



iNCOVACC® is now available on CoWin, priced at INR 800+GST for Private Markets and INR 325+GST for Governments

iNCOVACC® will be rolled out in the fourth week of January

- iNCOVACC® to be rolled out as booster dose for those above 18 years of age.
- iNCOVACC® to be priced at INR 325+GST dose for large volume procurement by State Governments and Govt of India.
- iNCOVACC® is the world's first Intranasal vaccine for COVID to receive approval for the primary 2-dose schedule, and as a heterologous booster dose.
- Phase III trials (as a 2-dose regimen) were conducted for safety, immunogenicity in ~3100 subjects, in 14 trial sites across India.
- Heterologous booster dose studies were conducted for safety and immunogenicity in ~875 subjects, with BBV154 intranasal vaccine administered in those previously completing a regimen of the commonly administered COVID vaccines. The trials were conducted in 9 trial sites across India.
- iNCOVACC® recipients demonstrated significant levels of Mucosal IgA antibody levels (measured in the saliva). Mucosal IgA antibodies in the upper respiratory tract may provide benefit in reducing infections and transmission.

Hyderabad, Dec 27, 2022: Bharat Biotech International Limited (BBIL), a global leader in vaccine innovation and developer of vaccines for infectious diseases, today announced that iNCOVACC® (BBV154), is scheduled to be introduced in the country as a booster dose shortly. Earlier this month, Bharat Biotech received approval from the Central Drugs Standard Control Organization (CDSCO) for the use of heterologous booster doses of iNCOVACC®. iNCOVACC® is now available on CoWin, and priced at INR 800+GST for private markets and priced at INR 325+GST for supplies to Govt of India and State Governments.

iNCOVACC® is a recombinant replication-deficient adenovirus vectored vaccine with a pre-fusion-stabilized SARS-CoV-2 spike protein. This vaccine candidate was evaluated in phases I, II and III clinical trials with successful results. iNCOVACC® has been specifically formulated to allow intranasal delivery through nasal drops. The nasal delivery system has been designed and developed to be cost-effective in low- and middle-income countries.

Dr. Krishna Ella, Executive Chairman said; “We have achieved the goals we set for ourselves during this pandemic. We have developed COVAXIN® and iNCOVACC®, two COVID vaccines from two different platforms, with two different delivery systems. The vectored intranasal delivery platform gives us the capability for rapid product development, scale-up, easy and painless immunization during public health emergencies and pandemics. We thank the Ministry of Health, CDSCO, Dept of Biotechnology, Govt of India, Technology Development Board, and Washington University, St Louis, for their support and guidance.”



As a needle-less vaccination, Bharat Biotech's iNCOVACC[®] will be India's first such booster dose. India will now have more options when it comes to third doses or precautionary doses. iNCOVACC[®]'s manufacturing platform has the double benefit of enabling faster development of variant-specific vaccines and easy nasal delivery that enables mass immunization to protect from emerging variants of concern.

Clinical trials were conducted to evaluate iNCOVACC[®] as a primary dose schedule, and as heterologous booster dose for subjects who have previously received two doses of the two commonly administered COVID vaccines in India.

iNCOVACC[®] was developed in partnership with Washington University, St. Louis, which had designed and developed the recombinant adenoviral vectored construct and evaluated in preclinical studies for efficacy. Product development related to preclinical safety evaluation, large-scale manufacturing scale-up, formulation and delivery device development, including human clinical trials were conducted by Bharat Biotech. Product development and clinical trials were funded in part by the Government of India, through the Department of Biotechnology's, COVID Suraksha Program.

Despite the lack of demand for COVID vaccines, Bharat Biotech continued product development in intranasal vaccines, to be well-prepared with platform technologies for future infectious diseases. iNCOVACC[®] has been designed for efficient distribution and easy pain free administration. Bharat Biotech has also initiated development of variant-specific vaccines for COVID in an attempt to be future ready.

iNCOVACC[®] is stable at 2-8°C for easy storage and distribution. Bharat Biotech has established large manufacturing capabilities at multiple sites across India, including Gujarat, Karnataka, Maharashtra and Telangana, with operations pan India.

About Bharat Biotech

Bharat Biotech International Limited has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 19 vaccines, four bio-therapeutics, registrations in more than 125 countries, and the World Health Organization (WHO) Prequalification. Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, BBIL has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution. Having delivered more than 5 billion doses of vaccines worldwide, BBIL continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis (JENVAC[®]), Rabies, Chikungunya, Zika, Cholera, and the world's first tetanus toxoid conjugated vaccine for Typhoid. BBIL's commitment to global social innovation programs and the public-private partnership resulted in introducing path-breaking WHO pre-qualified vaccines such as BIOPOLIO[®], ROTAVAC[®], ROTAVAC[®] 5D, and Typbar TCV[®] combatting polio, rotavirus, typhoid infections, respectively. Novel vaccines against malaria and tuberculosis are under development through global partnerships. The acquisition of Chiron Behring Vaccines has positioned BBIL as the world's largest rabies vaccine manufacturer with Chirorab[®] and Indirab[®]. Bharat Biotech's COVAXIN[®], India's indigenous COVID-19 vaccine was developed in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV).

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