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Bharat Biotech's oral cholera vaccine demonstrates success in Ph III clinical studies

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HillcholÂ® to have a major impact in addressing the global shortage of cholera vaccines



Hyderabad-based Bharat Biotech's Oral Cholera Vaccine Hillchol® has demonstrated success against both Ogawa and Inaba serotypes, proving non-inferior in healthy Indian adults and children, supporting its potential as an effective oral cholera vaccine (OCV).

The study findings have been published in the ScienceDirect, Vaccine journal 126998 to assess a double-blind, randomised phase III clinical trial to evaluate safety, immunogenicity, non-inferiority & lot-to-lot consistency of single component oral cholera vaccine Hillchol® in comparison to a comparator vaccine in a diverse participant group of 1,800 individuals, from infants to adults, across 10 clinical sites in India.

In this study, participants were divided into three age groups: adults over 18 years, children aged 5 to under 18 years, and infants aged 1 to under 5 years. They were randomised in a 3:1 ratio to receive either Hillchol® or a comparator vaccine.

The primary endpoint focused on the proportion of participants achieving >4-fold increase in vibriocidal antibody titres against Ogawa and Inaba serotypes 14 days after two doses. While secondary endpoints included Geometric Mean Titre (GMT) measurements and safety.

Hillchol® demonstrated a greater than 4-fold rise in vibriocidal antibodies against both Ogawa (68.3%) and Inaba (69.5%) serotypes, proving non-inferiority to licensed vaccines. Adverse events were mild and comparable between the two vaccines.

Dr Krishna Ella, Executive Chairman of Bharat Biotech said, "Cholera is a vaccine-preventable disease that has faced a surge in outbreaks along with a huge shortage of vaccines. The new generation Oral Cholera Vaccine Hillchol®, featuring a simplified single stable O1 Hikojima strain, inducing robust antibodies against both Ogawa and Inaba serotypes, aims to enhance production efficiency and affordability, particularly in lower- and middle-income countries where waterborne diseases continue to pose serious health threats."

Global demand for OCVs is close to 100 million doses a year, and given that only one manufacturer supplies them, there is a global shortage. Bharat Biotech's facilities in Hyderabad and Bhubaneswar have a capacity to produce up to 200 million doses of Hillchol®.