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 carys.calvert@gsk.com.

RTS,S MEDICAL AND SCIENTIFIC QUESTIONS & ANSWERS

For internal use only - NOT FOR DISTRIBUTION

For whom is Mosquirix™ indicated?

Following review by the European Medicines Agency [(a)], Mosquirix™ is indicated for active immunisation of children aged 6 weeks up to 17 months against malaria caused by *Plasmodium falciparum* and against hepatitis B. The use of Mosquirix should be based on official recommendations considering *Plasmodium falciparum* malaria epidemiology in different geographical areas.

Mosquirix should not be used for the prevention of hepatitis B in settings where prevention against malaria caused by *P. falciparum* is not sought. The safety and efficacy of Mosquirix in children younger than 6 weeks and older than 17 months of age (at first dose) has not been established. Data regarding the efficacy of Mosquirix are limited to children from sub-Saharan Africa.

In November 2015, WHO recommended 3-5 large pilot implementation projects in sub-Saharan Africa with moderate-to-high malaria transmission to understand how to best use RTS,S to protect young children against malaria. The pilot projects should evaluate the additional contacts with the health care system needed to deliver the four doses to children from the age of 5 months. [(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/*