

New studies: Vi-DT vaccine is safe and immunogenic, with booster dosing potentially eliciting long-term immune responses

SEOUL, REPUBLIC OF KOREA, January 28, 2022 /EINPresswire.com/ -- A new study shows that late booster dosing with Vi polysaccharide conjugated with diphtheria toxoid (Vi-DT), one of the typhoid conjugate vaccines (TCVs), at 27.5 months post-first dose is safe and elicits robust immune responses in children aged 6-23 months. The findings from this study newly published

online in [npj Vaccines](#) support the use of TCV booster doses to confer long-term protection against typhoid fever in young children. This publication, co-authored by Drs. Birkneh Tilahun Tadesse and Maria Rosario Capeding, reports the results from the Phase II clinical trial of Vi-DT conducted by the International Vaccine Institute (IVI) in collaboration with the Research Institute for Tropical Medicine in Manila, the Philippines and SK bioscience in South Korea.



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*Dr. Sushant Sahastrabudde,
Associate Director General of
IVI*

The average annual cases of typhoid fever are estimated to be 15 million worldwide, with infants and children especially exposed to the risk of mortality and morbidity from complications of typhoid fever. Over the past decade,

significant progress in the development of TCVs has presented an opportunity to control and potentially eliminate typhoid in high burden settings, yet there is limited understanding of the long-term persistence of immune response and protection against typhoid fever following vaccination using single dose of the new-generation TCVs. This study is a critical step in the ongoing efforts to understand vaccine efficacy, effectiveness, and long-term immunogenicity enabled by a Vi-DT booster dose.

A pivotal Phase III study conducted by IVI in collaboration with SK bioscience involving four hospitals in Kathmandu, Dhulikhel, Dharan, and Nepalgunj in Nepal has shown that the Vi-DT test vaccine is safe, immunogenic, and non-inferior to the WHO prequalified Vi polysaccharide-tetanus toxoid (Vi-TT) Typbar TCV vaccine in individuals aged 6 months to 45 years. Dr. Tarun Saluja, Project Technical Lead and one of the lead-authors, says that this trial paves the way for licensure of Vi-DT and from there to wider access in the endemic countries. The manuscript is published online in [The Lancet Infectious Diseases](#) in December 2021.

“These two studies investigated critical data gaps and findings will be important for WHO prequalification of this vaccine. We are confident that with these results, we are close to achieving our goal of developing a safe, effective, and affordable vaccine with long-lasting immunogenicity to protect individuals, especially infants and children, against typhoid fever,” said Dr. Sushant Sahastrabudde, Associate Director General at IVI and Director of the Typhoid Program.

Vi-DT was developed at IVI and its technology was transferred in 2013 to SK bioscience for manufacturing and commercialization. Following a Phase I safety trial with participants aged 2-45 years and a Phase II trial with infants under 2 years in the Philippines, large-scale Phase III studies with a single dose of Vi-DT started in the Philippines and Nepal in 2020. Vi-DT was shown to be safe in all trial participants and met its primary endpoints at the end of 2020. The vaccine will be submitted to the WHO for prequalification review after the Korean Ministry of Food and Drug Safety approves SK bioscience’s Marketing Authorization request, responding to the need for sufficient and sustainable supply of TCVs to prevent and control typhoid fever globally.

About typhoid

Typhoid fever is an invasive water-borne bacterial infection caused by *Salmonella enterica* serovar Typhi (*S. Typhi*) presenting with mild to severe symptoms and even resulting in death. Typhoid is most often contracted through ingestion of food or drink contaminated by bacteria shed by infected people. It is usually characterized by fever, headache, constipation, and malaise, though diagnosis can be difficult due to symptoms common to other febrile illnesses. Figures for burden of disease vary due to this difficulty, however the World Health Organization estimates that 128,000-161,000 people die every year from typhoid fever with 11-21 million annual cases.[1] Typhoid surveillance studies report that a quarter to more than half of all invasive cases are found in children under 5.[2]

[1] <https://apps.who.int/iris/bitstream/handle/10665/272272/WER9313.pdf?ua=1>

[2] J A Crump, E D Mintz Global trends in typhoid and paratyphoid Fever. *Clin Infect Dis* 2010;50(2):241–246.

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About the International Vaccine Institute (IVI)

The International Vaccine Institute (IVI) is a nonprofit inter-governmental organization established in 1997 at the initiative of the United Nations Development Programme (UNDP). IVI has 36 signatory countries and the World Health Organization (WHO) on its treaty, including Korea, Sweden, India, and Finland as state funders.

Our mandate is to make vaccines available and accessible for the world's most vulnerable people. We focus on infectious diseases of global health importance such as cholera, typhoid, shigella, salmonella, schistosomiasis, chikungunya, group A strep, Hepatitis A, HPV, TB, HIV, MERS, COVID-19, as well as antimicrobial resistance. For more information, please visit <https://www.ivi.int>

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