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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Will the emerging drug resistance to malaria drugs have also an effect on the efficacy of RTS,S, or vice versa?

The mechanisms by which the RTS,S malaria vaccine candidate prevents malaria cases from occurring are completely different from those used by drugs to attack the malaria parasite. There is no reason to assume that resistance of the malaria parasite against malaria drugs would also have an effect on the efficacy of the RTS,S malaria vaccine candidate.

In addition, there are no data available to substantiate that RTS,S would accelerate the emergence of resistance of the malaria parasite against malaria drugs. There is also no biologically plausible mechanism that could explain how such effect might happen. If the number of malaria cases would be reduced following the introduction of the RTS,S vaccine, there would be less need to use anti-malaria drugs and therefore potentially less pressure for drug resistance to emerge.