## RTS, S MEDICAL AND SCIENTIFIC QUESTIONS & ANSWERS

For internal use only - NOT FOR DISTRIBUTION

#### **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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Why is a partnership necessary to develop a malaria vaccine? Is it appropriate for a large pharmaceutical company like GSK to receive money from a non-profit organization for R&D?

Partnerships such as the collaboration between GSK and the MVI program at PATH are important for several reasons: (1) they help to share the risks and expenses of R&D and therefore help to both accelerate the development process and to build our scientific understanding more rapidly; (2) they leverage additional R&D funding for vaccines and medicines primarily targeting diseases of the developing world that would not normally meet a company's return on investment principle; and (3) they help to ensure that these vaccines and medicines reach those most in need as rapidly as possible.

The past and ongoing efforts to develop the RTS,S malaria vaccine candidate serve as an innovative model of how the public and private sectors can work together in a productive way to deliver an effective malaria vaccine as quickly as possible to those who need it most. Successful collaboration will also be key to ensuring long-term success for RTS,S—for example with national governments and their malaria control and EPI programs, multilateral agencies, GAVI, the Global Fund and other donors.