

Press Release Details

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 2006 Vaccine

Details

Bharat Biotech & Partners Develop an Indigenous Rotavirus Vaccine

The Indian Rotavirus Vaccine Development Project (RVDP), announced today encouraging results from a recent Phase I clinical trial of two live, natural reassortant, candidate rotavirus vaccines, 116E and I321, conducted in New Delhi, India. The RVDP consisting of the Department of Biotechnology (Govt. of India), Bharat Biotech International Limited, Hyderabad India, Society for Advanced Studies, New Delhi India, Centers for Disease Control, Atlanta GA, National Institutes of Health, the Indian Institute of Science Bangalore, India and Stanford University, Palo Alto CA have worked together for the past several years. Rotavirus is the leading cause of severe diarrhea in children worldwide and accounts for approximately 400,000 hospitalizations and 160,000 deaths in India alone.

In this randomized, double blind trial, 90 healthy infants aged 8-12 weeks were assigned into 3 groups (30 per group) to receive a single oral dose of either one of the two candidate rotavirus vaccines, strains 116E or I321, or placebo. Participants were monitored for adverse events, and stool and blood specimens were obtained to assess vaccine take measured by vaccine virus shedding and/or a rotavirus antibody response. The trial demonstrated that both vaccines were well tolerated and safe, and no serious adverse events or vaccine-related serious adverse events were reported. Vaccine take was reported for 73.3% of recipients of 116E vaccine candidate and 39.3% of recipients of I321 vaccine candidate.

The two candidate vaccines represent the products of two independent research teams from RVDP who have worked in parallel for more than a decade under the auspices of the Indo-US Vaccine Action Program (VAP) and have combined their efforts through the RVDP. The phase-I clinical trial in India has been carried out by Society for Applied Studies, New Delhi. The RVDP receives financial support primarily from the Gates Foundation, through the Program for Appropriate Technology in Health (PATH), Seattle, with additional support from the Indo-US VAP, the Department of Biotechnology, and Govt. of India.

Following the encouraging results of this phase I trial using pilot lots of the candidate rotavirus vaccines manufactured at the National Institutes of Health, USA, the RVDP is planning clinical trials with cGMP vaccine lots produced by Bharat Biotech, using the same strains, 116E and I321. Bharat Biotech International Limited Hyderabad is a leading manufacturer of vaccines and biotherapeutics in India. Bharat Biotech has successfully developed the 116E and I321 human rotavirus strains as vaccine candidates. The 116E and I321 vaccine candidates have undergone extensive characterization and quality control testing at Bharat Biotech and at external agencies with the global standards. These trials are planned to begin in Q2 of 2006.

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