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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Is GSK developing any other treatments for malaria beyond vaccines?

GSK is investigating tafenoquine, an 8-aminoquinoline, for the treatment and relapse prevention (radical cure) of *P. vivax* malaria. Tafenoquine is given as a single dose and is being co-administered with chloroquine to evaluate a 3-day treatment course. Tafenoquine is being developed in partnership with the Medicines for Malaria Venture (MMV). It was originally discovered by the Walter Reed Army Institute of Research (WRAIR) and licensed by GSK from the US Army in 1995.

Top-line safety and efficacy results from Part 1 (PhIIb, dose-selection) of the seamless Phase II/III Study (TAF112582 DETECTIVE) were published in the Lancet in December 2013[(a)]. The Part 2 of the study (Phase III, pivotal for first registration) is planned to start in 1H2014.

a. *Llanos-Cuentas A. et al. The Lancet, Early Online Publication, 19 December 2013. doi:10.1016/S0140-6736(13)62568-4*