



Our commitment to fighting malaria

An estimated 3.2 billion people – almost half the world's population – are at risk of contracting malaria. Each year there are around 200 million cases of malaria globally, and more than 550,000 malaria deaths, the vast majority in children under the age of five living in sub-Saharan Africa (SSA).

2015

GSK received a positive scientific opinion for its malaria vaccine candidate from the European Medicines Agency's Committee for Medicinal Products for Human Use.

Significant progress has been made against malaria. Increasing use of bed nets, anti-malarial treatments and insecticide sprays have all helped to push the disease back. But malaria still takes a devastating toll on communities and economies across Africa. The battle against the disease will continue to be fought on all fronts using a wide range of interventions, including, potentially, vaccines.

GSK has been involved in the fight against malaria for decades

We believe that a comprehensive approach to malaria is needed to help scale up use of control methods, while continuing to invest in the development and use of innovative tools. We have an active malaria research and development (R&D) programme – including developing a candidate vaccine against malaria. We work hand-in-hand with organisations at the local, regional and international levels to help ensure that our products complement existing malaria interventions.

GSK's malaria control strategy has three areas of focus:

- Innovation for new malaria medicines and vaccines
- Community investment activities through the Africa Malaria Partnership (AMP)
- Access for anti-malarials in least developed countries (LDCs) and SSA

In addition, we continue to advocate for government action to tackle malaria, and currently represent the private sector on the Board of the Roll Back Malaria Partnership.

Innovation: Vaccines

For three decades, GSK and its partners have been developing what could be the world's first vaccine to help protect children in Africa against malaria. Finding ways to overcome the malaria parasite's defence mechanisms is extraordinarily challenging. But we are now a step closer to fulfilling that goal.

In July 2015, the European Medicines Agency's Committee for Medicinal Products for Human Use granted our malaria candidate vaccine RTS,S, also known as Mosquirix™, a positive scientific opinion.

The World Health Organization has indicated that a policy recommendation for the vaccine candidate could be possible by the end of 2015. GSK would then apply for a WHO 'pre-qualification', before applying for marketing authorisation in sub-Saharan African countries. These decisions would, if successful, pave the way toward implementation of RTS,S through African immunisation programmes. If approved, RTS,S is intended to complement existing measures to fight malaria, such as bed nets and indoor residual insecticide spraying.

Partnership has been central to the development of RTS,S. A Phase III clinical trial programme, conducted at 13 sites in eight countries (Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique, Nigeria, and Tanzania), with 16,685 infants and young children participating was the largest malaria vaccine trial programme in Africa to date. This trial was run in partnership with the PATH Malaria Vaccine Initiative (MVI), together with prominent African research centres and their Northern research partners.

GSK, MVI, and other partners are working to do what they can to ensure that RTS,S – if approved for use – reaches the infants and children who need it most. GSK has committed the eventual price 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.

Innovation: Malaria treatments

GSK has a research facility in Tres Cantos, Spain dedicated to conducting R&D for diseases of the developing world, focused on malaria, tuberculosis and kinetoplastid diseases (such as leishmaniasis, sleeping sickness, and Chagas disease). At this facility, drug development projects are prioritised by their socio-economic and public health benefits, rather than by their commercial returns. There are over 120 GSK scientists at Tres Cantos, with around 25 scientists supported by the non-profit Medicines for Malaria Venture (MMV).

As resistance to current malaria treatments increases, we are committed to developing new medicines to treat the disease. In partnership with MMV, GSK researches potential therapies to address two pressing needs in malaria drug research: treatments for drug-resistant strains of the malaria parasite, and treatments for *Plasmodium vivax*. *P. vivax* malaria is predominant in Asia, Latin America and the horn of Africa, and can result in relapsing malaria months, or even years, after the initial infection.

Tafenoquine is our investigational medicine in development for the treatment and radical cure of *P. vivax* malaria. In December 2013, the FDA granted breakthrough therapy designation for tafenoquine. This designation is one of the newest of the FDA's programmes aimed at accelerating the development and review times of drugs for serious or life-threatening conditions. Phase III studies have commenced and we are also working with external collaborators to have a point-of-care test available to help ensure that, should tafenoquine be approved for use, only appropriate patients are dosed.

GSK's open innovation strategy

GSK is committed to tackling diseases that affect the world's poorest people. But the scale of the task means that no one organisation or group can do this alone. We are transforming our business model to be more responsive to developing world needs. This includes adopting a more open approach to R&D for diseases that affect developing countries, including malaria.



Our 'open innovation' strategy is designed to foster and facilitate more R&D for neglected tropical diseases and has three core elements:

Being more flexible with our IP & know-how: In October 2011, we joined WIPO Re:Search as a founding member. An evolution of GSK's Pool for Open Innovation against Neglected Tropical Diseases (POINT), WIPO brings together eight leading pharmaceutical companies in collaboration with multiple non-profit research organisations under the auspices of WIPO – a UN body – to help accelerate the development of new and better treatments against neglected tropical diseases, as well as malaria and TB.

Enabling access to our resources: GSK has created an Open Lab within Tres Cantos which provides the opportunity for independent researchers to access GSK facilities, resources, and expertise to help them advance their own research projects into diseases of the developing world. A not-for-profit foundation, the Tres Cantos Open Lab Foundation has been set up with £10 million investment for GSK to support these research projects.

Sharing our compounds and data: We have screened more than two million compounds in our chemical library to seek out those that could inhibit the malaria parasite. This process identified more than 13,500 compounds that showed the greatest activity. We have published the research findings and our malaria compound set is part of the 'malaria box' that MMV has sent to more than 160 groups around the world.

We hope that additional research is stimulated to help identify new potential treatments for malaria.

Community investment: Activities

Through the Africa Malaria Partnership (AMP), GSK supports malaria control initiatives in SSA. Since 2001, we have committed over £4.8 million to community initiatives and have partnered with organisations on the ground to promote the use of existing interventions, such as bed nets, indoor residual spraying, and anti-malarial treatments.



With a focus on building capacity of community health workers (CHWs) and encouraging behaviour change, our current projects include:

- **African Medical and Research Foundation (AMREF) in Mtwara Province, Tanzania:** The integrated maternal, newborn and child health project aims to train CHWs and mobilise communities to become frontline advocates in the fight against malaria.
- **FHI 360 in the Brong Ahafo Region of Ghana:** Working with CHWs and household caregivers to encourage health seeking behaviours and community mobilisation, the project works to improve early recognition of malaria and provide access to appropriate treatment.
- **Save the Children in North East Province, Kenya:** Through community campaigns, education, bed net distribution, and CHW training, the project has been working to reduce the malaria risk while improving access to primary health care for families in the Wajir district.
- **The Carter Centre in Plateau & Nasarawa States, Nigeria:** Working with the Federal Ministry of Health, to develop new and effective strategies for integrating malaria and lymphatic filariasis prevention interventions.
- **Tony Blair Faith Foundation (TBFF), Sierra Leone:** Engaging faith communities to deliver key education and messages to prevent malaria.

Access to anti-malarials

We are committed to helping our products reach the most possible people in a sustainable way. In the African and least developed countries where we supply anti-malarial medicines, they are priced competitively according to the local environment or, where applicable, capped at no more than 25% of prices charged in developed countries.