

## **Press Release**

**Bharat Biotech**

# ***Bharat Biotech Launches Typbar-TCV™, world's first clinically proven typhoid conjugate vaccine for infants 6 months & older and Adults***

***The new vaccine brings hope to millions of adults and infants older than 6 months, by protecting against typhoid fever caused by *Salmonella typhi*, a highly virulent and invasive enteric bacterium***

**Hyderabad, India, August 26, 2013:** Bharat Biotech ([www.bharatbiotech.com](http://www.bharatbiotech.com)) today announced the launch of World's first clinically proven typhoid conjugate vaccine **Typbar-TCV™**, a fourth generation vaccine against typhoid disease, proven to provide long term protection to adults and infants 6 months & older. Currently available Typhoid vaccines fall short in two major characteristics, namely long term protection and protection for children below 2 years of age, the population that needs it the most.

During its development since 2005 **Typbar-TCV™** was evaluated in ~1200 healthy subjects at 9 clinical sites. In the pivotal phase III clinical study, **Typbar-TCV™** presented 98% seroconversion in infants aged 6 months to 24 months, 99% in children between 2 to 15 years of age, and 92% in the 15 to 45 year age group, as measured by 4 fold increase in serum IgA responses. It proved to be superior to the Vi polysaccharide typhoid vaccines. **Typbar-TCV™** was also safe and well tolerated in all tested age groups.

"Typhoid fever remains an important public health challenge in many countries of the world mainly because of poor diagnostics and increasing resistance to antibiotics. At present fundamental prevention strategies like improved sanitation, good hygienic practices and access to clean water are still out of reach for many impoverished communities. One of the most cost effective approaches to prevent infectious diseases, are vaccines which are available now and could help control the disease resulting in reduction of unnecessary suffering and adverse financial consequences." Dr. Christian Loucq, M.D., Director-General of the International Vaccine Institute (IVI) said.

Typhoid fever is a life threatening illness caused by the bacterium *Salmonella typhi*, which is transmitted through food or drink contaminated by the faeces or urine of infected people. Symptoms include high fever, malaise, headache, constipation, diarrhoea, etc. Healthy carrier state may follow acute illness. It causes between 250,000 to 600,000 deaths and 20 million illnesses per year, affecting mostly school-age children. The World Health Organization reports 90 percent of typhoid deaths occur in Asia and persists mainly in children under 5 years of age. In India, Typhoid fever is observed throughout the year and a greater number of cases coincide with the rainy season. While typhoid fever can be cured by antibiotics, resistance to antimicrobials is widespread along with poor diagnostics, hence prevention of typhoid fever is better than the cure.

Acknowledging the effort of his team of scientists that led to this innovation Dr. Krishna M. Ella, Chairman and Managing Director of Bharat Biotech said "Bharat Biotech's Typbar-TCV™ induces 'T' cell dependent response with much higher antibody levels providing a very high rate of immunity. We hope this vaccine will reach millions of people and help reduce the burden of this devastating disease in infants and children." Dr. Ella added.

Bharat Biotech has commenced commercial production of Typbar-TCV™ in pre-filled syringes in its world class vaccine production facility in Genome Valley. The plant has capacity to produce 10 million doses each year, expandable to 50 million doses per year in the future. Bharat Biotech is the largest producer and supplier of Vi typhoid vaccine in the world having distributed over 50 million doses globally. **Typbar-TCV™** is available for supplies to global markets such as South East Asia, South America, Africa, Central Asia, and South Asia.

Bharat Biotech is an active member in the **Coalition against Typhoid (CaT)** a global forum of scientists and immunization experts working to save lives and reduce suffering by advancing typhoid vaccination in high burden communities. <http://www.coalitionagainsttyphoid.org>

### **About Bharat Biotech**

Based in Genome Valley India, Bharat Biotech ([www.bharatbiotech.com](http://www.bharatbiotech.com)) is a multidimensional Innovation- oriented biotechnology company specializing in R&D, Manufacturing and Distribution of vaccines and biotherapeutics with a focus on developing novel vaccines for region-specific neglected diseases in compliance with Global IPR. Built with an investment of over USD 100 million, Bharat Biotech is the first bio-pharma 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®, etc, and vaccine candidates against rotavirus, Japanese encephalitis, chikungunya etc. The company has pioneered the development of a novel rotavirus vaccine, the first in India catering to the requirements of developing world populations. Bharat Biotech holds a portfolio of 50 patents and has delivered more than two billion doses of vaccines to over 65 countries.

