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## **Bharat Biotech to produce world's first vaccine against Plasmodium falciparum malaria using GSK's adjuvant along with technology transfer and supply**



GSK, PATH, and Bharat Biotech (BBIL) on Jan 27, 2021, announced the signing of a product transfer agreement for the malaria vaccine, RTS,S/AS01<sub>E</sub>. 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 (AS01<sub>E</sub>) and will supply it to BBIL.

BBIL is an established supplier of global health vaccines to Gavi, the Vaccine Alliance, and to UNICEF. BBIL was selected through a comprehensive, competitive process undertaken by GSK and PATH, working in consultation with the World Health Organization (WHO).

The RTS,S/AS01<sub>E</sub> 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/AS01<sub>E</sub> is the first, and to date, the only malaria vaccine to have received a positive review by regulatory authorities. The first dose of the vaccine has reached more than 500,000 children.

This agreement with BBIL is the result of efforts by GSK, PATH, and WHO to help ensure long-term sustainable vaccine supply. GSK is committed to donating up to 10 million RTS,S/AS01<sub>E</sub> 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. GSK supplying the adjuvant AS01<sub>E</sub> to BBIL.

Thomas Breuer, GSK Vaccines Chief Medical Officer and Vaccines Global Health lead said: "Our 30year and ongoing commitment to RTS,S/AS01<sub>E</sub> represents significant leadership and investment in global health vaccines, but also a huge scientific achievement in the fight against malaria. With a child still dying of malaria every two minutes, helping secure the long-term future of the only vaccine available by working with an established leader like Bharat Biotech is vital for the continued fight against this devastating disease. GSK is delighted to sign this agreement with Bharat Biotech".