Fact Sheet: RTS,S/AS01 Malaria Vaccine (Mosquirix™)

- There were 212 million malaria cases worldwide in 2015 with 429,000 deaths. The majority of deaths are in children under the age of 5 living in sub-Saharan Africa. In Ghana, malaria causes about 2,000 deaths annually, approximately 48% of which afflict children under the age of five.

- Historically, vaccines have proved to be one of the most effective means of preventing disease and saving lives, particularly in the case of infectious diseases.

- Mosquirix™ is a vaccine that acts against Plasmodium falciparum, the most deadly malaria parasite globally, and the most prevalent in Africa.

- Mosquirix™ is the first malaria vaccine to obtain a positive scientific opinion by the European Medicines Agency, a stringent medicines regulatory authority.

  - The pilot implementation programme, coordinated by WHO, will assess the extent to which the vaccine’s protective effect shown in advanced clinical trials can be replicated in real-life settings.
  - Specifically, the pilot implementation programme will evaluate the feasibility of delivering the required 4 doses of the vaccine: the impact of the vaccine on lives saved; and the safety of the vaccine in the context of routine use.
  - The vaccine is recommended to be given as an injection in four doses to children, with the first dose given as soon as possible after the age of 5 months. In Ghana, it will be given at 6, 7, 9 and 24 months of age.

- The pilot implementation programme is due to begin in 2018. There is a great deal of preparatory work that will need to be done before the programme begin.

- The vaccine is being considered as a complementary malaria control tool in Ghana that could potentially be added to – and not replace – the core package of proven malaria preventive, diagnostic and treatment interventions such as bed nets and indoor spraying with insecticides.

- Ghana was chosen based on criteria including:
  - High malaria burden and well-functioning malaria and immunization programmes.
  - A desire to engage in the vaccine pilot programme by national stakeholders – particularly the Ministry of Health.
  - Previous participation in the advanced (Phase 3) clinical trials for Mosquirix™.

- Ghana applied based on the country’s experience with Mosquirix™ during the clinical trials, besides being a malaria endemic country. The existence of a robust regulatory, ethical and immunization systems and infrastructure in Ghana also played a critical role in the selection as part of three countries on the continent to participate in this programme.

- Mosquirix™ is a malaria vaccine that has been developed through a partnership between GSK and the PATH Malaria Vaccine Initiative (MVI), with support from the Bill & Melinda Gates Foundation and from a network of African research centres that performed the studies.