

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.

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How will you ensure that the vaccine, once approved, will reach those who need it?

If the vaccine is recommended for use and approved by regulatory authorities, MVI and GSK are committed to doing all they can to make the vaccine available to those who need it most: infants and young children in malaria endemic regions in sub-Saharan Africa. Indeed, the partners engaged early on—and continue to engage—with the WHO to help ensure they have all the information required to issue a policy recommendation and pre-qualification, and thus pave the way for procurement by UN and other agencies. In addition, the partners are engaging with malaria endemic African countries to ensure processes and systems are in place for decision making regarding the potential introduction of a malaria vaccine. Price should not be a barrier to access. MVI and GSK will collaborate closely with multilateral organisations such as GAVI, UNICEF, and others to allow these organisations to purchase the vaccine in large volumes at affordable prices.