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 does the acronym 'RTS,S' stand for?

'RTS,S' is a scientific name given to this malaria vaccine candidate and represents the composition of this vaccine candidate. The 'R' stands for the central repeat region of the circumsporozoite protein (CSP), a substance that is found in abundance on the surface of the sporozoite parasite and recognised as "foreign" by the body's immune system, the 'T' stands for the T-cell epitopes of the CSP and 'S' for the hepatitis B surface antigen (HBsAg), since in this malaria candidate vaccine the 'R' and 'T' portions of CSP are combined with 'S' and co-expressed in yeast cells with free 'S' protein to allow spontaneous formation of 'RTS,S' particles known to enhance immune responses to the antigen^(b,c).

- a. Cohen et al. Ann Pharm Françaises 2010;68:370-9
- b. Cohen et al. in Parasitology, Springer-Verlag Berlin Heidelberg 2011, Chapter 7