

## Effective Nanoscale Delivery System as an anti-Leishmania drug/ technological platform for drug delivery (BIRAD)

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### BACKGROUND

Leishmania parasites cycle between two hosts, insect host and mammalian macrophages. Infection in the mammalian host is caused by proliferation within macrophages, especially present in liver and spleen (visceral) or within macrophages in the skin (cutaneous Leishmaniasis). Leishmania infections are spread worldwide affecting millions of people in 88 countries from the Far East, India, Middle East, Southern part of Europe, Central and South America. The disease is also endemic in Israeli with a sharp increase since 2013. Currently, no efficient therapeutic treatment exists. L. major infections are treated with an ointment (Leishcutan made by Teva Pharmaceuticals), which contains the antibiotic Paromomycin. Resistant strains to Paromomycin already exist and L. tropica that causes the infection in Yehuda and Samaria and the Galilee are resistant to (Leishcutan of Teva) treatment.

### TECHNOLOGY OVERVIEW

We recently have developed a nanoparticulate drug-like nanomaterial, which we termed Nano-Lesh IL, which is based on iron-oxide nanoparticles decorated by polycationic polymer. NP surface binding is mediated via an innovative coordinative chemistry via use of doping cerium actions present on the NPs surface (ultra-sonochemistry NP surface engineering). These Nano Lesh IL NPs efficiently kill both relevant stages of the parasite; promastigotes (insect form, 100%) and amastigotes (mammalian host, ~80%). These same NPs were also tested against L. donovani and, therefore, an around 90% protection was observed in a mice model for this visceral disease. No toxicity has been observed on blood counts and liver enzymes after 4 intravenous injections of such therapeutic NPs (twice a week of 0.4mg/kg based on iron content). Additional successful results were obtained in vivo for cutaneous Leishmaniasis by incorporating these functional NPs into an ointment or gel formulations. The ointment can be used as a prophylactic treatment and avoid the development of lesion when administrated after injection of the parasite and can heal (90%) of the lesions induced by sub-cutaneous injection of parasites.

We plan to further develop these Nano-Lesh IL NPs for treatment of cutaneous leishmaniasis, under cGMP and complete Phase I-IIa.

### PATENT STATUS

Patent Pending.

### COMMERCIAL SIGNIFICANCE

Significant commercial relevance due to the high level of human diseases/contamination known in the world for these unmet cures.

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