

Korea gives license to Euvichol-S, simplified formulation of oral cholera vaccine

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EuBiologics' new low-cost vaccine expected to alleviate global cholera vaccine shortages

The International Vaccine Institute (IVI) and EuBiologics Co have announced the licensure for export by the Korean Ministry of Food and Drug Safety (KMFDs) of Euvichol-S, a simplified formulation of the oral cholera vaccine (OCV) Euvichol-Plus that is prequalified by the World Health Organization.

The licensure of Euvichol-S is the culmination of a comprehensive phase 3 clinical trial conducted by IVI and paves the way for a potential solution to the critical shortage of OCV worldwide.

The ongoing global shortage of OCV has hindered the deployment of effective cholera control efforts, exacerbating the impact of unprecedented cholera outbreaks in 2022 and 2023.

In 2019, IVI received support from the Bill & Melinda Gates Foundation to reformulate Euvichol-Plus, with the potential to reduce production costs by 20% and increase production capacity by 38%. IVI reformulated Euvichol-Plus by reducing components from five to two and the inactivation process from two to one.

The Phase 3 clinical trial comparing the lower-cost formulation, Euvichol-S, to Shanchol was successfully completed in Nepal in October 2022 to demonstrate the non-inferiority of Euvichol-S compared to Shanchol, laying the foundation for regulatory approvals. An application for licensure was submitted to KMFDs in March 2023, with a concurrent review for pre-qualification by the WHO.

The trial, encompassing 2530 participants, confirmed non-inferior seroconversion rates for Euvichol-S against *V. cholerae* O1 Inaba and Ogawa compared to Shanchol. With a robust safety profile, Euvichol-S emerges as a promising solution to bridge the gap between limited OCV supply and rising demand.

With the addition of Euvichol-S, EuBiologics is poised to ramp up its OCV production to 52 million doses including more than 15 million doses of Euvichol-S in 2024, while boosting its overall capability to produce OCV materials to up to 90 million doses annually.