

Hillchol® : Bharat Biotech's Oral Cholera Vaccine Demonstrates Success in Phase III Clinical Studies

- Hillchol® has successfully completed phase III clinical trials
- Hillchol® will have a major impact in addressing the global shortage of cholera vaccines

Hyderabad, India, May 21, 2025: Bharat Biotech's Oral Cholera Vaccine Hillchol® has demonstrated against both Ogawa and Inaba serotypes, proving non-inferior in healthy Indian adults and children, supporting its potential as an effective OCV.

The above study findings have been published in the **ScienceDirect, Vaccine journal 126998** to assess a double-blind, randomized 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 randomized 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.

Key highlights from the findings:

- **Robust Immunogenicity:** 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.
- **Strong Safety Profile:** Adverse events were mild and comparable between the two vaccines. **Broad Age Coverage:** The vaccine was well-tolerated and immunogenic across **all age groups**—including **infants (≥1 year), children, and adults**.

"This publication reaffirms our commitment to advancing vaccines built on rigorous research, thorough clinical trials, and reliable clinical data. It highlights our continued commitment to providing affordable, effective, and accessible vaccines for the populations who need them the most," said **Dr. Krishna Ella, Executive Chairman of Bharat Biotech**.

Dr. Ella added, "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."

Cholera is an acute diarrhoeal infection caused by ingesting food or water contaminated with *Vibrio cholerae* bacteria. Studies have estimated that 2.86 million cases and 95,000 deaths occur annually. With



Hillchol®, Bharat Biotech strengthens its commitment to combating global infectious diseases through innovation and clinical excellence. As cholera continues to threaten communities lacking clean water and sanitation, Hillchol® provides a streamlined, scalable solution designed to support global health programs and ensure equitable access to life-saving vaccines.

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®.

Published in the ScienceDirect, Vaccine journal:

<https://www.sciencedirect.com/science/article/pii/S0264410X25002956?via%3Dihub>

About Bharat Biotech:

Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 19 vaccines, 4 biotherapeutics, registrations in more than 125 countries, and the World Health Organization (WHO) Pre-qualifications. Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution. Having delivered more than 9 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis (JENVAC®), Rabies, Chikungunya, Zika, Cholera, and the world's first tetanus-toxoid conjugated vaccine for Typhoid.

Bharat's commitment to global social innovation programs and public-private partnerships resulted in introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, ROTAVAC 5D®, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. HILLCHOL®, an oral vaccine against cholera, was launched in 2024. The acquisition of Chiron Behring Vaccines has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer with Chirorab® and Indirab®. To learn more about Bharat Biotech, visit www.bharatbiotech.com.

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