



Department of Biotechnology
Government of India

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**Rotavirus Vaccine Developed in India Demonstrates Strong Efficacy
Public-Private Partnership Announces Phase III Clinical Trial Results at Conference in
Delhi**

New Delhi, India—The Government of India's Department of Biotechnology (DBT) and Bharat Biotech announced positive results from a Phase III clinical trial of a rotavirus vaccine developed and manufactured in India. Data from the trial, presented today 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 clinical study demonstrates 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 100,000 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.”

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 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 M.K. 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 randomized, double-blind, placebo-controlled Phase III clinical trial enrolled 6,799 infants in India (aged six to seven weeks at the time of enrollment) 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. The Clinical Operations Management Unit headed by Dr Nita Bhandari at SAS oversaw the day-to-day coordination and logistical complexities of this multi-site study and played a pivotal role in the conduct of this trial. The Principal Investigators were Dr Temsunaro Rongsen-Chandola at SAS, Dr Ashish Bavdekar at KEM, and Dr Gagandeep Kang at CMC.

The Data Safety Monitoring Board (DSMB), an independent group of experts established to protect

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the participating infants' rights and needs during the Phase III trial, determined that the trial met the highest standards for ethics and patient care and complied with international standards for good clinical practices.

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.

“With its low price and strong efficacy, *ROTAVAC*[®] has the potential to significantly reduce the incidence of severe diarrhoea due to rotavirus among children in India,” said Dr M.K. Bhan, Advisor to the Indian Academy of Pediatrics and former DBT Secretary.

The vaccine efficacy compares favourably with the efficacy of the currently licensed rotavirus vaccines in low-resource countries. The study results showed clear evidence of protection across different rotavirus strains and continued efficacy in the second year of life.

Infants enrolled in the study received *ROTAVAC*[®] and the Universal Immunization Programme (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*[®].

“Vaccines work to save and protect children from diseases like rotavirus for a lifetime,” said Bill Gates, Co-Chair of the Bill & Melinda Gates Foundation. “This public-private partnership is an exemplary model of how to develop affordable technologies that save lives.”

The vaccine development partnership was supported by DBT, the Bill & 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*[®] 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 UIP vaccines recommended at these ages.

“*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—we are proud, yet humbled by our contribution to this social innovation project and global public health priority. We are thankful to all the partners in the Rotavirus Vaccine Development Project—DBT, the Indian Council of Medical Research, PATH, the Bill & Melinda Gates Foundation, NIH, CDC, and Stanford University—for their valuable support in this unique international public-private partnership.”

Prior to conducting the study, the investigators received approvals from the DCGI, the Institutional Review Board for DBT, and the ethics review committees of each study site. The study partners also consulted with the State Governments of Delhi, Maharashtra, and Tamil Nadu, as well as the Ministry of Health and Family Welfare. In addition, the study was approved by the Western Institutional Review Board in the United States and met the highest international clinical trial standards. The DSMB strictly monitored the trial throughout for adherence to these standards and

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protocols. The trial design included a strong safety net to identify and treat illnesses, especially gastroenteritis, among study infants as early as possible. All of the infants enrolled in the trial received high-quality medical and emergency care during the trial period.

The support laboratory was the Translational Health Science and Technology Institute with Dr Sudhanshu Vрати 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.

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Additional resources for media:

- Description of the social innovation partnership that developed *ROTAVAC*[®]
- Fact sheet on rotavirus disease burden in India
- Fact sheet on efficacy and impact of rotavirus vaccines
- Additional quotes and media statements from experts

This document is available online in English, Hindi, Tamil, Telugu, and Marathi:
<http://www.defeatdd.org/rotavac-clinical-trial-results>

DBT website: <http://dbtindia.nic.in>

Bharat Biotech website: <http://www.bharatbiotech.com>

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