# 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 <u>carys.calvert@gsk.com</u>.

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### What is the estimated cost-effectiveness of RTS,S?

Adding Mosquirix™ to current malaria control interventions is highly cost-effective. (b)

Model predictions were made by four modelling groups based on the final phase 3 efficacy results.<sup>(a)</sup> Estimations assumed a vaccination program starting in 2017 across a range of estimated parasite prevalence among 2-to-10 year-olds (*Pf*PR<sub>2-10</sub>) and access to treatment of 45%. Vaccination was done at the ages of 6, 7.5 and 9 months (90% coverage for 3<sup>rd</sup> dose) and a 4<sup>th</sup> dose at age 27 months (72% coverage, i.e., 80% of dose 3). <sup>(b)</sup>

The Incremental Cost-effectiveness ratios (ICER) estimates for vaccination of young children living in regions with a PfPR<sub>2-10</sub> of 10-65% from the age of 6 months with 4th doses (at a price of US\$ 5 per dose) was US\$87 (\$43-240) per DALY averted. (b)

These estimates are higher than for LLINS, but similar to estimates for IRS however, not directly comparable due to studies conducted in different settings. In comparison, average incremental costs per DALY averted for other interventions (2009 prices) was for LLINs \$27(\$8.15-\$110), for IRS \$143(\$135-\$150), for IPT \$24(\$1.08-\$44.24) (c)

- a. RTS,S Clinical Trial Partnership. The Lancet, 2015. dx.doi.org/10.1016/S0140-6736(15)60721-8
- b. Penny et al. Lancet 2015
- c. White et al. Malaria J. 2011;10:337