

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 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.

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What is an Adjuvant? Why does GSK use an Adjuvant System in the RTS,S malaria vaccine candidate?

An adjuvant is a substance which enhances the immune response against a vaccine antigen. Adjuvants, such as aluminium salts, have been used in vaccine formulations to enhance the immune response of vaccines for more than 80 years.

GSK's proprietary Adjuvant Systems (AS) utilise a combination of two or more different adjuvants to enhance and guide the immune responses against the antigens contained in the vaccine. Phase I and Phase II clinical trials evaluated different Adjuvant Systems for the RTS,S malaria vaccine candidate and demonstrated that the enhanced antibody and cellular immune responses observed with AS01 also resulted in a trend towards improved vaccine efficacy against malaria infection and disease while maintaining an acceptable safety profile. This most promising AS01 adjuvanted formulation of the RTS,S malaria vaccine candidate was selected for further testing in the ongoing Phase III studies.