasis.

The product can be combined together with existing and future therapies.

Novel composition for additional skin lesions such as actinic keratosis, solar elastosis and localized squamous cell carcinoma of the skin.

The Market

A new report by [vision gain](#) predicts the world [psoriasis](#) drug market will be worth \$8.9bn in 2018. Those products, treating that indication, generated \$6bn in 2012, according to [Psoriasis Treatment: World Drug Market 2013-2023](#), published in September 2013. This fast growth in the seven markets - the US, France, Germany, Italy, Spain, the UK and Japan - will be due to increases in drug treatment rates and the uptake of current key and emerging novel treatments.

Treatments for psoriasis cover the spectrum of topical (mostly topical steroids), phototherapy, systemic immunosuppressive agents and biologics. These therapies can be used as monotherapy, in combination, or on a rotational or sequential basis.

The worldwide incidence and prevalence of psoriasis is varied:

- * In children it ranges from 0% (Taiwan) to 2.1% (Italy). In children, the reported incidence estimate (United States) was 40.8/100,000 person-years.
- * In adults it varies from 0.91% (United States) to 8.5% (Norway).
- * In adults, it varies from 78.9/100,000 person-years (United States) to 230/100,000 person-years (Italy). The data indicates that the occurrence of psoriasis varies according to age and geographic region, being more frequent in countries that are further away from the equator.
- * In general - it affects ~2-3% of the population, making it one of the most prevalent inflammatory diseases worldwide. It can be associated with other inflammatory conditions, such as psoriatic arthritis, inflammatory bowel disease, the metabolic syndrome and coronary artery disease.

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