

India set to get its indigenous rotavirus vaccine by 2014

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It was a belief that was shown some twenty eight years ago and might have been looked at with lot of skepticism back then. But it was Dr M K Bhan, former secretary of department of biotechnology (DBT) whose dream of manufacturing an indigenous rotavirus vaccine one day kept the efforts multiplying and project expanding. Now, finally the announcement regarding the positive results from a phase III clinical trial of a rotavirus vaccine developed and manufactured in India, were made by the DBT and Bharat Biotech, on May 14, 2013. The data from the trial, presented at the International Symposium on Rotavirus Vaccines for India- The Evidence and the Promise, showed ROTAVAC to have an excellent safety and efficacy profile.

The vaccine originated from an attenuated (weakened) strain of rotavirus that was isolated from an Indian child at the All India Institute of Medical Sciences in New Delhi in 1985-86. Since then, partners have included DBT, Bharat Biotech, the US National Institutes of Health (NIH), the US Centers for Disease Control and Prevention (CDC), Stanford University School of Medicine, and the nongovernmental organization, PATH. Dr MK Bhan, who recently completed his service as DBT secretary, was tireless in fostering the social innovation partnership and ensuring the highest standards for the vaccine

The clinical study demonstrated for the first time that the India-developed rotavirus vaccine ROTAVAC is efficacious in preventing severe rotavirus diarrhoea in low-resource settings in India. ROTAVAC significantly reduced severe rotavirus diarrhoea by more than half; 56 percent, during the first year of life, with protection continuing into the second year of life. Moreover, the vaccine also showed impact against severe diarrhoea of any cause.

"This is an important scientific breakthrough against rotavirus infections, the most severe and lethal cause of childhood diarrhoea, responsible for approximately 1,00,000 deaths of small children in India each year," said DBT Secretary Dr K VijayRaghavan. "The clinical results indicate that the vaccine, if licensed, could save the lives of thousands of children each year in India."

ROTAVAC is an oral vaccine and is administered to infants in a three-dose course at the ages of 6, 10, and 14 weeks. It is given alongside routine immunizations in the Universal Immunization Program (UIP) vaccines recommended at these ages. The vaccine was developed through a unique social innovation partnership that brought together the experience and expertise of Indian and international researchers as well as the public and private sectors.

The randomized, double-blind, placebo-controlled phase III clinical trial enrolled 6,799 infants in India (aged six to seven weeks at the time of enrolment) at three sites—the Centre for Health Research and Development, Society for Applied Studies (SAS) in New Delhi; Shirdi Sai Baba Rural Hospital, KEM Hospital Research Centre in Vadu, Pune; and Christian Medical College (CMC) in Vellore.

Bharat Biotech previously announced a price of US\$1.00/dose (or approximately INR 54/dose) for ROTAVAC and will soon file for registration of the vaccine in India. If licensed by the Drugs Controller General of India (DCGI), the vaccine will be a more affordable alternative to the rotavirus vaccines already on the market.

Infants enrolled in the study received ROTAVAC and the UIP vaccines, including Oral Polio Vaccine (OPV). When the immune responses to OPV were tested, the result showed that infants receiving OPV at the same time as ROTAVAC generated comparable immune responses to all three polio serotypes as the infants receiving OPV without ROTAVAC; this result supports the concurrent administration of OPV and ROTAVAC.

The vaccine development partnership was supported by DBT, the Bill and Melinda Gates Foundation, the Research Council of Norway, and the UK Department for International Development. Bharat Biotech invested important technical, manufacturing, and financial resources towards vaccine development.

"ROTAVAC represents the successful research and development of a novel vaccine from the developing world with global standards," said Dr Krishna M Ella, chairman and managing director of Bharat Biotech. "ROTAVAC is a testament of our strong vision and commitment to develop affordable health care solutions for infectious diseases."

The support laboratory was the Translational Health Science and Technology Institute with Dr Sudhanshu Vrat as the lead. Quintiles was responsible for several aspects of the trial including medical monitoring, data management, site monitoring, pharmacovigilance, and biostatistics. Good Clinical Practice compliance of the clinical trials was audited by ANTHA Clinical Quality Assurance.