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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Why is GSK/MVI looking to develop another malaria vaccine if the RTS,S Phase III trial is not yet complete?

The Malaria Vaccine Advisory Committee to the World Health Organisation (WHO), coordinated by the WHO Initiative for Vaccine Research (IVR) called for a collective effort to explore and address the challenges in developing a successful malaria vaccine. This effort resulted in the Malaria Technology Roadmap([a]) that set the goal for a 'second generation' malaria vaccine. The roadmap was updated in November 2013, and aims to, by 2030, license vaccine**s** targeting *P. falciparum* and *P. vivax*. The vaccines should demonstrate an efficacy of at least 75% against clinical malaria over at least two years, with not more than annual boosters. Another objective is a vaccine that reduce transmission as a tool for elimination eg through mass campaigns.

The Roadmap identified as an interim, landmark goal the development by 2015 of a vaccine with 50% efficacy against severe disease and death that lasts more than one year.

Although the RTS,S malaria vaccine candidate has the potential to substantially reduce the malaria disease burden in Africa, the protection it appears to provide is not complete.

Vaccine development takes a long time and even if the first results of an early-stage trial with a second-generation vaccine candidate are promising, there will still be a lot of work required before it could be implemented in malaria endemic regions. It is therefore unlikely that a second-generation vaccine could be implemented on a large scale before 2025. However, if based on the PhIII trial results the RTS,S malaria vaccine candidate is approved by regulatory authorities and recommended by public health authorities, it could potentially start preventing malaria cases about ten years before a second-generation vaccine would be available for use.

a. *www.who.int/immunisation/topics/malaria/vaccine_roadmap/en*