FREQUENTLY ASKED QUESTIONS (FAQS) ON THE R21 MALARIA VACCINE

1. What is the R21 Malaria Vaccine?

The R21 Malaria Vaccine (Recombinant, Adjuvanted) also known as Matrix M1 is the second malaria vaccine shown to provide partial protection against malaria in young children.

The R21 Malaria Vaccine was developed by the University of Oxford Jenner Institute, UK and manufactured by the Serum Institute of India Private Ltd, India.

The vaccine is indicated for active immunization of children aged 5 to 36 months against malaria caused by *Plasmodium falciparum.*

2. Why did Ghana approve the R21 Malaria Vaccine?

Scientists at the FDA reviewed all documentation (i.e. quality, non-clinical and clinical), submitted in accordance with established Guidelines for Registration of Vaccines, and are satisfied that the vaccine is safe, efficacious, and of good quality. This include safety, and efficacy data from all phases (phases I, II, III) of the primary vaccination series (0,1 and 2 months) and the booster dose from phase II of clinical trials conducted.

3. Where was the pivotal phase III efficacy and safety trial conducted?

The pivotal phase III efficacy and safety trial was conducted at 5 sites in 4 African countries, Burkina Faso, Mali, Tanzania, and Kenya with a wide range of malaria transmission intensities. More than 4,800 children from 5-36 months of age were randomized in a 2:1 ratio to evaluate efficacy and safety of R21 Malaria Vaccine when given according to a 0, 1, and 2-month schedule. In addition, these children received per protocol a 4th (fourth) dose, administered 12 months after the third dose.

4. What do we know about the efficacy of the R21 Malaria Vaccine?

The R21 Malaria Vaccine has shown efficacy in clinical trials enrolling over 5,300 participants. The efficacy of the vaccine reached 75% in a phase IIa, a phase IIb and a recent phase III trial in the first year of follow-up. In the phase IIb trial, this efficacy has been followed consistently for a three-year period, and it appeared well maintained at 73%, with a single booster dose at the end of the first year.

5. What do we know about the safety of R21 Malaria Vaccine?

An analysis of safety data from more than 5300 children vaccinated with the R21 Malaria Vaccine in clinical trials with 3 or 4 doses showed that the vaccine has an acceptable safety profile.

Like all other vaccines, R21 Malaria Vaccine has side effects such as fever, injection site pain, injection site swelling, injection site redness, decreased appetite, diarrhea, and irritability. These side effects were mild or moderate in intensity and participants recovered without sequelae /abnormalities.

6. Who is qualified to receive the R21 Malaria Vaccine and how is the Vaccine given?

The vaccine is to be used in children from 5 months of age up to 36 months of age (at first dose). Three doses should be given at monthly intervals. A fourth dose is recommended 12 months after the third dose. The R21 Malaria Vaccine is administered by intramuscular injection.

7. Why, when existing interventions appear to be working, do we need a malaria vaccine?

The R21 Malaria Vaccine is intended to complement existing measures to fight malaria. An effective well tolerated vaccine could be important add-on to existing interventions that have helped to reduce malaria deaths significantly for malaria control efforts. These include bed nets, indoor residual insecticide spraying, seasonal malaria chemoprevention and ongoing vaccinations in some parts of Ghana.

This could be particularly helpful in those areas most affected by malaria and where progress in controlling the disease has recently plateaued.

8. When might the vaccine become available for use in Ghana?

Just like other medicines and vaccines for public health programs, the FDA the National Regulatory Authority, has granted authorization to R21 Malaria Vaccine as is the mandatory requirement, to enable the Ministry of Health/Ghana Health Service to take decisions on timelines and other procedures for implementation into the routine immunization program in Ghana.

9. Does the FDA Ghana have the technical capacity to review this vaccine?

The capacity of the FDA to approve such products is well documented. The Authority was assessed and designated by the World Health Organization (WHO) in April 2020 as

Maturity Level (ML) 3 in regulatory functions (Maturity Level 4 for Pharmacovigilance) for vaccines and medicines regulatory oversight including granting Marketing Authorization of procured vaccines. It has previously provided expert advice on a similar vaccine authorized under European Medicines Agency's Article 58. The Authority has reviewed and granted approvals to forty-five (45) other human vaccines including COVID-19 vaccines during the pandemic.