



Bharat Biotech Launches ROTAVAC 5D[®] - Lowest dose volume rotavirus vaccine in the world

The vaccine was launched by the Vice President of India, He also announced the milestone of 100 million doses of supplies of ROTAVAC[®], the first-generation Made in India rotavirus vaccine from Bharat Biotech.

New Delhi / Hyderabad, India, Dec 3rd, 2019: Hyderabad based Bharat Biotech announced [today](#) the commercial roll-out of ROTAVAC 5D[®] - Lowest dose volume rotavirus vaccine in the world. Vice President of India, Shri M Venkaiah Naidu, launched the vaccine in New Delhi. The first generation, rotavirus vaccine, ROTAVAC[®] was developed under a Public-Private Partnership with the Department of Biotechnology, Govt. of India and other international partners.

Congratulating Bharat Biotech about its milestone achievement in delivering 100 Million doses of ROTAVAC[®] vaccine and launching the new generation ROTAVAC 5D[®] In his address the Vice President of India Shri. M Venkaiah Naidu urged the media and medical professionals to create awareness about various health problems. He said "There is a need for vaccination at the right time, while the government is doing its best, it is a greater social responsibility which every medical professional should take upon themselves, remove apprehension about vaccination, for prevention of diseases and to better the health of the nation and its people."

Developed by Bharat Biotech, oral rotavirus vaccine ROTAVAC 5D[®] is safe and effective in the prevention of rotavirus diarrhoea. ROTAVAC 5D[®] can be stored at 2-8°C, administered in 5 drops. ROTAVAC 5D[®] is available in single-dose, multi-dose vials, and pre-filled syringes. The company received commercial licensure and the vaccine is available for sale.

Speaking on the launch of ROTAVAC 5D[®], Dr. Krishna Ella the Chairman and Managing Director of Bharat Biotech said, "We are proud to announce the milestone of 100 million doses of ROTAVAC[®] supplies, the fastest among rotavirus vaccines in the world. Building on this success, we are pleased to announce the introduction of ROTAVAC 5D[®] the lowest dose volume rotavirus vaccine in the world."

Dr. Ella added, "We have designed and developed a vaccine that is cost-effective due to its efficacy and low cold chain footprint. ROTAVAC 5D[®] presented in multi dose vials, results in savings of ~ \$ 0.30 / dose in supply chain and delivery costs."

ROTAVAC 5D[®] has been evaluated in clinical trials in India and other countries. This vaccine is safe, effective and affordable, besides being cross-protective against a variety of rotavirus strains. Its efficacy

compares favorably 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. Currently, over 25 countries have granted patents for ROTAVAC 5D®.

Dr. Ella also revealed, “Bharat Biotech has invested ~ \$ 20 million to develop new manufacturing facilities and supporting infrastructure in its Genome Valley plant in Hyderabad, with an installed manufacturing capacity of ~ 200 million doses/year. The project was supported in part by the Bill & Melinda Gates Foundation.”

ROTAVAC 5D® is a miniaturized affordable rotavirus vaccine, delivering a potent product with a dose volume of 0.5ml. It enables complete delivery of the antigenic payload in 5 drops, avoiding spit-ups observed with larger dose volumes. ROTAVAC 5D® is available in multidose vials with cold chain footprints of ~4 cm³ / dose, with the smallest cold chain footprint of rotavirus vaccines, and saving cold chain costs due to storage, distribution, administration, and disposal. ROTAVAC 5D® can be stored at 2-8°C for 24 months and is stable at 37°C for 7 days. The vaccine stability combined with its small cold chain footprint enables its use in low resource settings and outreach programs.

The occasion also commemorates the achievement of ~100 million doses of worldwide supplies of ROTAVAC®. This is a great achievement of manufacturing scale up, within 2 years of WHO Prequalification, and Bharat Biotech’s ability to provide global access to this important vaccine. With supplies to national immunization programs, UNICEF and GAVI, ROTAVAC® has become a truly global vaccine.

“The introduction of this rotavirus vaccine has helped protect millions against the leading cause of deadly diarrhoea in children worldwide,” **said Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance,** “and has been critical in ensuring better supply availability as well as diversity of product profiles. Bharat Biotech has been a key partner for Gavi, and I commend the company and its employees for reaching this milestone so quickly.”

The proactive approach by the Government of India to include rotavirus vaccines in the national immunization program and its efficient programmatic implementation, presents a successful model for new vaccine introductions worldwide. 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.

“Rotavirus continues to cause severe diarrheal disease and deaths, mostly among the most vulnerable children in the world,” **said Steve Davis, President and CEO of the nonprofit global health organization PATH.** “We are proud of PATH’s partnership with Bharat Biotech and other international researchers in the development of ROTAVAC® and ROTAVAC 5D®, and we are pleased to see them helping to improve the supply of affordable rotavirus vaccines as they are rolled out in public health programs in India and around the world.”

Globally rotavirus disease burden is estimated at ~ 200,000 deaths and ~ 2.0 million hospitalizations annually, 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.

ADDITIONAL INFORMATION

The journey of ROTAVAC 5D®

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 Biotech 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 Biotech, 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.

The randomized, double-blind, placebo-controlled phase III efficacy clinical trial of ROTAVAC® that began in [March 2011](#), enrolled 6,799 infants six to seven weeks of 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 ROTAVAC 5D® which was built upon the data from ROTAVAC®. 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 timeline 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 \$ 250 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 Zika, Chikungunya, Chandipura, HPV, Ebola, Paratyphi A , Salmonella Enteridis, Salmonella typhimurium, Inactivated polio vaccine, etc. Bharat Biotech holds a portfolio of more than 100 patents and has delivered more than 3 billion doses of vaccines to over 70 countries.

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