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28 April 2016 | News | By BioSpectrum Bureau

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Advancing closer to its vision of bridging the vaccination gap in developing nations, Hilleman Laboratories, a first-of-its-kind joint-venture between Merck Sharp & Dohme (MSD) and the Wellcome Trust, has announced the initiation of Phase I/II clinical trial of its innovative vaccine, an oral, lyophilized, heat-stable Rotavirus vaccine, against Rotavirus disease.

After successful completion of the preclinical stage and obtaining regulatory clearance, Hilleman Laboratories has initiated a clinical study to establish proof-of-concept for its heat stable Rotavirus vaccine candidate.

Hilleman Laboratories also obtained regulatory clearance for its innovative oral Cholera vaccine to conduct a Phase I/II clinical study that is intended to lead to an affordable vaccine against devastating Cholera infection.

Commenting on these developments, Dr Davinder Gill, CEO, Hilleman Laboratories said, "These are exciting times at Hilleman Laboratories with several of our initiatives moving closer to meeting their objectives. There is a real need for safer and more effective vaccines to address the unmet needs of low-income nations. We have designed both Rotavirus and Cholera vaccine candidates keeping in view the socio-economic and demographic needs of developing nations. While on one hand, our heat-stable technology will offer longer stability to the Rotavirus vaccine in extreme climates, the next-generation oral Cholera vaccine will be affordable and easy-to-administer."

Dr Gerd Zettlmeissl, Chairman of Board of Directors, Hilleman Laboratories said, "I congratulate the entire team at the Hilleman Laboratories on achieving this significant milestone. These developments further strengthen my belief in our vision of saving millions of lives lost due to preventable diseases in low income settings." In light of the World Immunization Week themed 'Close the Immunization Gap' by WHO, the new developments gives a massive impetus to the company's commitment towards realizing this goal.

The clinical trials for both the vaccine candidates will be conducted at Bangladesh-based International Centre for Diarrheal Disease Research (ICDDR, B), an international health research organization. Dr John David Clemens, Executive Director, ICDDR, B, who is spearheading the trials said, "Increasing access to high impact vaccines will be the key to eradicate enteric diseases that are a leading cause of deaths in developing countries. Since beginning our collaboration with Hilleman Laboratories, we have been closely monitoring the development of both the Rotavirus and Cholera vaccines. We are now thrilled to get an opportunity to translate research into preventable treatment."

Lauding the Indian government's efforts to reduce child mortality by including Rotavirus vaccines under the Universal Immunization Program, Dr Gill added, "This is a welcome step taken by the Government of India. However, high dependence on cold-chain for vaccine preservation, is a major gap in the delivery system. With our heat-stable Rotavirus vaccine, we aim to further support the government's efforts of expanding coverage and reducing child mortality."

Rotavirus is the leading cause of severe diarrhea and death among children less than 5 years of age, 90% of these deaths occur in developing countries. According to the Ministry of Health and Family Welfare , nearly 80,000 to 100,000 children in India die due to Rotavirus diarrhea annually while nearly 900,000 children are admitted to hospitals with severe diarrhea.

According to the World Health Organization, Cholera Vaccine production is low, with demands currently exceeding supply. Cholera is endemic in over 50 countries with estimated mortality of 100,000 - 120,000 deaths and a morbidity of 3.8 - 4.4 million annual cases attributed to this disease .

In 2014 Hilleman Laboratories partnered with Gotovax AB of Sweden and Incepta Vaccines of Bangladesh for the development of an affordable Cholera vaccine. "In less than two years, with the strong assistance of our partners, we have successfully advanced our Cholera program from signing our partnership agreement to initiating clinical trials. This only enforces our aim to contribute in enhancing the supply of a much-needed vaccine across the world," added Dr Gill.