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GSK, PATH, Bharat Biotech join hands for novel malaria vaccine

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Bharat Biotech to produce antigen for worldâ??s first vaccine against Plasmodium falciparum malaria



GSK, PATH, and Bharat Biotech (BBIL) have announced the signing of a product transfer agreement for the malaria vaccine, RTS,S/AS01E 1. The agreement includes the transfer of manufacturing of the RTS,S antigen part of the vaccine and the grant of a license on all rights pertaining to the RTS,S/AS01 malaria vaccine to BBIL. GSK will retain the production of the adjuvant of the vaccine (AS01E) and will supply it to BBIL.

The RTS,S/AS01E malaria vaccine, developed by GSK for more than 30 years, and in partnership with PATH since 2001, is currently being piloted in regions of Ghana, Kenya, and Malawi under the Malaria Vaccine Implementation Programme (MVIP). Ministries of health are leading the implementation of the vaccine, which is being given to young children through the three countries' routine immunisation programmes, with WHO providing technical and scientific leadership, playing a coordinating role, and working in collaboration with GSK, PATH, and a range of other partners.

RTS,S/AS01E is the first, and to date, the only malaria vaccine to have received a positive review by regulatory authorities (positive scientific opinion from the European Medicines Agency and approval by the regulatory authorities of Ghana, Kenya, and Malawi for use in the MVIP). The first dose of the vaccine has reached more than 500,000 children since the pilots were initiated by ministries of health in the three participating countries in 2019.

This agreement with BBIL is the result of efforts by GSK, PATH, and WHO to help ensure long-term sustainable vaccine supply, in the event of a WHO policy recommendation for broader use and a commitment of sustained funding. This builds on existing GSK commitments to donate up to 10 million RTS,S/AS01E doses for use in the pilot, and to supply up to 15 million doses annually until 2028 if the product is recommended for wider use by WHO. It is expected that by 2029, at the latest, BBIL will be the sole supplier of the vaccine, with GSK supplying the adjuvant AS01E to them.