MINISTRY OF HEALTH

Landmark malaria vaccine introduced in parts of Kenya

Promising new tool expected to provide additional protection to young children from malaria when used in combination with other malaria prevention measures

September 2019 13, NAIROBI, KENYA – Kenya today, in partnership with the World Health Organization (WHO), rolled out the world's first malaria vaccine in a landmark phased introduction programme taking place in certain parts of Homabay, Kisumu, Migori, Siaya, Busia, Bungoma, Vihiga, and Kakamega counties. The country is among three in Africa that will administer the vaccine, known as RTS,S, to children up to 2 years of age, as part of the country's routine childhood immunization programme. Other countries rolling out the vaccine are Malawi and Ghana.

In recent years, Kenya has made tremendous progress in the fight against malaria by rolling out proven control measures, including insecticide-treated mosquito nets, indoor residual spraying, prompt diagnosis, and prevention with antimalarial medicine. In spite of these efforts, in 2016, malaria caused an estimated 3.5 million infections and just over 10,000 deaths in Kenya, overwhelming the health facility capacity in the Lake Endemic Region. New interventions are needed to complement those currently in use to further drive down the disease burden in the country.

"It's an exciting time for Kenya as we roll out this vaccine in parts of the country where the burden of malaria is the highest. Over the years, we have worked to introduce several malaria control measures and this vaccine represents an additional tool that will boost Kenya's efforts in reducing malaria infections and deaths among children, who are at greatest risk of life-threatening complications from malaria," said Sicily Kariuki, Cabinet Secretary for Health, Kenya.

The malaria vaccine, which will be delivered through the routine national immunization programmes, is given at 6 months, 7 months, 9 months and 24 months of age. To get the most protection, a child who receives the vaccine must get all four doses and continue other practices to prevent malaria, including sleeping under a mosquito net every night and throughout the year.

"The vaccine, where it is available, is part of the package of recommended malaria prevention measures," said Dr. Grace Ikahu, the head of the National Malaria Control Program, Ministry of Health, Kenya. "If parents and caregivers continue to use existing preventive measures (such as ITNs) the addition of the vaccine provides the potential to save thousands of young lives in Kenya." Dr Ikahu, the head of the National Malaria Control Programme also noted that," Kenya has made great progress in reducing the prevalence of malaria of malaria through the use of current malaria interventions. As we aim for malaria

elimination in parts of this country, we are excited to deploy the malaria vaccine in our malaria endemic regions and monitor its impact on malaria prevalence in the country.

The injectable vaccine, RTS,S, was developed to protect young children from the most deadly form of malaria caused by *Plasmodium falciparum*. Clinical testing showed that the vaccine prevented about 4 in 10 cases of malaria and 3 in 10 cases of life-threatening, severe malaria over a four-year period. There were also significantly fewer hospital admissions, anaemia, and need for blood transfusions required to treat life-threatening malaria anaemia

The malaria vaccine pilot aims to reach about 120 000 children in Kenya, and 360,000 children per year across the three participating countries.

Phased introduction

In Kenya, the vaccine will be introduced as an additional malaria control measure in select counties where the proportion of people infected with malaria is 20 percent or greater, where coverage for other childhood vaccines is high, and where there are sufficient numbers of children at the right age to receive the vaccine.

The areas named to be part of the phased introduction include Homabay, Kisumu, Migori, Siaya, Busia, Bungoma, Vihiga, and Kakamega counties. Within the eight targeted counties, some sub-counties will have the opportunity to introduce the vaccine into their immunization schedules, while others are expected to introduce the vaccine later.

Decisions on which sub-counties would receive the vaccine initially and which ones would introduce the vaccine later took various factors into account, including the burden of malaria and vaccine coverage. The selections were made randomly to give each sub-county an equal opportunity.

“As with many new vaccine introductions, the phased approach will give us the opportunity to learn valuable lessons for improving the implementation before scaling up to all eligible populations,” explained Dr Rudi Eggers, the WHO Representative in Kenya. “The aim of this phased introduction is to vaccinate at least 120,000 children per year in the selected areas,” he added.

The first malaria vaccine to successfully complete a Phase III clinical trial

RTS,S was developed by GSK and is the first malaria vaccine to have successfully completed a Phase 3 clinical trial. The trial was conducted between 2009 and 2014 through a partnership involving GSK, the PATH Malaria Vaccine Initiative (with support from the Bill & Melinda Gates Foundation), and a network of African research sites in seven African countries. Clinical studies in Kenya involved more than 4,000 children at three sites: Kombewa, Siaya and Kilifi.

RTS,S is also the first malaria vaccine to have obtained a positive scientific opinion from a stringent medicines regulatory authority, the European Medicines Agency (EMA). In May 2018, the Kenya Pharmacy and Poisons Board (PPB) approved the phased introduction of the vaccine.

Notes to the editors:

- **Country selection**: Following a request by WHO for expressions of interest, Kenya, alongside Malawi and Ghana, was selected from among 10 African countries. Key criteria for selection included well-functioning malaria and immunization programmes, and areas with moderate to high malaria

transmission.

- **Proven results**: In Phase 3 trials conducted in Africa, between 2009 and 2014, children receiving 4 doses of RTS,S experienced significant reductions in malaria and malaria-related complications, in comparison to those who did not receive RTS,S. The vaccine prevented 4 in 10 cases of clinical malaria; 3 in 10 cases of severe malaria; and 6 in 10 cases of severe malaria anaemia, the most common reason children die from malaria. Significant reductions were also seen in overall hospital admissions and the need for blood transfusions, which are required to treat severe malaria anaemia. These and other benefits were in addition to those already seen through the use of insecticide-treated nets (bed nets); prompt diagnosis; and effective antimalarial treatment.

- **Child vaccination schedule**: In selected areas in the three countries, the vaccine will be given in 4 doses: 3 doses at 6 months, 7 months and 9 months of age and the fourth dose provided at 24 months.

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