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 other malaria control interventions were used in this Phase III trial?

The trial was implemented on top of the national guidelines and recommendations for malaria treatment and prevention. By working with those responsible for the malaria prevention programmes access to recommended malaria prevention measures (such as long-lasting insecticide treated bed nets, indoor residual insecticide spraying, rapid diagnosis and appropriate treatment of malaria cases with artemisinin-based combinations therapies) has been strengthened and facilitated. When access to insecticide treated bed nets was not ensured by existing programs, they were distributed by the clinical trial staff. Other preventive measures were implemented in line with national guidelines. Parents of study children were encouraged to use ITNs and to present rapidly if their child was sick.

A survey conducted 14 months after the first vaccination showed that approximately 78% of children 5-17 months of age and 86% of infants 6-12 weeks of age were using insecticide treated bed nets in each of the study groups.