



GSK/PATH Malaria Vaccine Initiative (MVI) RTS,S malaria vaccine candidate

GSK photo

Disease Impact

- Each year there are around 207 million cases of malaria globally, and 627,000 malaria deaths. Most deaths from malaria occur in Africa in children under the age of five.
- Although existing interventions have helped to reduce malaria deaths significantly over the past decade, a well-tolerated and effective vaccine with an acceptable safety profile could add an important component to malaria control. To date, no vaccine against malaria has been licensed.



Key facts about vaccine R&D project

- **Candidate vaccine name:** RTS,S
- **Partners:** For the past 30 years, GlaxoSmithKline (GSK) scientists have been working with others around the world to try and develop a vaccine against malaria. A vaccine candidate—RTS,S—is being developed in partnership with PATH Malaria Vaccine Initiative (MVI) with grant monies from the Bill & Melinda Gates Foundation.
- **Current phase:** Phase III. The latest results from the ongoing large Phase III clinical efficacy trial of RTS,S presented at the 6th Multilateral Initiative on Malaria Pan-African Malaria Conference in October 2013, showed that RTS,S reduced malaria cases by almost half over 18 months of follow up in young African children 5-17 months of age, and by around a quarter in infants aged 6-12 weeks over the same time period. RTS,S had an acceptable safety and tolerability profile.
- **Countries where clinical trials are carried out:** The Phase III program covers 13 African research centers in 8 African countries (Burkina Faso, Gabon, Ghana, Kenya, Tanzania, Mozambique, Malawi and Nigeria). With 16,685 infants and young children participating, it is the largest malaria vaccine trial program conducted in Africa to date.
- **Number of researchers / scientists involved:** more than 200 experts involved in the development of the malaria vaccine.
- **Investments in candidate vaccine to date:** With more than US\$200 million in grant monies from the Bill & Melinda Gates Foundation, MVI contributes financial, scientific, managerial, and field expertise to the development of RTS,S. GSK takes the lead in the overall development of RTS,S and has invested more than \$350 million to date and expects to invest more than \$260 million until development is completed.
- **The way forward:** The RTS,S malaria vaccine candidate is still under development and subject to the evaluation of its safety, efficacy, and quality, as well as its benefits and risks, by regulatory and public health authorities. GSK intends to submit, in 2014, a regulatory application to the European Medicines Agency (EMA) using a specific procedure allowing the agency to assess, in collaboration with the WHO, a medicinal product for a disease of major public

health interest, but intended exclusively for use outside the European Union (Art.58). If this regulatory review concludes with a positive scientific opinion, GSK shall subsequently apply for Marketing Authorizations to National Regulatory Authorities (NRAs) in sub-Saharan Africa.

- Furthermore, if the EMA issues a positive opinion following its regulatory assessment and if the required public health information, including safety and efficacy data from the Phase III program, is deemed satisfactory, the WHO has indicated that a policy recommendation for the RTS,S malaria vaccine candidate is possible by the end of 2015, paving the way for local regulatory submissions and decisions by African nations and large-scale implementation of the vaccine through their national immunization programs.
- GSK has committed that the eventual price of RTS,S will cover the cost of manufacturing the vaccine together with a small return of around 5% that will be reinvested in research and development for second-generation malaria vaccines or vaccines against other neglected tropical diseases.

Long-term commitment and R&D specific challenges and complexities

For the past 30 years, GSK scientists have been working with others around the world to try to develop a vaccine

against malaria. The RTS,S malaria vaccine candidate is currently the most advanced in development globally. It was created in 1987 by scientists working at GSK's laboratories.

If approved, the RTS,S vaccine would be the first human vaccine against a parasite. Challenges are due to the complex cycle of the parasite within the vector and the host.

Why it matters

Malaria continues to exact a heavy burden on the health and economies of communities across Africa. In the Phase III clinical efficacy trial, the public health impact of the RTS,S vaccine candidate was evaluated in variety of malaria endemic settings and in the context of existing malaria control measures, including insecticide-treated bed nets. The latest trial results found that during 18 months of follow-up, RTS,S was estimated to prevent from 37 to 2365 cases of clinical malaria per 1000 children vaccinated across the 11 sites in the trial—in areas with high malaria incidence, where children may experience 4 or more cases of clinical malaria per year, this translates into potentially preventing 2 clinical malaria cases or more per child vaccinated. Despite its lower efficacy in young infants, RTS,S was estimated to prevent from -10 to 1402 cases of clinical malaria per 1000 young infants vaccinated across the 11 sites in the trial—in areas with high malaria incidence this translates into potentially preventing more than one malaria case per infant vaccinated.

Lean more

About GSK Vaccines

GSK Vaccines is active in vaccine research and development. Headquartered in Belgium, GSK Vaccines has 13 manufacturing sites strategically positioned around the globe. Of the 883 million doses of GSK vaccines distributed in 2012, over 80% went to developing countries, which include the least developed, low- and middle-income countries.

GSK—one of the world's leading research-based pharmaceutical and healthcare companies—is committed to improving the quality of human life by enabling people to do more, feel better, and live longer. For further information please visit www.gsk.com.

About PATH Malaria Vaccine Initiative (MVI)

The PATH Malaria Vaccine Initiative (MVI) is a global program established at PATH through an initial grant from the Bill & Melinda Gates Foundation. MVI's mission is to accelerate the development of malaria vaccines and catalyze timely access in endemic countries. MVI's vision is a world free from malaria. For more information, visit www.malaria vaccine.org

PATH is an international organization that drives transformative innovation to save lives and improve health, especially among women and children. It accelerates innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness its entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, PATH takes innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together with partners, PATH delivers measurable results that disrupt the cycle of poor health. Learn more at www.path.org.



For more information visit www.ifpma.org/resources/case-studies/case-study-malaria.html