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## Press Clips

### MSN News

#### [New vaccine launched to battle typhoid](#)

26 August 2013

Hyderabad: Bharat Biotech, a leading biotechnology company specializing in vaccines, Monday launched a new vaccine for typhoid that can be given to infants below two years of age and to adults too. Typbar-TCV is said to be the world's first clinically proven typhoid conjugate vaccine which can provide long term protection to adults as well as children six months old and above.

Krishna M. Ella, chairman and managing director of Bharat Biotech, told the media that the fourth generation vaccines offers hope to millions around the world as the currently available vaccines lack long-term protection and are not meant for children below two years of age. The Hyderabad-based company has commenced production of the new vaccine. The plant has the capacity to produce 10 million doses annually, expandable to 50 million doses in future.

Typbar-TCV, which will be available in the market in a couple of weeks, will be supplied to global markets such as South East Asia, South America, Africa, Central Asia and South Asia. The Rs.300 crore company is already the largest producer and supplier of Vi typhoid vaccine, having distributed over 50 million doses globally.

**The existing vaccine in India is available for Rs.180 but the new vaccine is going to cost more. Krishna said the price would be announced soon. The company invested Rs.65 crore to develop the vaccine, which was evaluated in over 1,200 people at nine clinical sites.**

Launching the vaccine, Christian Loucq, Director General of the International Vaccine Institute (IVI), said typhoid every year affects 20 million people and causes 250,000-600,000 deaths, mostly in developing countries. According to the World Health Organization (WHO), 90 percent of typhoid deaths occur in Asia. Most victims are children under five years of age.

Krishna pointed out that 62 percent of the deaths occur in Asia, with India and Pakistan accounting for the highest numbers. Bharat Biotech gets Rs.40-50 crore of its revenues from the typhoid vaccine launched in 2003. It supplied the vaccine to many countries including Pakistan and Bangladesh where it is part of their national immunization programme.

With the launch of conjugate vaccine, the company hopes to increase the revenue to Rs.100 crore. Typhoid fever is a life threatening illness caused by the bacterium salmonella typhi, which is transmitted through food or drink contaminated by the faeces or urine of infected people.

"This disease, unfortunately, has been around for too long. In the 21st century, it is not acceptable any more," said Loucq, the head of Seoul-based institute, which has the mission to develop and deliver safe and affordable vaccines for developing nations.

He said the new vaccine would prove effective against typhoid, which has become drug resistant. S. Sanjay of the Indian Academy of Pediatricians called for re-including typhoid vaccine in the national immunization programme. He pointed out that it was part of the national immunization chart till 1985. ###

### **Thomas Reuters Foundation**

[Indian firm develops new vaccine to fight typhoid fever](#)

27 August 2013

NEW DELHI (Thomson Reuters Foundation) - Indian pharmaceutical company Bharat Biotech says it has developed the world's first clinically proven typhoid vaccine giving long-term protection to infants and adults.

Typhoid fever causes between 250,000 and 600,000 deaths a year and makes 20 million people a year ill. Around 90 percent of typhoid deaths occur in Asia and the disease occurs mainly in children under 5, the World Health Organisation says.

It is caused by Salmonella Typhi, a highly virulent and invasive bacterium, which is transmitted through food or drink contaminated by the faeces or urine of infected people.

"Bharat Biotech's Typbar-TCV™ (vaccine) induces 'T' cell dependent response with much higher antibody levels providing a very high rate of immunity," Bharat Biotech Chairman and Managing Director Krishna M. Ella said in a statement on Monday.

"We hope this vaccine will reach millions of people and help reduce the burden of this devastating disease in infants and children."

