

## 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](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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#### **With the decline in malaria, why invest in a malaria vaccine which has only moderate efficacy instead of in current malaria control interventions**

Despite major efforts in control measures over the past decade one child dies every minute due to malaria, mainly in sub-Saharan Africa. Moreover, the remarkable progress achieved the last decade is threatened by the spread of insecticide resistant mosquitoes and drug resistant parasites and also sustainability. <sup>(a)</sup> A vaccine that would allow to further reduce the remaining malaria disease burden by 30-50% would still provide a significant public health benefit. The use of other malaria interventions (mainly ITNs and ACTs) has been optimized in the pivotal RTS,S phase III efficacy trial according to the national guidelines and recommendations for malaria treatment and prevention. The clinical efficacy of RTS,S as measured in the trial therefore actually reflects the protection provided by RTS,S in addition to the protection provided by the other interventions.

As an example of the success of vector control combined with bednets and effective drug treatments, Zanzibar's control program has exceeded expectations, but we need to keep in mind that Zanzibar is an island, isolated from mainland, and that considerable resources from outside donors are needed to maintain their multipronged control strategy. Another example of success has been Rwanda, which achieved remarkable reductions in malaria incidence between 2005 and 2008. However in 2009, due to a delay in ITNs availability, the malaria incidence increased again until new bednets became available and were distributed, demonstrating the challenges to sustaining success in an environment where a prevention program had significantly reduced the disease threat. A mix of existing and new tools is needed to further reduced the burden of malaria. Even a moderately effective malaria vaccine, as an additional tool for a comprehensive toolbox, could help to achieve improved and sustained malaria control.

a. *World Malaria Report, WHO 2014*

b. *Greenwood B, et al. Parasite Immunol, 2009, 31, 582-86*