RTS,S MEDICAL AND SCIENTIFIC QUESTIONS & ANSWERS

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Disclaimer

The primary focus of this resource is to be an internal training tool for RTS,S malaria vaccine candidate, containing related data in the format of a Q&A for Medical Affairs personnel. Information presented here is not for external distribution.

Whilst this document can be inspirational for reactive responses to experts or medical enquiries, local regulations, the GSK Code of Practice, scientific engagement principles and/or medical information processes should be followed appropriately.

Please Note

- For media enquiries, please refer to the specific reactive Q&A for Media Enquiries and notify the Global Pipeline Communications team before you respond to a request for an interview so that they can help you to prepare (contact person: Aoife Pauley at aoife.x.pauley@gsk.com).
- The vaccine RTS,S/AS01 has completed phase 3 clinical program and positive regulatory assessment from the European Medicines Agency, but is not yet authorized for marketing in any country. The RTS,S vaccine is being developed in Public Private Partnership with PATH-MVI, as an additional tool to be added to the currently available malaria preventive interventions and for implementation through the national immunization programs in malaria endemic regions in sub-Saharan African countries.
- When referencing clinical data on RTS,S any statements should be prefaced by "In this study...", to make it clear that it is too early to make any general statement on the vaccine profile outside the context of the ongoing clinical trails.
- Have you found what you were looking for? If you have any suggestions for information which should be included in this tool please contact us at the following address: Carys Calvert at carys.calvert@gsk.com.

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What is the design of the Phase III efficacy trial?

This Phase III efficacy trial is a double-blind, randomized, controlled trial conducted in 11 clinical trial sites in seven countries in sub-Saharan Africa[a]. 15,460 participants aged 6-12 weeks or 5-17 months first received three vaccine doses, one month apart, of either the RTS,S malaria vaccine candidate or a comparator vaccine. In the younger age category, administration was done concomitantly with the EPI vaccines DTPw-HepB/Hib and OPV. In the older age category, no other vaccine was co-administered to avoid confounding factors. After a year and a half (18 months), participants received a fourth dose of either the RTS,S malaria vaccine candidate or a comparator vaccine to assess whether such a "booster" dose will provide benefit. All subjects were followed up over 32 months post dose 1. In addition, follow-up continued until Dec 31, 2013 leading to a median follow-up of 48 months for children and 38 months for infants post dose 1.

Neither the volunteers nor the investigators know which vaccine is being administered in order to ensure there is no bias when interpreting the results (double-blind).

Researchers monitor cases of clinical malaria that are characterized by fever and the presence of malaria parasites in the blood, as well as the incidence of severe malaria and other relevant public health endpoints. Different case definitions have been used through a range of parasite levels; these are described in a separate document. To measure the vaccine's efficacy, occurrence of clinical and severe malaria cases will be compared between infants and children who received the RTS,S malaria vaccine candidate and those who received the comparator vaccine. In addition, researchers will continue to monitor safety and potential side effects as well as effect of RTS,S on growth and assess the safety and immunogenicity in HIV-infected and malnourished children.

a. *Leach A, et al. Malaria Journal 2011; 10: 224.*

b. *gsk.com-clinical trial register study ID 110021 (Malaria-055)*