

Hilleman Lab licenses Oral Cholera Vaccine Hillchol to Bharat Biotech

26 June 2019 | News

Collaboration seeks to accelerate the development, licensure, manufacture and supply of an affordable, next-generation Cholera vaccine to support access in low and middle-income countries



Hilleman Laboratories, a global research and development organization focused on delivering high-impact and affordable vaccines, has announced that it has entered into a collaboration with Bharat Biotech International Ltd. (BBIL), a leading vaccine and biotechnology company in India for further development, manufacturing and commercialization of its next-generation Oral Cholera Vaccine, Hillchol®.

This collaboration will strengthen the ability of both organizations towards prevention of Cholera through rapid and cost-effective deployment of vaccine doses in low and middle-income countries.

Cholera is an acute diarrheal infection caused by *Vibrio Cholerae* and has been responsible for seven pandemics till date. Cholera is a poverty-related disease, endemic in South Asia and Africa, and is on the WHO priority list.

Globally, Cholera accounts for ~2.8 million cases and an estimated 95,000 deaths annually. In India, about 30% of the population - 375 million people - remain at risk. Deployment of oral Cholera vaccines (OCVs) are an essential public health component of comprehensive Cholera prevention and control, recommended by the WHO and an element of its "EndCholera" initiative.

Hillchol® was designed at the University of Gothenburg in Sweden and subsequently developed by Hilleman Labs including demonstration of safety and immunogenicity in an age de-escalating Phase I/II clinical trial conducted in Bangladesh with the assistance of icddr,b and Incepta Vaccines Ltd.

Prof. Jan Holmgren, University of Gothenburg who along with his colleague Dr. Michael Lebens and their team invented the vaccine commented, "Hillchol® contains a single recombinant Hikojima strain which expresses both Inaba and Ogawa antigens, resulting in a shorter and simpler manufacturing process as compared to licensed OCVs. Hillchol® will therefore be of great importance and value to help to meet the urgent demands from Cholera afflicted countries for much expanded oral Cholera vaccines manufacturing and supplies for the control of Cholera globally"

Speaking about the partnership, Dr. Davinder Gill, Chief Executive Officer, Hilleman Laboratories said, "Vaccines play a critical role in improving healthcare outcomes globally, and Hilleman Laboratories is honoured to work with Bharat Biotech, a leading vaccine manufacturer in India for development, and if licensed, eventual manufacturing and commercialization of our innovative oral Cholera vaccine Hillchol®. Availability of an affordable Cholera vaccine is particularly significant considering that more than 50 GAVI eligible countries have been categorized as Cholera-endemic. We hope this collaboration will provide an innovative vaccine solution which is both affordable and accessible."

Dr. Krishna Ella, Chairman & Managing Director of Bharat Biotech International Limited, said, "We are delighted to lead the scale-up, development, manufacturing and commercialisation efforts for Hillchol® with our collaboration marking an important step. Our capacity to deliver 50 million doses per year and the addition of a WHO pre-qualification of Hillchol® in the future, will not only solve the demand uncertainty but aid in affordability thereby resulting in the wider use of such a vital oral Cholera vaccine worldwide."

Dr. Gerd Zettlmeissl, Chairman, Hilleman Laboratories congratulated both partners on entering into collaboration agreement to align efforts and said "By working together, we can move even closer to meeting the critical public health goal of reducing Cholera burden by 90% by 2030, a key objective of WHO End Cholera initiative"

For further development of Hillchol®, Hilleman Labs has entered into a licensing and manufacturing agreement with BBIL, who will scale the manufacturing process to commercial stage and establish product specifications required for WHO pre-qualification.