



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 nearly 500,000 malaria deaths, the vast majority in children under the age of five living in sub-Saharan Africa (SSA).

2016

WHO announced that our malaria vaccine candidate will be introduced to sub-Saharan African countries through a pilot implementation programme



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 fighting malaria for more than 100 years

GSK’s legacy of fighting malaria stretches back more than a century, beginning with Sir Henry Wellcome pioneering organised research of tropical diseases. We believe that a comprehensive approach to malaria is needed to help scale up use of current 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
- Supporting health workers and strengthening health systems
- Access for anti-malarials in least developed countries (LDCs) and SSA

In addition, we continue to advocate for government and stakeholder action to tackle malaria.

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. We have reached two more significant milestones towards this ambition.

In July 2015, the European Medicines Agency granted our malaria candidate vaccine RTS,S a positive scientific opinion. The World Health Organization announced in January 2016 that GSK’s malaria vaccine candidate will be introduced to sub-Saharan African countries through a pilot implementation programme to be used alongside 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 15 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 countries' 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.

Strengthening health systems

Through the Africa Malaria Partnership, GSK has supported 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 projects have included:

- ▶ Working with Amref Health Africa in Tanzania to train CHWs and mobilise communities to become frontline advocates in the fight against malaria.
- ▶ Working with Save the Children in the North East province of 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.

Partnering with Comic Relief

Building on our commitments to tackling malaria on all fronts, in December 2015, GSK launched a partnership with Comic Relief to help fight malaria and strengthen health systems.

The partnership aims to support the World Health Organization's target to cut malaria case incidence and mortality rates by 90% over the next 15 years.

A new fund – created through a £17 million donation from GSK and £5m from Comic Relief – will provide targeted grants over the next five years to organisations on the frontline, tackling malaria and improving health in five malaria endemic countries in sub-Saharan Africa and Asia.

These grants, made and managed by Comic Relief, will complement current malaria programmes and help build sustainable ways to ensure people can access diagnosis and prevention at the right time and in the right place.

Grants will be guided by a London School of Hygiene and Tropical Medicine study. This is scoping out how the partnership can best complement and enhance access to healthcare provision and current malaria interventions in endemic countries.