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 <u>carys.calvert@gsk.com</u>.

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How does the MSP3 malaria vaccine candidate reported in the September edition of the NEJM 2011 relate to the RTS.S malaria vaccine?

The results published in the NEJM letter to the editor regarding the MSP3 vaccine candidate have no relation to the RTS,S malaria vaccine candidate^(a). In the letter, it was reported that a blood-stage malaria vaccine targeting the MSP3 protein showed evidence of effectiveness in an initial Phase Ib study. This study was designed to investigate the vaccine's safety, not its efficacy. However, the study was performed in a highly endemic region of Burkina Faso, and the researchers observed vaccine efficacy in their long-term safety monitoring of the children. These results are still very preliminary as the trial size was very small. Further Phase II and Phase III studies will provide stronger assessments of the efficacy of this vaccine candidate

GSK and MV		liverse efforts to	develop scien	tifically reasona	SP3 malaria vacc ble approaches to	
a. Sirima	S, et al. NEJM 201	1; 365: 1062-64.				