

Press Release

Hilleman Labs achieves successful outcome of Phase I/II Clinical Trial of its Oral Cholera Vaccine Hillchol™

12th October 2017, New Delhi: Delivering on its mission to develop affordable vaccines for global health, Hilleman Laboratories today announced that it has successfully completed the Phase I/II Clinical Trials of its novel Oral Cholera Vaccine Hillchol™ to address growing need to stop Cholera in the developing world. The Phase I/II clinical study was conducted in partnership with the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). Results of the clinical trials were announced at the Vaccines for Enteric Diseases Conference 2017 recently held in Albufeira, Portugal.

Sharing results of the clinical study, Dr. Ajit Pal Singh - Vice President Clinical R&D at Hilleman Labs stated, "Hillchol™ was tested in 840 subjects that included adults, adolescents as well as small children. We were able to demonstrate safety and tolerability of Hillchol™ in our Phase I/II trials. Our vaccine consists of a novel Hikojima strain that expresses both the Ogawa and Inaba serotypes. When compared against Shanchol, the Cholera vaccine pre-qualified by WHO, we could achieve non-inferiority in terms of seroconversion as well as Geometric Mean Titre for both the Ogawa and Inaba serotypes. These results are very **encouraging and warrant further development of our Cholera vaccine.**"

Dr. Tarun Sharma, Director R&D at Hilleman Labs stated, "The Hillchol™ Phase I/II clinical trial results support our Hikojima vaccine design and mirror the impressive results we have been able to achieve in Preclinical studies. This encourages us to conduct further clinical studies as well as undertake further research in our labs for additional innovations in next-generation **Oral Cholera Vaccines**"

Talking about the accomplishment, Dr Davinder Gill, CEO Hilleman Laboratories said, "There is an urgent need for effective and affordable Cholera vaccines for use in both Cholera outbreaks and in mass vaccination campaigns. Currently, WHO recommends Oral Cholera Vaccines for humanitarian crises and in outbreaks. With the advancement of Hillchol™, we hope to make available to the global health community, an affordable vaccine for mass vaccination in hotspots against Cholera-endemic countries. This will greatly assist in the global initiative recently announced by WHO to reduce Cholera deaths by 90% by the year **2030**".

According to the WHO, Cholera is endemic in over 50 countries with estimated mortality of 100,000 - 120,000 deaths annually, and a morbidity of 3.8 - 4.4 million annual cases attributed to this disease. Cholera vaccine production is low, with demands currently exceeding supply. In 2014 Hilleman Laboratories partnered with Gotovax AB of Sweden and Incepta Vaccines of Bangladesh for the development of an affordable Cholera vaccine. Clinical trial design and development was supported by the icddr,b.

About Hilleman Laboratories

Hilleman Laboratories is a first-of-its-kind joint-venture partnership formed between MSD a global research-driven pharmaceutical organization and Wellcome Trust, a global charitable foundation dedicated to human and animal health by supporting the brightest minds. Hilleman Laboratories has been named after renowned scientist and father of modern vaccines Dr. Maurice Hilleman. His dedication to making a difference through the practical application of



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vaccine research and delivering vaccines to people in need forms the core mission of Hilleman Laboratories.

Hilleman Laboratories aims to become a global voice for vaccine development and access for public health in the developing world. For further information, please visit: www.hillemanlabs.org