

Biological E unveils new typhoid conjugate vaccine

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K T Rama Rao Inaugurates BE's Plant at Genome Valley



K T Rama Rao, Minister for Information Technology, Industries & Commerce, Municipal Administration and Urban Development, Government of Telangana, inaugurated Biological E. Limited's (BE) Plant and unveiled its new Typhoid Conjugate Vaccine (TCV) in the Special Economic Zone at Genome Valley in Kolthur Village on the outskirts of Hyderabad.

Addressing the gathering, IT and Industries Minister K T Rama Rao appreciated the expansion initiatives of Biological E. Limited and said: "We are committed to making the State of Telangana number one State in terms of industrial growth and employment generation with a special focus on life sciences. In fact, these growth engines will not only boost the economy of the State but also improve the livelihood of people, who depend directly or indirectly on these industries. We are happy to see that this massive state-of-the-art plant, the foundation stone for which was laid during BioAsia 2017, is getting inaugurated during this 17th edition of BioAsia."

Welcoming the gathering, Mahima Datla, Managing Director, Biological E. Limited, thanked the honourable Minister for inaugurating the plant and unveiling the vaccine. Mahima said: "BE has invested around Rs.300 crore for building this plant, which is now ready for commercial production, on about 29 acres of land. This Plant would generate employment opportunities for around 1000 people. This new facility will help our existing Vaccines Plant enhance the production and manufacture new products, which are in the pipeline."

Recently, BE received the authorisation from the health regulatory authorities of India to license and market a new Typhoid Conjugate Vaccine. The approval from the Central Drugs Standard Control Organisation (CDSCO) is based on a thorough assessment of the vaccine's efficacy and safety profile.. TCV is an injectable single-dose vaccine to be administered to children from 6 months old as well as adults and it contains Vi Polysaccharide derived from *C. Freundii* conjugated to CRM197 protein. The clinical studies conducted in India demonstrated that the safety and immunogenicity profiles of this vaccine are comparable to the other licensed and WHO Pre-qualified Typhoid conjugate vaccine.

This vaccine was developed in partnership with the GSK Vaccines Institute for Global Health, based in Siena (Italy), which first developed the asset and transferred it to BE in 2013. Subsequent developmental work on the vaccine was done by BE, including manufacturing process optimization and scale up, pre-clinical studies and full clinical trials in India. This vaccine will be manufactured in BE's GMP manufacturing facilities in Hyderabad, India and could be commercially available within 3

months.

With this authorization from CDSCO the vaccine is now approved to be marketed in India, and it also allows BE to submit the vaccine for WHO pre-qualification (PQ) and registration in several other countries. This will help to expand its current portfolio of seven WHO PQ vaccines.

Mahima Datla, Managing Director, Biological E. Limited, commented on the development: “We are happy that our joint efforts have successfully produced a promising Typhoid vaccine. This is a remarkable milestone in our collaborative journey with the GSK Vaccine Institute for Global Health to save the maximum number of people, particularly children, around the world from Typhoid, which is a deadly, yet vaccine preventable disease.”

Dr Thomas Breuer, Chief Medical Officer of GSK Vaccines, commented: “Having this new vaccine approved is an important milestone for Global Health. It shows that GSK’s innovative and sustainable partnership model works to deliver vaccines based on GSK latest science to help protect people in developing countries against major health threats. We are very pleased with the excellent and close collaboration with BE.”

Upon pre-qualification by WHO, which is anticipated in 2020, this new vaccine is anticipated to significantly contribute to the unmet public health need in developing countries by helping protect children against typhoid fever and by contributing to securing the supply typhoid vaccines.

Photo Caption : Left to Right Mahima Datla, Managing Director, Biological E Limited, Kiran Mazumdar-Shaw, KT Rama Rao, Minister for IT, MA&UD, Govt. of Telangana, Prof. Baron Peter Piot, Director, London School of Hygiene & Tropical Medicine, And Jayesh Ranjan.