

RTS,S MEDICAL AND SCIENTIFIC QUESTIONS & ANSWERS

For internal use only - NOT FOR DISTRIBUTION

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 trials.
- 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.

RTS,S MEDICAL AND SCIENTIFIC QUESTIONS & ANSWERS

For internal use only - NOT FOR DISTRIBUTION

Will the implementation of the RTS,S malaria vaccine candidate in malaria endemic areas replace the current malaria control interventions?

Mosquirix is being considered as a complementary intervention, i.e. one that would be deployed in addition to fully scaled-up access to and use of other malaria preventive measures, prompt diagnostic testing and effective anti-malarial medicines. The efficacy data published for Mosquirix were generated on top of the use of these existing interventions.

Results to date indicate that the RTS,S malaria vaccine candidate has the potential to reduce the risk of malaria by 30-50% among infants and young children living in malaria endemic areas in sub-Saharan Africa on top of existing malaria interventions (mainly bednets). Taking into account the disease burden of malaria in this region, with one child dying every minute^(a), even a vaccine with moderate efficacy could provide substantial public health benefit. However, given the efficacy profile of the vaccine candidate to date, it will be important to also continue using other malaria control interventions (such as long-lasting insecticide treated bednets, indoor residual insecticide spraying, rapid diagnosis and appropriate treatment of malaria cases with artemisinin-based combinations therapies) according to national recommendations.

a. *World Malaria Report, WHO 2014* (<http://www.who.int/malaria/publications/>)