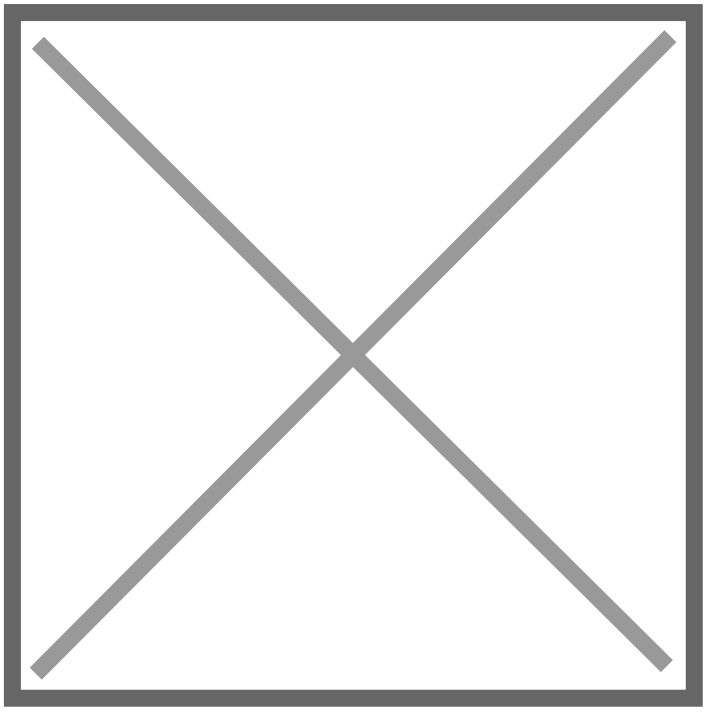
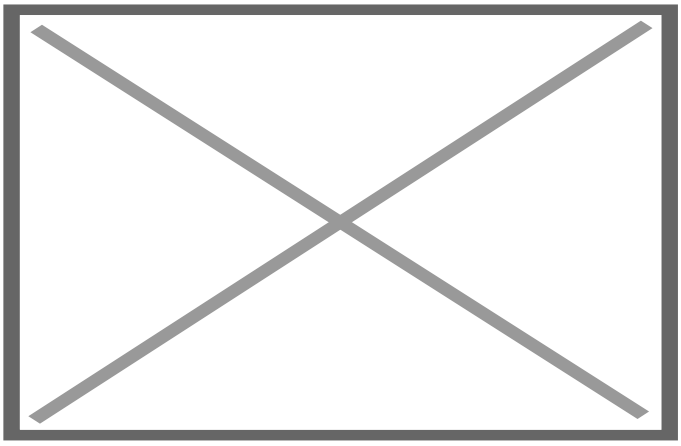
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Mission: An indigenous rotavirus vaccine

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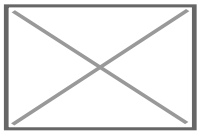




An exemplary partnership between Bharat Biotech, government agencies and research institutes, has made the dream of an indigenous vaccine for rotavirus come true

Rotavirus is the leading cause of severe diarrhea in children worldwide. In order to improve access to better, affordable rotavirus vaccines and to prevent mortality, Bharat Biotech has produced a prototype vaccine of 116E, the most promising candidate under good manufacturing practices (GMP) conditions. This live attenuated oral vaccine, which is based on the rotavirus strain 116E, was co-developed by the present secretary of the Department of Biotechnology (DBT), Dr M K Bhan, in the 1980s. The vaccine is undergoing the final efficacy tests.

The 116E human monovalent vaccine candidate is a naturally occurring re-assortant human strain with one gene (VP4) derived from a bovine rotavirus. The 116E strain was first isolated from an asymptomatic rotavirus-infected neonate in a hospital in New Delhi, India. The virus is grown on Vero cells, and the candidate has undergone extensive characterization and quality control testing at Bharat Biotech and other laboratories worldwide.



The Hyderabad-based company's rotavirus vaccine development project is a public-private partnership with the Department of Biotechnology, Government of India; Society for Applied Studies, National Institute of Immunology; Translational Health Sciences Technology Institute; the Indian Institute of Science; and the All India Institute of Medical Sciences. The project was also backed by funding and expertise from the Bill and Melinda Gates Foundation, Program for Appropriate Technologies in Health, Centers for Disease Control, National Institutes of Health and Stanford University, US.

Since 2001, PATH has also been part of the collaborative effort to develop and evaluate 116E, supporting Bharat Biotech in conducting early-stage clinical trials. PATH also supported the Society for Applied Studies (SAS) and the NII in close collaboration with the DBT and Bharat Biotech to prepare for a phase III efficacy trial. In June 2008, Bharat Biotech and India's SAS announced encouraging data from a phase I/II clinical trial in New Delhi, India. The trial evaluated two different dosages in nearly 400 infants and after three administrations, the results showed 90 percent protection or Ã¢â?¬Å?immunogenecity rateÃ¢â?¬?. Ã¢â?¬Å?The key to our success is our novel concepts in vaccine development and innovative manufacturing processes with public health in mind,Ã¢â?¬? says Dr Krishna Ella, chairman and managing director, Bharat Biotech.

The way forward

With successful completion of phase I and II trials and encouraging results from phase III trials, Bharat Biotech on June 6, 2011, announced that ROTAVAC, India's first indigenously developed rotavirus vaccine, will be sold to global public markets and governments worldwide, including UN procurement agencies at around 50 ($1) per dose. The company is expecting the India licensure of the vaccine in 2014 and WHO pre-qualification in 2015 for supply to UN agencies. The vaccine is currently undergoing phase III clinical development for safety and efficacy in 8,000 subjects, one of the largest clinical trial ever conducted in India. Bharat Biotech has an installed capacity of 300 million doses and is well-positioned to manufacture and supply ROTAVAC to United Nations Children's Fund, Pan American Health Organization and other national immunization programs.

Ã¢â?¬Å?In 2001, I made a commitment to the Gates Foundation to develop and supply a novel rotavirus vaccine at $1 a dose. We are extremely happy to honor that commitment. It is a reaffirmation of our commitment to make vaccines affordable globally,Ã¢â?¬? says Dr Ella.

Rahul Koul in New Delhi