



Final Results of Pivotal Phase 3 RTSS Malaria Vaccine Trial Conducted in Kintampo and other African research centres.



The final results of the pivotal phase 3 trial of GSKs RTSS Malaria vaccine trial has been released today. The results demonstrate that vaccination with the 3-doses and a booster of the RTSS malaria vaccine reduced clinical malaria cases by 36% in young children and 26% in infants over a period of 3 - 4 years. Though percentages are low, the public health impact of this vaccine candidate can be enormous; about 1700 clinical malaria episodes were prevented among 1000 children vaccinated over the course of the trial, and even more in areas where malaria burden is

high. The safety profile of the vaccine was found to be acceptable.

The Director of KHRC Dr. Owusu-Agyei in his message to staff and colleagues said " In marking the World Malaria Day this year, we are excited to announce these results as our scientific contribution to malaria control in Ghana and in other malaria endemic countries. It is our hope that the results will quickly be reviewed by policy makers and drug regulators in Africa; and if acceptable be deployed to children who need it most. We are grateful to our community leaders and members, the Ghana Health Service and all our collaborators in helping to achieve this important milestone"

The RTS,S malaria vaccine candidate is the most clinically advanced to date globally. It became the first vaccine candidate to show in clinical trials that it can help protect young children (in 2004) and infants (in 2007) living in malaria-endemic areas against clinical disease and infection caused by Plasmodium (P.) falciparum, the most deadly species of the malaria parasite. Like vaccines generally, RTS,S aims to trigger the body's own immune system to defend against disease, in this case, malaria. Specifically, RTS,S is designed to prevent the malaria parasite from infecting, maturing, and multiplying in the liver, after which the parasite would normally re-enter the bloodstream and infect red blood cells, leading to disease symptoms.

A Phase III efficacy and safety trial was conducted at 11 trial sites in seven African countries with different malaria transmission intensities and patterns: the sites were in Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique, and Tanzania. The participants were children aged 5 to 17 months and infants aged 6 to 12 weeks at the time of the first vaccination. Leading African research centers, and in some instances their Northern partners, conducted the trial together with GlaxoSmithKline (GSK) and the PATH Malaria Vaccine Initiative (MVI). The research centers were selected for their track records of clinical research, strong community relations, and commitment to meeting the highest international ethical, medical, clinical, and regulatory standards.



The data from this trial has been submitted to the European Medicine Agency for review and an opinion on the data is expected sometime late this year. Thereafter, the African drug regulators will also review the data and make an opinion on whether their countries should use it or not.

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Email: enquiries@kintampo-hrc.org