

## 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](mailto: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](mailto:carys.calvert@gsk.com).

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### **What will the product presentation of RTS,S be? What is the pack size?**

The RTS,S candidate vaccine presentation is a two-dose presentation with two vials clipped together, lyophilized RTS,S in one vial and the liquid adjuvant AS01 in the other vial. There is no preservative in either RTS,S or the AS01 adjuvant. The product is stable for 3 years at +2-8°C. RTS,S must be reconstituted with AS01 prior to administration. After reconstitution, the product is stable for 6 hours.

Each pack will contain 100 vials (50 pairs of RTS,S/AS01) and equals 100 doses. This is similar to the standard for GSK vaccines in 3mL vials supplied by UNICEF. The pack dimension of the inner carton will be Length: 18cm; width 14.9cm; height 3.7cm for a total volume of 9.92cm<sup>3</sup>/dose.