FIT Biotech Oy
Combating HIV and TB with the help of GTU®

An immunomodulator from FIT Biotech was central to the success of a recent Phase II clinical trial and represents the first time that an immune-based HIV intervention has reduced viremia in previously untreated patients. The trial opens up the prospect of an alternative to ART therapy for millions of HIV-infected patients.

While most HIV vaccine efforts have been aimed at developing a preventive HIV vaccine to protect non-infected individuals against future exposure, vaccinating people already infected offers the best hope for chronically HIV-infected individuals – especially where resources and access to antiretroviral (ARV) therapy are limited.

A vaccine that can modify the course of HIV infection by maintaining a low viral load and high or constant CD4 cell counts is needed to do this. To address the ability of the HIV virus to mutate rapidly, FIT Biotech has used its novel GTU® vector technology to produce a novel immunomodulator, known as FIT-06.

Based on an antigenic artificial protein composed of sequences from six HIV genes with antigens from the A, B, C, and FGH HIV clades, FIT-06 is estimated to cover more than 95% of the theoretical antigenic variability within known HIV strains.

TRIALS MOVING AHEAD
A Phase II therapeutic clinical trial with 60 treatment-naïve HIV-infected individuals in Soweto by the University of Witwatersrand’s Perinatal HIV Research Unit showed a significant reduction in viral load and an increase in CD4 cell counts in individuals vaccinated with FIT-06.

A larger Phase IIIB/III study, aimed at confirming the clinical efficacy of the product by administering FIT-06 in association with ART in Phase II therapeutic trials, has started in France involving people infected with HIV and already on medication for the disease. The results of this study are expected in 2013.

A VERSATILE PLATFORM
The FIT-06 immunomodulator used in the South African trials is based on FIT Biotech’s GTU® technology platform, a special DNA plasmid that can deliver selected genes to human cells. In addition to providing up to 100 times stronger and more persistent gene expression than standard plasmids, this technology offers versatility and cost-efficient production opportunities, together with freedom from the safety risks typical of viral vectors.

GTU® technology is also being used to develop a more efficient vaccine against tuberculosis (TB) than the existing BCG vaccine. TB remains a major global health problem, with a third of the global population estimated to be infected with mycobacterium and almost 2 million people dying of the disease annually.

Based on an immune response induced by genes of mycobacterial origin, a DNA vaccine using GTU® technology has the potential to elicit long-lasting, cell-mediated immunity.

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