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New typhoid conjugate vaccine Bio-TCV receives approval in Indonesia

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Bio-TCV is a Vi polysaccharide vaccine conjugated to the diphtheria toxoid carrier protein



South Korea-based International Vaccine Institute (IVI) and Bio Farma, a biotechnology company based in West Java, Indonesia, have announced that Bio Farma's Bio-TCV typhoid conjugate vaccine (TCV) has been licensed in Indonesia following marketing approval from Badan Pengawas Obat dan Makanan (BPOM), the national regulatory authority.

Bio-TCV is a Vi polysaccharide vaccine conjugated to the diphtheria toxoid carrier protein (Vi-DT), initially developed at IVI and transferred to Bio Farma in 2014. From the outset, the scope of the joint vaccine development programme included preclinical development and Phase I-III clinical trials followed by technical support through local licensure and submission for prequalification (PQ) from the World Health Organization (WHO), a designation that enables agencies such as Gavi, the Vaccine Alliance to purchase the vaccine for global public health use. This decade-long partnership in pursuit of another safe, effective, and affordable TCV has been in part funded by a grant from the Bill & Melinda Gates Foundation.

IVI and Bio Farma confirmed the safety and immunogenicity of a single dose of Vi-DT and its non-inferiority to a control WHO-prequalified TCV in a Phase III clinical trial across three provincial capital cities in Indonesia.

With the results of this study, BPOM approved the vaccine for national use in individuals ages 9 months to 45 years. Bio Farma will submit the dossier for WHO PQ, which, if achieved, will add an affordable TCV to the global public market that will be made available to low-income countries through Gavi, the Vaccine Alliance.

IVI is working with vaccine manufacturers around the world to make more TCVs available in the public market.