The Hyderabad-based company said this was the world's first clinically proven fourth generation vaccine, providing long-term protection against typhoid to adults and infants of six months and older.

It said currently available typhoid vaccines fell short in two major characteristics, namely long-term protection and protection for children below 2 years of age.

"Typhoid fever remains an important public health challenge in many countries of the world. At present fundamental prevention strategies like improved sanitation, good hygienic practices and access to clean water are still out of reach for many impoverished communities," said Christian Loucq, director-general of the International Vaccine Institute.

"One of the most cost-effective approaches to prevent infectious diseases are vaccines which are available now and could help control the disease, resulting in reduction of unnecessary suffering and adverse financial consequences."

Bharat Biotech said it had begun commercial production of the vaccine in pre-filled syringes and would produce 10 million doses a year, expandable to 50 million doses in the future, which would be available globally.

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## **The Financial Express**

### [Bharat Bio eyes Rs 100-cr market with new vaccine](#)

27 August 2013

The R300-crore Bharat Biotech has launched what it claims to be the world's first clinically proven typhoid conjugate vaccine Typbar-TCV (a fourth generation vaccine against typhoid disease), proven to provide long-term protection to adults and infants nine months and older.

Currently available typhoid vaccines fall short in two ways: long term protection and protection for children below two years of age.

The market potential is estimated to be R100 crore and the company has invested about R65 crore in research activities.

During its development since 2005, Typbar-TCV was evaluated in about 1,200 healthy subjects at nine clinical sites. In the pivotal phase III clinical study, Typbar-TCV presented 98% seroconversion in infants aged six months to 24 months, 99% in children between two to 15 years of age, and 92% in the 15 to 45 year age group. It proved to be superior to the Vi polysaccharide typhoid vaccines. Typbar-TCV was safe in all tested age groups.

"Typhoid fever remains an important public health challenge in many countries mainly because of poor diagnostics and increasing resistance to antibiotics. At present fundamental prevention strategies like improved sanitation, good hygienic practices and access to clean water are still out of reach for many impoverished communities. One of the most cost effective approaches to prevent infectious diseases are vaccines." Christian Loucq, MD, DG of International Vaccine Institute said at the launch.

The World Health Organization reports 90% of typhoid deaths occur in Asia and persists mainly in children under five years of age.

In India, typhoid fever is observed throughout the year and a greater number of cases coincide with the rainy season. While typhoid fever can be cured by antibiotics, resistance to antimicrobials is widespread along with poor diagnostics, hence prevention of typhoid fever is better than cure. "Typbar-TCV induces 'T' cell dependent response with much higher antibody levels, providing a very high rate of immunity. We hope this vaccine will reach millions of people," Krishna M Ella, CMD, said. Bharat Biotech has started commercial production of Typbar-TCV in pre-filled syringes in its vaccine production facility in Geno-me Valley near Hyderabad.

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## **The Economic Times-India**

### [Bharat Biotech launches conjugate typhoid vaccine](#)

26 August 2013

HYDERABAD: Bharat Biotech launched the world's first clinically proven conjugate Typhoid vaccine 'Typbar-TCV', which offers long-term protection and can be given to children as young as six months.

The fourth-generation conjugate typhoid vaccine Typbar-TCV will be available in the market in the next couple of weeks. It will also be exported to countries in South East Asia, South America, Africa, Central Asia and South Asia.

The Rs 300 crore, Hyderabad-based biotechnology firm invested Rs 65 crore to develop Typbar-TCV. It plans to get about Rs 100 crore in business from its typhoid portfolio in the next couple of years from about Rs 40 crore to Rs 50 crore now.

Yet to be priced, Typbar-TCV (0.5ml) will be costlier than the company's existing typhoid vaccine-Typbar, which is priced at Rs 180 a dose.

According to the World Health Organization Typhoid causes 2.5 lakh to 6 lakh deaths and about 20 million illnesses every year.

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### **India Medical Times**

#### [New vaccine launched to battle typhoid](#)

26 August 2013

Hyderabad: Bharat Biotech, a leading biotechnology company specializing in vaccines, on Monday launched a new vaccine for typhoid that can be given to infants below two years of age and to adults too.

