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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Can the RTS,S be used in the renewed effort to eliminate/eradicate malaria?

The RTS,S vaccine candidate is being developed to reduce the number of cases of malaria and their consequences among the most vulnerable population – infants and children under the age of five in sub-Saharan Africa. If approved for use, a safe and effective vaccine would be an important component of a comprehensive malaria control programme and could potentially save hundreds of thousands of lives. Enhanced disease control being the primary focus, the development of the RTS,S malaria vaccine candidate is currently not targeted toward being a component of a malaria elimination or eradication strategy.

However, the RTS,S vaccine candidate, being a pre-erythrocytic malaria vaccine, has a clear direct biological effect on *P. falciparum* infection, which may be a useful component for a malaria elimination/eradication program. Such program would probably however require malaria interventions that are highly efficacious in reducing parasite transmission to be applied to a wider age group than only infants and young children.