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Translational development and preclinical efficacy of a multiantigen T cell epitope: Enriched DNA vaccine against *Leishmania*sis

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A vaccine against human *leishmania*sis, a cluster of neglected, vector-borne diseases caused by the protozoan parasite *Leishmania*, is urgently needed. *Leishmania*sis severely affects large populations in tropical and subtropical regions worldwide. Treatment options are limited due to toxicity, variations in efficacy, and high costs of the available drugs, and increasing drug-resistance, andeffective preventative measures are not available. A vaccine for prevention, control and elimination of *leishmania*sis should be immunogenic in populations of different geneticbackgroundsin endemic regions, and efficacious against the various species of *Leishmania*. We have developed a multiantigen T cell epitope-enriched DNA vaccine against *leishmania*sis. Five vaccine antigens were selected as genetically conserved in various *Leishmania* species, different endemic regions, and over time. In natural infection, the antigens induced T cell-based immunity as demonstrated with T cells from individuals who had recovered from *leishmaniasis*. All five antigens harbor epitopes for both CD4 and CD8 T cells in genetically diverse human populations of different endemic regions. The vaccine proved immunogenic and protective in a mouse model of visceral leishmaniasis. In studies with single and multiple vaccinations, agood safety profile of the vaccine was demonstrated. The entire development strategy for the vaccine was translational: First, the immunology of vaccine antigens was established in human populations of endemic regions, followed by the proof-of-principle for induction of specific immune responses and protection against *Leishmania* infection in mice. A simple and up-scalable GMP production process is in place. The vaccine is ready to be tested in clinical trials.

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