Typbar-TCV is said to be the world's first clinically proven typhoid conjugate vaccine which can provide long term protection to adults as well as children six months old and above.

Krishna M Ella, chairman and managing director of Bharat Biotech, told the media that the fourth generation vaccines offers hope to millions around the world as the currently available vaccines lack long-term protection and are not meant for children below two years of age.

The Hyderabad-based company has commenced production of the new vaccine. The plant has the capacity to produce 10 million doses annually, expandable to 50 million doses in future.

Typbar-TCV, which will be available in the market in a couple of weeks, will be supplied to global markets such as South East Asia, South America, Africa, Central Asia and South Asia.

The Rs 300 crore company is already the largest producer and supplier of Vi typhoid vaccine, having distributed over 50 million doses globally.

**The existing vaccine in India is available for Rs 180 but the new vaccine is going to cost more. Krishna said the price would be announced soon.**

The company invested Rs 65 crore to develop the vaccine, which was evaluated in over 1,200 people at nine clinical sites.

Launching the vaccine, Dr Christian Loucq, director general of the International Vaccine Institute (IVI), said typhoid every year affects 20 million people and causes 250,000-600,000 deaths, mostly in developing countries.

According to the World Health Organisation (WHO), 90 per cent of typhoid deaths occur in Asia. Most victims are children under five years of age.

Krishna pointed out that 62 per cent of the deaths occur in Asia, with India and Pakistan accounting for the highest numbers.

Bharat Biotech gets Rs 40-50 crore of its revenues from the typhoid vaccine launched in 2003. It supplied the vaccine to many countries including Pakistan and Bangladesh where it is part of their national immunization programme.

With the launch of conjugate vaccine, the company hopes to increase the revenue to Rs 100 crore.

Typhoid fever is a life threatening illness caused by the bacterium salmonella typhi, which is transmitted through food or drink contaminated by the faeces or urine of infected people.

“This disease, unfortunately, has been around for too long. In the 21st century, it is not acceptable any more,” said Dr Loucq, the head of Seoul-based institute, which has the mission to develop and deliver safe and affordable vaccines for developing nations.

He said the new vaccine would prove effective against typhoid, which has become drug resistant.

Dr S Sanjay of the Indian Academy of Paediatrics (IAP) called for re-including typhoid vaccine in the national immunization programme. He pointed out that it was part of the national immunization chart till 1985. [IANS]

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### **The Times of India**

[Hyderabad pharma company unveils new typhoid vaccine](#)

27 August 2013

HYDERABAD: City-based vaccine major Bharat Biotech on Monday launched what it claimed was the world's first clinically proven typhoid conjugate vaccine, Typbar - TCV, for infants above six-months as well as adults.

The company that already manufactures and markets typhoid vaccines, said the newly launched typhoid conjugate vaccine would help make the vaccinated immune to the disease for a longer period of time as against the existing vaccines in the market that provide protection only for two to three years.

However, the company did not announce the pricing of the new vaccine that is slated to hit the markets in two weeks time.

**According to Bharat Biotech chairman and managing director Krishna M Ella, the typhoid conjugate vaccine would be priced higher than its existing typhoid vaccine that costs Rs 180 per dose. However,**

the company would follow the dual pricing model, wherein the vaccine for public usage would be pegged lower than for the product being sold in the private market.

"It took us almost eight years to come up with the world's first clinically proven typhoid conjugate vaccine. We have invested around Rs 65 crore for its development. We expect a business of Rs 100 crore from this new vaccine while our existing typhoid vaccine has earned us around Rs 40 - 50 crore business," he said. "The company has commenced commercial production of Typbar-TCV in pre-filled syringes at its vaccine production facility in Genome Valley here. The plant has a capacity to produce 10 million doses each year, which is expandable to 50 million doses per year in the future," he said.

Typhoid is a common disease in the Indian subcontinent that is transmitted through food or drink contaminated by the faeces or urine of infected people. According to a World Health Organization report, 90% of the typhoid deaths occur in Asia and the disease persists mainly in children under five years.