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Hilleman steps up efforts on oral cholera vaccine

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Hilleman Laboratories, an equal joint-venture partnership between Merck and Wellcome Trust, has signed a memorandum of understanding (MoU) with Bangladesh-based ICDDR,B (formerly the International Centre for Diarrheal Disease Research, Bangladesh), an international public health research organization, and Incepta Vaccine, a leading pharmaceutical company in Bangladesh.

As per the terms of reference of the MoU, Hilleman Laboratories will provide its expertise in further development, which will include the process, formulation and pre-clinical development of the vaccine. ICDDR,B will provide expertise with respect to clinical development and studies of the vaccine candidate and Incepta will support the development program in the area of process development, scale-up and cGMP manufacturing for pre-clinical and clinical studies.

"This collaboration will allow the three organizations to work together and bring forward a cheap effective cholera vaccine to meet the needs of the developing world," said Dr Davinder Gill, chief executive officer, Hilleman Laboratories.

"We are sensitive to the fact that cholera is endemic in developing nations, especially in the Bengal delta and sub-Saharan Africa. Identifying like-minded partners within four months of attaining the world-wide rights to the vaccine candidate in a strategic collaboration with Gotovax AB, has given a boost to our confidence in accelerating the process of optimizing the oral vaccine candidate and offer increased shelf life and reduce the projected gap in supply of cholera vaccine by the current manufacturers," added Dr Gill.

Expressing his views, Dr John Clemens, executive director, icddr,b said, "Cholera is a major public health problem in several developing countries and we are excited to have the opportunity to translate research into prevention. An important challenge is to understand the effectiveness of vaccines in resource poor, high-risk settings. For a variety of reasons, responses to oral vaccines in the developing world are often lower than those seen in industrialized countries. Optimizing a vaccine candidate

to fit such settings and saving lives is synonymous with our philosophy."

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. The burden has led to a demand for an effective, low-cost cholera vaccine for use in epidemic outbreaks as well as for mass vaccinations in endemic settings.

A market also exists for travelers to endemic regions. Demand estimates for cholera vaccines vary significantly across scenarios with an expected 30 million doses needed by 2016 rising to expected 200 million doses by 2025, assuming vaccination of all 1-14-year-old children in high risk populations.

The GAVI Alliance has also expressed concern that current cholera vaccine manufacturers may not be able to meet the projected increase in demand, further strengthening the requirement for alternate, low-cost vaccine supply.