Reviewer's report

Title: Evaluation of two formulations of adjuvanted RTS,S malaria vaccine in children aged 3 to 5 years living in a malaria-endemic region of Mozambique: a Phase I/II randomized double-blind bridging trial

Version: 4 Date: 19 September 2006

Reviewer: Francois Spertini

Reviewer's report:

General

This study aims to compare previously tested RTS,S/AS02A with a pediatric variant RTS,S/AS02D which contains the same constituents as 0.25 ml of RTS,S/AS02A but in 0.5 ml, according to EPI practices.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1) Both cellular and humoral responses seem crucial to obtain protection against P. falciparum. This validation study only assess the humoral responses induced by the formulations. This does not give information on the potential inferiority/non inferiority with regards to the cellular responses, in particular CD4+ or CD8+IFNgamma+ responses. How does this partial validation potentially modifies the conclusions?

2) Study was terminated 30 days only after the third immunization. This does not give information on the persistence of the humoral response at later time points (6, 9 mo).

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

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Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.