

# GSK welcomes WHO recommendation for broad roll-out of its RTS,S/AS01e (RTS,S) malaria vaccine

 PUBLISHED OCT 6, 2021  
BY [GSK](#)

For media and investors only

Issued: 6 October, London UK

- Based on the recommendation of its global advisory bodies for immunization and malaria, WHO has recommended the wider use of GSK's RTS,S malaria vaccine in children living in sub-Saharan Africa and other regions with moderate to high malaria transmission.
- Malaria vaccine pilot programmes in Ghana, Kenya and Malawi have shown high impact in real-life childhood vaccination settings, strong community demand and that RTS,S can be effectively delivered through routine child immunization platforms.
- Recommendation follows shortly after new data show that RTS,S, in combination with seasonal administration of antimalarials, lowers clinical episodes of malaria, hospital admissions with severe malaria, and deaths by around 70%.

GlaxoSmithKline (GSK) plc welcomes and applauds the WHO recommendation for the broader deployment of GSK's RTS,S malaria vaccine to reduce childhood illness and deaths from malaria in children living in sub-Saharan Africa and other regions with moderate to high transmission as defined by WHO. RTS,S is the first and only malaria vaccine to have been shown in pivotal long-term clinical trials to significantly reduce malaria in children. The vaccine is the result of over 30 years of research led by GSK, with PATH and other partners.

Thomas Breuer, Chief Global Health Officer, GSK, said:

GSK is proud that RTS,S, our ground-breaking malaria vaccine,

developed over decades by our teams and partners, can now be made available to children in sub-Saharan Africa and other regions with moderate to high malaria transmission. This long-awaited landmark decision can reinvigorate the fight against malaria in the region at a time when progress on malaria control has stalled. Both real world evidence and clinical trial data show that RTS,S, alongside other malaria prevention measures, has the potential to save hundreds of thousands of lives.

In anticipation of the decision and wider roll-out beyond the pilot programmes in Malawi, Kenya and Ghana, GSK is working with partners to develop solutions to ensure equitable and long-term access to the RTS,S vaccine for the people who need it. GSK has committed to donate up to 10 million RTS,S doses for use in the pilots, and to supply up to 15 million doses annually, following a recommendation and funding for wider use. A Product Transfer, including technology transfer for long-term antigen production, is also underway with Bharat Biotech of India. GSK will now work closely with partners, funders and governments to support additional supply of the vaccine, and has committed to make the 15 million annual doses available at no more than 5% above cost of production.

This recommendation from WHO, informed by data generated from the pilot programme, is a second key milestone for the RTS,S malaria vaccine in recent weeks. In August, data from a study of 6,000 children by the London School Hygiene and Tropical Medicine, published in the New England Journal of Medicine, showed that after three years the combination of seasonal administration of antimalarials (known as Seasonal Malaria Chemoprevention/SMC) and RTS,S vaccination lowered clinical episodes of malaria, hospital admissions with WHO-defined severe malaria, and deaths from malaria by about 70% compared to SMC alone. These data indicate that the impact of RTS,S vaccination can be increased to further reduce mortality, especially when combined with other recommended malaria control interventions in a seasonal setting.

Since the launch of the malaria vaccine pilots in 2019, 3 countries (Ghana, Kenya and Malawi) have led the introduction of the vaccine in selected areas of moderate to high malaria transmission, reaching more than 800,000 children with at least 1 dose of the vaccine. More than 2.3 million vaccine doses have been administered to date.

Community demand for the vaccine is strong and evidence shows it can effectively be delivered through the routine child immunization platform.

GSK believes that beating malaria is a shared responsibility and demands a range of tools – from accessible testing and treatment to preventative measures like a vaccine, complemented by bed nets as well as trained health workers to support prevention and treatment in the community.

GSK continues active research in malaria as part of its extensive Global Health research and development programme, and also works with partners such as Comic Relief and AMREF Health Africa to increase public health awareness, train health workers in underserved communities to better diagnose and treat malaria, and increase access to testing and medications.

GSK is a science-led global healthcare company. For further information please visit [www.gsk.com/about-us](http://www.gsk.com/about-us).

#### Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2020 and any impacts of the COVID-19 pandemic.

Daniel Chandramohan et al. Seasonal Malaria Vaccination with or without Seasonal Malaria Chemoprevention. New England Journal of Medicine, August 2021.

*Press release distributed by Wire Association on behalf of GSK, on Oct 6, 2021. For more information subscribe and [follow us](#).*

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