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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When will RTS,S be made available for implementation?

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. [(a)] 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 as well as potential impact on mortality. WHO estimates that the pilot implementation programme will generate critical evidence to enable decision-making about the potential wider scale use of this vaccine in 3-5 years' time. [(a)]

A WHO policy recommendation is the global equivalent of a national public health authority's (e.g. Ministry of Health's) decision about use of vaccines. Many countries appreciate guidance from the WHO policy recommendation process on which vaccines they should consider for introduction in their national immunization programmes. Similarly, donor agencies, such as the GAVI Alliance, require a WHO recommendation for use before funding procurement of vaccines for developing countries.

The last step will be the application for marketing authorisation to national health authorities in sub-Saharan Africa. EMA's positive scientific opinion [(b)] will be the basis for these applications that are a mandatory step on the way toward the implementation of Mosquirix through African national immunisation programmes.

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

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