Justification for Thai phase III HIV vaccine trial

A previous commentary by Dr Dennis Burton and colleagues, regarding concerns over the wisdom of the US government sponsoring a large-scale HIV-1 vaccine trial in Thailand,* has received a formal response from Dr John G McNeil from the National Institute of Allergy and Infectious Diseases, Bethesda, US, and colleagues.

Dr McNeil and colleagues state that the phase III evaluation of a combination vaccine regimen, referred to as prime-boost, *is* "*scientifically justified, morally correct, and strategically important*". Although they agree that "*identifying correlates of protective immunity and improved immunogens is critical*", Dr McNeil and colleagues comment that " *with five million new infections each year, the luxury of time is absent*".

Both the prime canarypox vector ALVAC and the boost of monomeric gp120 are derived from HIV strains that circulate in Thailand, and responses induced by this combination "*are different from those induced by each component alone*", say Dr McNeil and colleagues. The decision to proceed with the trial was based on phase II results and was supported by ALVAC-induced protection in nonhuman primates (NHP). Indeed, the potential efficacy of this combined vaccine has continued to receive support in subsequent NHP studies, they remark.

Dr McNeil and colleagues note that the ongoing prime-boost trial was "*reviewed and endorsed by 11 international governmental and academic scientific, ethical, and regulatory review bodies*" in Thailand and the US, along with the WHO and the joint UN Programme on HIV/AIDS (WHO-UNAIDS). They comment on the scientific and practical reasons behind the inclusion of the gp120 component following two failed efficacy trials; this includes the notion that advancing the underlying vaccine hypothesis of cell-mediated plus antibody-mediated immunities requires both vaccine components. "*Although there is a real chance that this candidate vaccine may not be efficacious, there is a very high probability that information gained will advance HIV vaccine development*", say Dr McNeil and colleagues. They add that the study will be independently monitored to determine if its continuation is scientifically and ethically justified, or whether it should be terminated early.

* see Inpharma 1423:2, 7 Feb 2003; 800943995

McNeil JG, et al. HIV vaccine trial justified. Science 303: 961, 13 Feb 2004

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