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# IVI-SK's new typhoid conjugate vaccine meets primary endpoints in ph III study in Nepal

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### Primary analysis also confirms safety of Vi-DT

Vi-DT typhoid conjugate vaccine, developed jointly by the International Vaccine Institute (IVI) and SK bioscience, has met the primary endpoints in a phase III study in Nepal. The primary endpoints were based on immune non-inferiority with the WHO-prequalified typhoid conjugate vaccine, Typbar-TCV®, in terms of serconversion rate, which confirms the new candidate TCV induces an immune response that is not inferior to Typbar-TCV®.

Three different production lots of vaccine were administered in the clinical trial, and the analysis also shows that these different batches were similar in immunogenicity. Lot-to-lot consistency in manufacturing is an important requirement to ensure the quality of Vi-DT.

In addition to immune non-inferiority, the Vi-DT vaccine was also shown to be safe in all 1,350 participants ranging in age from 6 months to 45 years.

This study is a significant milestone in an effort to license Vi-DT TCV. Another phase III study is nearing completion in the Philippines and SK bioscience plans to submit a Marketing Authorization request to the Korean Ministry of Food & Drug Safety in January 2021. After the Ministry of Food and Drug Safety approves the vaccine, it will be submitted for pre-qualification review at the World Health Organization. WHO pre-qualification is necessary for a vaccine to be sold to United Nations agencies responsible for vaccine purchases.

"It was a challenging project to get the sites in Nepal ready," said Dr. Tarun Saluja, MD, the project lead of this study. "However, with the help of the authorities in Nepal and our collaborators, we managed to complete this study within timeline and with quality."

"These data are the culmination of 10 years of work at IVI," said Dr. Sushant Sahastrabuddhe, MD, Director of IVI's Typhoid Program. "With the successful initial results from phase I and II studies in the Philippines, this phase III study was critical to make sure Vi-DT vaccine completes the regulatory milestones for use in endemic countries."

“With this encouraging data from the Phase 3 trial, we have taken a step closer to the commercialization of the vaccine,” said Jae-yong Ahn, CEO of SK bioscience. “In collaboration with IVI and other partners, we will develop a vaccine that is universally accessible to help free children in developing countries from typhoid.”

Vi-DT was developed at IVI and its technology was transferred in 2013 to SK bioscience in South Korea for manufacturing and commercialization. A Phase I safety trial of Vi-DT was first conducted in the Philippines in volunteers aged 2-45 years and showed that the vaccine was safe and immunogenic four weeks after first dose. Following the successful completion of a Phase II trial with infants under 2 years, large-scale Phase III studies with a single-dose of Vi-DT started in the Philippines and Nepal this year.