

Bharat Bio develops new vaccine

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Hyderabad 13: The Indian Rotavirus Vaccine Development Project (RVDP) announced on Monday that the results from the recent Phase I clinical trials of two live, natural reassortant, candidate rotavirus vaccines - 116E and I321 - were encouraging. The RVDP has the department of biotechnology, city-based Bharat Biotech International Ltd, Society for Advanced Studies, New Delhi, Centers for Disease Control, Atlanta, National Institutes of Health, the Indian Institute of Science, Bangalore and Stanford University as its members. The project has been focusing on developing rotavirus vaccine for the several years.

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. Bharat Biotech has successfully developed the 116E and I321 human rotavirus strains as vaccine candidates. These trials are likely to begin in the second quarter of 2006.

Rotavirus is the leading cause of severe diarrhoea in children worldwide and accounts for about 400,000 hospitalisations and 160,000 deaths in India alone.

Giving the details of the Phase I trials, Bharat Biotech said, 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 was carried out by the Society for Applied Studies, New Delhi. The RVDP receives financial support primarily from the Gates Foundation.