

Phase III trial of \$1 vaccine RotaVac completed

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Pune: The phase III trial of RotaVac, India's first indigenously developed rotavirus vaccine, has been completed and the data is presently being analyzed for further development of the same.

The announcement was made at the Vaccine World Summit, being held in Pune from March 5-7. While highlighting some of the developments in the vaccine space of India, Dr T S Rao, advisor, Department of Biotechnology under the Ministry of Science and Technology, India, said RotaVac, which promises to be a \$1 per dose vaccine, has been tested on 6,800 subjects at three locations: SAS Delhi, CMC Vellore and KEM Mumbai.

The vaccine is being developed by Bharat Biotech with support from institutions such as DBT, Gates Foundation, Program for Appropriate Technologies in Health (PATH), Centers for Disease Control, USA, National Institutes of Health NIAID, USA, Society for Applied Studies, Translational Health Sciences Technology Institute, Indian Institute of Science, All India Institute of Medical Science and Stanford University. In 2011, Dr Krishna Ella, chairman and MD, Bharat Biotech, had announced that

Rotavac would be available at a price of \$1 per dose. The company expects India licensure during 2014 and WHO prequalification in 2015 for supply to UN agencies.

India's vaccine market stands at \$260 million at the moment. Centers for Disease Control estimates say rotavirus causes approximately 352,000-to-592,000 deaths each year in children below the age of five.

Praising the effort of this public-private partnership, Dr Rao said, "This is the best model for vaccine development and a perfect PPP model. Seeing the efficiency of the Rotavac project, a similar model has been adopted for malaria vaccine development."

Discussing the challenges in vaccine development, he commented, "One of the challenges in vaccine space is clinical trials of new vaccines. DBT is closely working with the DCGI to solve this issue regarding clinical trials."

The event at Pune is providing a platform for leading vaccine players to explore partnership opportunities at various stages of the vaccine life cycle, from the earliest basic research to licensure of the vaccine.