

## **Bharat Biotech Launches Next Generation Oral Cholera Vaccine HILLCHOL<sup>®</sup>; Expands Manufacturing to Address Global Shortage**

*Bharat Biotech is committed to make HILLCHOL<sup>®</sup> accessible and affordable for countries with the highest burden of disease.*

- Bharat Biotech's collaboration with MSD, Wellcome-Trust Hilleman Laboratories aims to address the critical shortage of OCVs
- Global demand for Oral Cholera Vaccines (OCVs) exceeds 100 million doses annually, making them crucial for cholera control
- **Globally, there is a shortage of OCVs as there is only one manufacturer. The deficit is ~40 million doses per year, Bharat Biotech plans to bridge this gap with its HILLCHOL<sup>®</sup> vaccine**
- HILLCHOL<sup>®</sup>'s safety and efficacy have been rigorously tested in pre-clinical and Phase I and Phase II clinical studies
- **A multi-stage clinical evaluation process, culminating in a Phase III study, confirmed the vaccine's safety, immunogenicity and non-inferiority to existing OCVs, establishing its potential for widespread public health use.**

**Hyderabad, India - August 27, 2024** — Bharat Biotech International Limited (BBIL) announced the launch of HILLCHOL<sup>®</sup> (BBV131), a novel single-strain Oral Cholera Vaccine (OCV). HILLCHOL<sup>®</sup> was developed by Bharat Biotech under license from **Hilleman Laboratories** (funded by Merck, USA and Wellcome Trust, UK), to combat cholera, a significant advancement in global health.

Currently, only one manufacturer supplies OCVs worldwide, resulting in a yearly deficit of ~40 million doses. To mitigate this global shortage of oral cholera vaccine, Bharat Biotech has established large-scale manufacturing facilities in Hyderabad and Bhubaneswar with a capacity to produce up to 200 million doses of HILLCHOL<sup>®</sup>.

While cholera is preventable and treatable, global cases and deaths have risen steadily since 2021. From early 2023 to March this year, 824,479 cases and 5,900 deaths were reported in 31 countries.

**HILLCHOL**<sup>®</sup> vaccine is administered orally on Day 0 and Day 14 and is suitable for individuals older than one year. It is presented as a single-dose respule and should be stored between +2°C and +8°C. HILLCHOL<sup>®</sup> is presented in a mono-multidose format, one of the first such presentations for vaccines.

**Dr. Krishna Ella, Executive Chairman of Bharat Biotech**, said, "Vaccines provide the best intervention to prevent, limit and control cholera outbreaks. HILLCHOL<sup>®</sup> is an excellent success story of partnership leading to public health solutions. Our new large-scale cGMP production facilities in Hyderabad and Bhubaneswar will significantly enhance our production and supply capabilities for this Oral Cholera Vaccine, advancing our efforts to combat Cholera globally."

"I congratulate the team at Bharat Biotech, our partners for developing this novel vaccine and thankful to the CDSCO, Govt of India, and WHO Geneva, for their regulatory guidance and support." Dr. Ella, added.

HILLCHOL<sup>®</sup> marks a significant milestone in global cholera prevention efforts. It will contribute substantially to the Global Task Force on Cholera Control (GTFCC)'s goal of reducing cholera-related deaths by 90% by 2030, alongside improvements in water and sanitation infrastructure.

The launch of the HILLCHOL<sup>®</sup> vaccine is the result of extensive international collaboration involving Hilleman Laboratories, Bharat Biotech, the University of Gothenburg and Gotovax AB.

Ever since it was founded by Wellcome and MSD, Hilleman Laboratories is proud of its role in this joint effort and its dedication to advancing global health equity through affordable, high-impact and sustainable solutions for those who are most susceptible to this disease.

Although the cholera vaccine provides additional protection against infections, it is essential to emphasize that it does not substitute for other preventive measures.

Cholera continues to pose a significant public health challenge, especially in regions with inadequate sanitation. The spread of cholera is primarily attributed to the faecal contamination of water and food supplies, a problem exacerbated by natural disasters and among people living in crowded conditions with insufficient access to clean water.

## **About Bharat Biotech**

Bharat Biotech (BBIL) is a biotech company in Genome Valley, Hyderabad, India. BBIL is a global leader with 145 patents, ~20 vaccines and bio-therapeutics, and registrations in 125 countries. These vaccines were developed through clinical trials in more than 20 countries worldwide and have been published in more than 100 peer-reviewed journals. The company has manufactured and supplied more than 9 billion doses of vaccines globally, saving millions of lives and livelihoods annually.

The company has world-class vaccine and bio-therapeutics research, product development, manufacturing, and distribution facilities. BBIL has developed vaccines for infectious diseases, including Hepatitis B, Pentavalent (DPT+HepB+Hib), Rabies, Typhoid, polio, H1N1 influenza, Japanese Encephalitis (JENVAC<sup>®</sup>), India's first Rotavirus vaccine, the world's first Typhoid conjugate vaccine, TYPBAR TCV<sup>®</sup>, novel vaccines for COVID-19 such as COVAXIN<sup>®</sup> and INCOVACC<sup>®</sup>. BBIL introduced WHO pre-qualified vaccines, namely BIOPOLIO<sup>®</sup>, ROTAVAC<sup>®</sup>, ROTAVAC 5D<sup>®</sup>, and TYPBAR TCV<sup>®</sup>, in several countries worldwide.

BBIL has a strong pipeline of innovative vaccines against malaria, tuberculosis, Para Typhi A, non-typhoidal salmonella, chikungunya, and Zika. The acquisition of Chiron Behring Vaccines has positioned Bharat Biotech as one of the world's largest rabies vaccine manufacturers with CHIRORAB<sup>®</sup> and INDIRAB<sup>®</sup>. To learn more about BBIL, visit [www.bharatbiotech.com](http://www.bharatbiotech.com).

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