



Prime Minister of India launches Made in India ROTAVAC® Vaccine for the world

Developed by Bharat Biotech the oral rotavirus vaccine ROTAVAC® is safe and effective in prevention of rotavirus diarrhea. This announcement fulfills Bharat Biotech's promise of a \$ 1 / dose vaccine to governments in low income countries and also realized nation's vision to "Make in India" vaccine. The company received commercial licensure and the vaccine is available for sale.

New Delhi/Hyderabad, India, March 9th 2015: Hyderabad based Bharat Biotech announced today the commercial roll out of the Made in India vaccine ROTAVAC®. The vaccine was launched by the Hon'ble Prime Minister of India, Shri Narendra Modi today in New Delhi. ROTAVAC® is one of the first novel vaccines to be developed completely in the developing world.

The three- dose highly affordable ROTAVAC® vaccine made in the country will help in significant reduction in the 100,000 infant deaths in India due to rotavirus diarrhea and could contribute greatly for the prevention of such infant deaths worldwide. During clinical trials ROTAVAC® was found to be safe and effective in the prevention of Rotavirus diarrhea and reducing hospitalizations due to diarrhea. Results from the pivotal phase III clinical trials were published in Lancet during 2014.

The vaccine efficacy compares favourably with the efficacy of the currently licensed rotavirus vaccines in low-resource countries. The study results showed clear evidence of protection across different rotavirus strains and continued efficacy in the second year of life.

Speaking on the occasion Dr. Krishna Ella the Chairman and Managing Director of Bharat Biotech said "We have realized a dream by bringing out the first Made in India Molecule. We have also maintained our pledge to offer ROTAVAC® for \$ 1 to governments in low income countries. Our vaccine is affordable, safe and effective, besides being cross-protective against a variety of rotavirus strains".

Bharat Biotech developed an innovative manufacturing process, which enabled reduction of manufacturing costs. Bharat Biotech has invested ~ \$ 20 million to develop new manufacturing facilities and supporting infrastructure in its Genome valley plant. The facility has an installed manufacturing capacity of 300 million doses / year.

Dr. Ella also appreciated the proactive approach by the Government of India to include rotavirus vaccines in the national immunization program during 2015. A novel vaccine innovated in India, developed in India and to be made in India, which he said is a big boost to the "Make in India" initiative by the Government of India. Today's launch fortifies our mission to identify public health problems and make affordable life-saving vaccines to children wherever they are born, he stated.

ROTAVAC® was developed through a unique social innovation partnership under the Indo-US Vaccine Action Program that brought together the experience and expertise of Indian and international researchers as well as the public and private sectors. The vaccine originated from an attenuated (weakened) strain of rotavirus that was isolated from an Indian child at the All India Institute of Medical Sciences (AIIMS) in New Delhi in 1985-86. Since then, partners have included DBT, Bharat Biotech, the US National Institutes of Health and Centers for Disease Control and Prevention, Stanford University School of Medicine, and the nongovernmental organization, PATH.

Speaking on the occasion Dr. Maharaj Bhan said “Ideas are good only when they are pursued to the very end. The ROTAVAC® story is a good mix of innovation and purpose”.

The vaccine development partnership was supported by DBT, the Bill & Melinda Gates Foundation, the Research Council of Norway, and the UK Department of International Development. Bharat Biotech invested important technical, manufacturing, and financial resources towards vaccine development.

Dr. Harry Greenberg Associate Dean at Stanford University added "The ROTAVAC® project is a beautiful example of the great power of team science. The vaccine is a culmination of a very large and disparate group of people and organizations all working together for a common goal: to produce a safe, effective and affordable vaccine to prevent severe rotavirus associated diarrhea in Indian children".

Globally rotavirus disease burden is estimated at ~ 450,000 deaths, and ~ 2.0 million hospitalizations, mostly in low income countries. Prevention of rotavirus infections would lead to a significant reduction in infant mortality rates and reduce economic impact of hospitalizations to national governments across the globe.

