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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Why is RTS,S being tested in African children?

The RTS,S vaccine candidate targets the *Plasmodium falciparum*. More than 90% of all malaria cases caused by the *P. falciparum* malaria parasite and the great majority of malaria deaths occur in children under the age of five in sub-Saharan Africa. We therefore are developing this vaccine for the population in most need.

In other malaria endemic areas such as Asia and Latin America, malaria can also be caused by other forms of the *Plasmodium* parasite, against which RTS,S is not providing protection. To cover areas with different malaria transmission intensities, 11 research centres across seven sub-Saharan African countries were selected to participate in the large scale Phase III efficacy trial.

Before starting clinical trials in African children, the safety and efficacy of the RTS,S malaria vaccine candidate had been evaluated in adult volunteers in the United States, Belgium and The Gambia. The RTS,S clinical trials are designed to adhere to the strictest international and national safety and ethical guidelines, including rigorous informed consent procedures.