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 efficacy of a fourth dose?

The phase III efficacy trial has evaluated a fourth dose of RTS,S/AS01 given 18 months after the primary series of 3 doses.[(a)]

- Protection against clinical malaria was prolonged in both children and young infants by a fourth dose.
- The increased risk for severe malaria in the older age-category as compared to the control group was reduced by the administration of a fourth dose of RTS,S/AS01.
- The proportional increase in efficacy against clinical malaria associated with a fourth dose was similar in children and young infants but efficacy after the fourth dose remained lower in those who received their primary vaccination when aged 6-12 weeks rather than at the age of 5-17 months.
- The incremental vaccine efficacy against clinical malaria provided by the booster dose (i.e., VE of the fourth dose in addition to the protection provided by the primary vaccination course) was (ATP cohort):
- In children: 29% over the first year after dose 4 and 21% up to study end.
- In infants: 24% over the first year after dose 4 and 20% up to study end.

a. *RTS,S Clinical Trial Partnership. The Lancet, 2015. dx.doi.org/10.1016/S0140-6736(15)60721-8*