“The huge burden of Rotavirus disease worldwide underscores the need for a safe, effective and affordable rotavirus vaccine for all countries. All children are infected with rotavirus in their first few years of life and in India, Rotavirus kills an estimated 80,000 children each year and is responsible for more than one third of all hospitalizations for diarrhoea in children. The impact of this vaccine to improve child survival is enormous. Our groups at CDC and NIH are proud to be an integral part of this longstanding and enormously successful collaboration with our Indian colleagues “added Dr. Roger Glass, Director Fogarty International Center NIH USA.

ADDITIONAL INFORMATION

The journey of ROTAVAC®

The vaccine originated from a new strain of rotavirus 116E, isolated from an Indian asymptomatic infant at the All India Institute of Medical Sciences in New Delhi in 1986. The virus strain 116E showed exceptional promise because infants infected with this strain manifested strong immunity against subsequent infections. The noteworthy aspect of rotavirus infection from this particular strain is it is capable of providing immunity from other strains as well.

The Rotavirus Vaccine program at Bharat has demonstrated that an international group of scientists from government and academia working with a common goal, and supported initially by a government program, the Vaccine Action Program, could develop a totally new vaccine from an Indian strain of rotavirus, manufactured by an Indian company, Bharat, tested in clinical trials conducted in India with

support from the Government of India's Department of Biotechnology with the help of many other players. This vaccine demonstrates that India is capable of conducting the research needed to develop totally new vaccines of high quality that address problems that are of national and global priority. Furthermore, through this unique consortium of partners, the launch price of this vaccine, \$1.00/dose, should make this affordable for national immunization programs in India and throughout the developing world.

The randomized, double-blind, placebo-controlled phase III efficacy clinical trial that began in March 2011, enrolled 6,799 infants of six to seven weeks age at three sites in India. The results of this trial demonstrated good efficacy and a good safety profile; the trial was also approved by the Data Safety Monitoring Board (DSMB). Additionally, the vaccine was also compatible with the oral polio vaccine.

Almost 2 decades of hard work has gone into making of the ROTAVAC® vaccine. Over these years, the global team contributing to the development of ROTAVAC® has included scientists and health experts at the Government of India's Department of Biotechnology (DBT), the Indian Council of Medical Research, the Indian Institute of Science (IISc), the All India Institute of Medical Sciences (AIIMS), the Translational Health Sciences and Technology Institute (THSTI), the Society for Applied Studies (SAS), Christian Medical College (CMC) Vellore, King Edwards Memorial Hospital (KEM) Pune, Bharat Biotech International, Ltd. (Bharat Biotech), Stanford University School of Medicine, the US National Institutes of Health (NIH), the US Centers for Disease Control and Prevention (CDC), and the nonprofit organization PATH.

This project could not have advanced without the help of many people and institutions. We have to acknowledge the steadfast support of Bill and Melinda Gates who recognized the importance of rotavirus early on and committed funds for this project from the beginning of its commercial development through the pivotal trials.

DBT and NIH have co-hosted the Indo US VAP and provided early and continuing support to build a long-term collaboration between groups. Bharat Biotech team led by Dr. Krishna Ella and Suchitra Ella and their commitment to the project is equally noteworthy which lent to the project a prolonged clinical time line and wonderful outcomes despite several complexities of developing a novel investigational product.

About Bharat Biotech

Based in Genome Valley India, Bharat Biotech (www.bharatbiotech.com) is a multidimensional Innovation-oriented biotechnology company specializing in R&D, manufacturing, marketing and distribution of vaccines and biotherapeutics. The core focus of the company is on the development of novel health care solutions for region-specific neglected diseases in compliance with Global IPR. Built with an investment of over USD 100 million, Bharat Biotech is the first biopharma facility in India to be approved by Korean Food & Drugs administration (KFDA).

Innovation at Bharat Biotech has resulted in products such as Revac-B+®, REGEN-D®, HNVAC®, COMVAC5®, BIOPOLIO®, INDIRAB®, Typbar TCV®, BIOHIB®, JENVAC®, ROTAVAC® and vaccine candidates against Chikungunya, Chandipura, HPV, Ebola etc. Bharat Biotech holds a portfolio of 50 patents and has delivered more than 2.5 billion doses of vaccines to over 65 countries.

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