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BHARAT BIOTECH ANNOUNCES SUCCESSFUL COMPLETION OF ITS PHASE I/II CLINICAL TRIAL FOR 116E ROTAVIRUS VACCINE

Press release dated: 28th May, 2008

The Indian Rotavirus Vaccine Development Project (RVDP) announced today encouraging results from a recent Phase I/II clinical trial of a live, natural reassortant, Oral Rotavirus Vaccine 116E (ORV 116E), conducted in New Delhi, India. RVDP is a collaborative effort with support and guidance from the Department of Biotechnology, Government of India; PATH; US Centers for Disease Control and Prevention (CDC); Stanford University; US National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID); Society for Applied Studies; National Institute of Immunology, New Delhi; Indo-US Vaccine Action Program; All India Institute of Medical Sciences and Bharat Biotech International Limited.

Rotavirus infections are the single largest cause of severe diarrheal disease among infants and children worldwide and cause more than 500,000 deaths in infants and children each year, with 90% of these deaths occurring in the world's poorest countries. Rotavirus diarrhea causes more than 120,000 deaths in India alone.

The Phase I/II trial was designed as a Double-blind Randomized Placebo Controlled Dose Escalating Study of ORV 116E in healthy non-malnourished infants 8-20 weeks of age with safety and immunogenicity as the primary and secondary objectives, respectively. The study was conducted by the Society for Applied Studies in New Delhi. The doses selected for administration were $10^{4.0}$ and $10^{5.0}$ FFU with reactogenicity, immunogenicity and viral shedding as the study endpoints. One-hundred and eighty-seven infants were enrolled for the $10^{4.0}$ FFU dosage and 182 were enrolled for the $10^{5.0}$ FFU dosage.

ORV 116E was well tolerated after three administrations with no differences observed in mild, moderate or severe adverse events among vaccine and placebo recipients in both the $10^{4.0}$ and $10^{5.0}$ FFU dosages. ORV 116E was immunogenic with 62.1% and 89.7% of the infants seroconverting after three doses of the $10^{4.0}$ and $10^{5.0}$ FFU dosages, respectively. These favorable early clinical results are encouraging and warrant further development of ORV 116E as a new rotavirus vaccine for young infants in developing world settings.

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Bharat Biotech International Limited Hyderabad is a leading manufacturer of vaccines and biotherapeutics in India. Bharat Biotech has successfully developed the commercial manufacturing, testing and release processes for ORV 116E. The 116E vaccine candidate has undergone extensive characterization and quality control testing at Bharat Biotech and at external agencies abroad. The Phase III clinical trials for ORV 116E are planned to start in 2009.

Important information about forward-looking statements

Certain statements in this press release may be considered "forward-looking". Such forward-looking statements are based on current expectations, and, accordingly, entail and are influenced by various risks and uncertainties. The Company therefore cannot provide any assurance that such forward-looking statements will materialize and does not assume an obligation to update or revise any forward-looking statement, whether as a result of new information, future events or any other reason.

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