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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What is the regulatory process?

An application was submitted to the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP), to obtain a scientific opinion using a specific procedure called *Article 58* of the EU medicines legislation. This procedure allows the EMA to assess the quality, safety and efficacy of a candidate vaccine or medicine for a disease of major public health interest, but intended exclusively for use outside the European Union while being manufactured in the European Union. This assessment is done by the EMA in collaboration with WHO, and requires products to meet the same standards as vaccines or medicines intended for use in the European Union.

The positive opinion from the EMA in July 2015 [(a)] is the first step in the regulatory and policy process toward making Mosquirix available as an addition to existing tools currently recommended for malaria prevention. Next, GSK will seek WHO prequalification for Mosquirix™, in order to allow United Nation agencies, such as UNICEF, to purchase the vaccine in partnership with developing countries. This positive opinion would also be the basis for Marketing Authorisation Applications to National Regulatory Authorities (NRAs) in sub-Saharan Africa.

In addition to regulatory processes, the pathway to implementation also requires policy recommendations by international and national public health authorities. [(b)]

a. *Mosquirix SmPC July 2015; European Medicines Agency, ema.europa.eu/ema/*

b. *WHO Q&A on malaria vaccines Nov 2015 who.int/immunization/research/development/malaria_vaccine_qa/en/*