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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Can RTS,S be co-administered with other childhood vaccines?

Mosquirix™ can be given concomitantly with any of the following monovalent or combination vaccines including diphtheria (D), tetanus (T), whole cell pertussis (Pw), acellular pertussis (Pa), hepatitis B (HepB), *Haemophilus influenzae* type b (Hib), oral polio (OPV), measles, yellow fever, rotavirus and pneumococcal conjugate vaccines (PCV). [a]

- If RTS,S/AS01 is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different sites.[a]
- Concomitant administration of rotavirus and pneumococcal conjugate vaccines with RTS,S/AS01 may reduce the antibody response to the circumsporozoite (CS) antigen of RTS,S. The impact of this observation on the level of protection induced by RTS,S/AS01 is currently unknown. [a]
- The co-administration of Mosquirix™ with PCV increases the risk of fever within 7 days post-vaccination [a]

RTS,S/AS01 vaccine formulations were evaluated in co-administration with the following licensed vaccines[c,d]: DTPw/Hib (*TETRActHib*), DTPa/Hib *(Infanrix Hib)*, DTPw-HepB/Hib (*Tritanrix-HepB/Hib*), OPV (*Polio Sabin*), measles (*Rouvax/Attenuated Live Measles Vaccine*), yellow fever (*Stamaril*), rotavirus *(Rotarix)* and pneumococcal conjugated *(Synflorix)* vaccines.

The non-inferiority of the immune response was demonstrated for D, T, Pw, Pa, Hib, polio and pneumococcal antigens (except for pneumococcal serotype 18C); although there was a trend for lower antibody geometric mean concentrations (GMCs) for these antigens when compared to the control group. These observations were considered as not clinically significant.[a]

In a clinical study in infants aged 8-12 weeks, fever was reported more frequently in infants receiving PCV in co-administration with Mosquirix, DTPa/Hib and OPV simultaneously (26%), as compared to infants receiving only Mosquirix, DTPa/Hib and OPV (14%). However, the frequency of grade 3 fever (defined as axillary temperature > 39.0°C) was low (≤ 1%).[a,d]

Another study, **Malaria-073**[e], is a Phase IIIb randomized, open-label, controlled study to evaluate the non-inferiority of immune response and the safety of the RTS,S/AS01, when administered as primary vaccination with or without co-administration of yellow fever (*Stamaril*®), measles and rubella (*MR-VAC*™) vaccines at 6, 7.5 and 9 months of age to children living in sub-Saharan Africa.

a. *Mosquirix Global Datasheet v03, February 2015*

b. *Leach A, et al. Malaria Journal 2011; 10: 224.*

c. *Agnandji S, et al. J Infectious Diseases 2010, 202(7):1076–1087*

d. *Malaria-063, ClinicalTrials.gov NCT01345240 (GSK study ID 113681)*

e. *Malaria-073, (GSK study ID 200596)*