

RVDP plans clinical trials with cGMP vaccines

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Hyderabad, Feb. 13: Following encouraging results of phase I trials using pilot lots of candidate rotavirus vaccines, manufactured at the National Institutes of Health, US, the Indian Rotavirus Vaccine Development Project (RVDP) is planning clinical trials with cGMP vaccine lots produced by Bharat Biotech International Ltd (BBIL), using the same strains, 116E and I321. The proposed trials are planned to begin during the second quarter of 2006.

BBIL, engaged in manufacturing of vaccines and biotherapeutics, has successfully developed the 116E and I321 human rotavirus strains as vaccine candidates. The 116E and I321 vaccine candidates have undergone extensive characterisation and quality control testing at BBIL and at external agencies with global standards, according to Krishna Ella, Chairman, BBIL.

The Indian Rotavirus Vaccine Development Project (RVDP), announced the encouraging results from a recent phase I clinical trial of two live, natural reassortant, candidate rotavirus vaccines, 116E and I321.

The RVDP, consisting of the Department of Biotechnology, BBIL, Society for Advanced Studies, New Delhi, Centers for Disease Control, Atlanta, National Institutes of Health, the Indian Institute of Science, Bangalore and Stanford University, Palo Alto CA, the US, are working together in this programme.

It may be mentioned that Rotavirus is the leading cause of diarrhoea in children worldwide and accounts for approximately 400,000 hospitalisations and 160,000 deaths in India alone, according to a company statement.

Further, explaining about the project, the release pointed that a randomised, double blind trial consisting of healthy infants aged eight-12 weeks were assigned into three groups (30 per group) to receive a single oral dose of either one of the two candidate rotavirus vaccines, strains 116E and 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 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 was carried out by the 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, the release said.