



## A DNA Vaccine Formulation In Cationic Liposome Vehicle Useful For Maximizing Vaccine Potency For Leishmaniasis.

**INTRODUCTION** Visceral leishmaniasis (VL) is a fatal and systemic disease, if left untreated. There are an estimated 700,000 to 1.0 million new human cases of VL reported annually with 50,000 deaths. Sustaining control of VL in terms of proper and prevailing immunity development is a global necessity amid unavailability of a prophylactic vaccine. To this end, we herein report, for the first time, novel cationic liposomes containing monophosphoryl lipid A (MPLA) intercalated into the 1,2-distearoyl-*sn*-glycero-3-phosphocholine (DSPC) lipid bilayer as an adjuvant for a DNA vaccine to enhance antileishmanial immunity. Interestingly, this MPLA-liposomal formulation strongly amplified the *Leishmania donovani* cysteine protease C (*Ldcpc*) DNA vaccine (i.e., pVAX1-*cpc*)-induced polyfunctional CD4<sup>+</sup> and CD8<sup>+</sup> T cells together with antibody responses with a Th1 biased profile. MPLA-liposomes could also activate the splenic DCs *in vivo* in BALB/c mice, for robust protective immunity against VL.

### CHALLENGE:

- The major challenges behind clinical development of anti-leishmanial vaccine is poor antigen presentation, insufficient cell mediated immune response and lack of long-lasting memory .

### APPLICATION:

- The effective dose of TLR agonist MPLA in liposomal form is about 35 times lower than that of MPL-TDM.
- This vaccine can be used with or without any existing drug for prophylaxis and therapy against leishmaniasis for generating immunity.

**Opportunity:** Prophylactic application of a DNA vaccine entrapped in cationic liposome with MPLA as an immune stimulator resulting in successful adaptive immunity against leishmaniasis with induction of protective immunity against parasite.

**STAGE OF TECHNOLOGY DEVELOPMENT:** Business Development Voucher fund from GCRF, Durham University, UK has been received. An industrial partner, Lifecare Innovations Pvt. Ltd, a leading Indian pharmaceutical company is working to commercialize this liposomal vaccine.

### REFERENCES:

**Das A, Asad M, Sabur A, Didwania N, Ali N.** Monophosphoryl Lipid A Based Cationic Liposome Facilitates Vaccine Induced Expansion of Polyfunctional T Cell Immune Responses against Visceral Leishmaniasis. *ACS Applied Bio Materials*. (2018) 1, 4, 999–1018. doi: <https://doi.org/10.1021/acsabm.8b00184>

**Indian Patent Application** 132NF2013/IN / BR

**PCT** PCT/IN2015/000268, dated: 29/06/2015

**PROJECT INVESTIGATORS:** Prof. Nahid Ali