Malaria takes a devastating toll on communities and economies across Africa. The battle against the disease must be fought on all fronts using a wide range of interventions, including insecticide-treated bed nets, indoor residual spraying, effective medicines and treatments and, eventually, vaccines.

GSK has been involved in the fight against malaria for decades. We believe that a comprehensive approach to malaria is required to scale up and use all established tools of control, while continuing to invest in the development and use of innovative new tools. We have an active malaria research and development (R&D) programme and work hand-in-hand with organisations at the local, regional and international levels to 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 2014, GSK intends to submit a regulatory application to the EMA for its malaria vaccine candidate.

Innovation: Vaccines
Our RTS,S malaria vaccine candidate is in a Phase III clinical efficacy trial at 11 sites in seven African countries: Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique and Tanzania. RTS,S aims to protect infants and young children living in malaria-endemic areas of SSA against infection and clinical disease caused by Plasmodium falciparum, the most deadly species of the malaria parasite.

The vaccine is being developed in partnership by GSK and the PATH Malaria Vaccine Initiative (MVI), together with prominent African research centres and their Northern academic research partners. If and when the vaccine is approved, further partnerships and collaborations will be necessary to help facilitate its delivery and implementation across Africa as quickly as possible.

The latest results from the ongoing large Phase III clinical efficacy trial of RTS,S presented at the 6th MIM 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. Widespread coverage with insecticide-treated bed nets amongst trial participants indicated that RTS,S can reduce malaria in addition to the effect of existing malaria control interventions.

An estimated 3.3 billion people – more than half the world’s population – are at risk of contracting malaria. Each year there are around 215 million cases of malaria globally and more than 660,000 malaria deaths, the vast majority in children under the age of five living in sub-Saharan Africa (SSA).
Based on this data, GSK now intends to submit a regulatory application to the European Medicines Agency (EMA) on RTS,S in 2014. The EMA will evaluate data on the quality, safety and efficacy of the RTS,S vaccine candidate in collaboration with the World Health Organization (WHO), before issuing a scientific opinion. A positive opinion from EMA would enable licensing applications to African regulatory authorities for RTS,S. If the required public health information, together with safety and efficacy data from the Phase III programme, is deemed satisfactory, the WHO has indicated that a policy recommendation for the RTS,S malaria vaccine candidate is possible in 2015, paving the way for decisions by African nations regarding large scale implementation of the vaccine through their national immunisation programmes.

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.

**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 100 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, the strain of malaria that is predominant in Asia and Latin America.

**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 most 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 organizations under the auspices of WIPO – a UN body – to help accelerate the development of new and better treatments against neglected tropical diseases.

- **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 £10m investment for GSK to support these research projects.

- **Sharing our compounds & 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 13,533 compounds that showed greatest activity. We have published the research findings and shared these compounds with a number of groups around the world in the hope that additional research is stimulated to help identify new potential treatments for malaria.

**Community Investment: Activities**

Through the Africa Malaria Partnership (AMP), GSK works to improve the prevention and treatment of malaria in sub-Saharan Africa. Since 2001, we have committed over £3 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 current treatments.

The GSK AMP currently supports partnerships to build the capacity of community health workers and encourage behaviour change. With a total commitment of £1.5 million over three years, the projects include:

- **African Medical and Research Foundation (AMREF) in Mtwara province, Tanzania:** The partners are training community health workers and mobilising communities to become frontline advocates in the fight against malaria.

- **Family Health International (FHI) in the Brong Ahafo region of Ghana:** With community health workers and household caregivers, the project is working improve early recognition of malaria and provision of appropriate treatment, and to encourage health seeking behaviours and community mobilisation.

- **Save the Children in North East province, Kenya:** Through community campaigns, education, bed net distribution and community health worker trainings, the project has been working to reduce the malaria risk while improving access to primary health care for families in the Wajir district.

**Access: Preferential Pricing for Anti-Malarials**

We provide our anti-malarial medicines at deeply discounted prices in LDCs and sub-Saharan Africa to ensure access for as many people as possible.

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$350m

invested in the development of our RTS,S malaria vaccine candidate to date

Read more about our progress at gsk.com/responsibility