

The Farmabrasilis Infectious Disease Proposal

A new, powerful, affordable immunomodulator and a strategy for large-scale deployment

Goal

To contribute to the fight against TB, malaria and other infectious diseases, particularly in developing countries, where the problem is compounded by the spread of HIV-AIDS.

Medicine candidate:
the immunomodulator
P-MAPA

A new therapeutic approach

Background

Ineffective immunity in TB and Malaria infections is often associated with depressed T-helper type 1 cytokine response, and reduced production of Interferon-gamma (IFN γ). IL-10 is thought to be a central mediator of the depressed IFN γ response.

Previous TB immunotherapy attempts

Exogenous IFN γ as a therapeutic adjuvant has been found to improve clinical outcome of TB patients, co-infected or not with HIV. However, this may not be suitable for large-scale implementation in developing countries due to its high cost.

An innovative therapeutic approach

To administer adjuvant agents that enhance production of physiological amounts of IFN γ and modulate IL-10 production to help reestablish immunocompetence in patients of TB and other infectious diseases.

P-MAPA seems to have this ability, possibly even under concomitant infection by HIV.

A new medicine

The immunomodulator P-MAPA is a proteinaceous aggregate of ammonium and magnesium phospholipoleate palmitoleate anhydride derived from *A. oryzae*

P-MAPA antimicrobial effects *in vivo*

Mycobacterium tuberculosis: significantly reduces the bacterial load in the lungs.

Listeria monocytogenes: modulates growth and differentiation of CFU-GM and increases cytokine production resulting in remarkable resistance to infection.

Plasmodium chabaudi: significantly reduces parasite proliferation.

P-MAPA Immunomodulating properties

Reestablishment of the immunocompetence by the increase of IFN γ levels and modulation of IL-10 production in cancer and infectious diseases.

P-MAPA safety *in vivo*

Non-toxic to mice, rats, dogs and monkeys. Non-teratogenic to mice and rats. Non-toxic to humans (clinical trial phase I).

P-MAPA is ready for clinical trial phase II

Strategy for large-scale deployment

P-MAPA is an affordable immunomodulator, obtained by a classical fungal fermentation process. No high technology needs to be involved.

Farmabrasilis has developed a large-scale, low-cost production technology of P-MAPA, and is in a position to transfer the know-how to its partners, even in countries with no tradition of pharmaceutical manufacture.

In order to allow universal use of P-MAPA against TB and other infectious diseases, the production technology can be licensed without royalties in the case of neglected diseases and economically disadvantaged populations

P-MAPA, in combination with current therapies, may be an important contribution to the treatment of infectious diseases caused by intracellular pathogens, such as TB and malaria, possibly even under concomitant infection by HIV.

Combined with the policy of shared research and cost-free licensing for disadvantaged populations, we hope that the Farmabrasilis Infectious Disease Proposal will benefit large numbers of people in geographic regions with a high prevalence of HIV.