

Bharat Biotech's iNCOVACC world's first Intra Nasal vaccine receives approval for emergency use in India

The World's first Intranasal vaccines to receive approvals for primary 2 dose schedule

- iNCOVACC receives approval under Restricted Use in Emergency Situation for ages 18 and above.
- Bharat Biotech is a global leader in intranasal vaccine technologies.
- Phase III trials 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 post 2 doses of the two commonly administered covid-19 vaccines. The trials were conducted in 9 trial sites across India.

Hyderabad, Sept 06, 2022: Bharat Biotech International Limited (BBIL), a global leader in vaccine innovation and developer of vaccines for infectious diseases, today announced that iNCOVACC (BBV154), has received approval under Restricted Use in Emergency Situation for ages 18 and above.

iNCOVACC is a recombinant replication deficient adenovirus vectored vaccine with a prefusion stabilized spike protein. This vaccine candidate was evaluated in phase 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.

iNCOVACC was developed in partnership with Washington University St. Louis, which had designed and developed the recombinant adenoviral vectored constructs and evaluated them 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.

Clinical trials were conducted to evaluate iNCOVACC ^{as} a primary dose schedule, as heterologous booster dose for subjects who have previously received 2 doses of the two commonly administered covid vaccines in India.

Immunogenicity was evaluated through serum neutralizing antibodies by PRNT assays and serum IgG's through ELISA's. To evaluate vaccines taken through the intranasal route, IgA's were evaluated by ELISA in serum and saliva. Evaluation was also carried out for ability iNCOVACC ^{to} elicit long term memory T and B cell responses against the ancestral and omicron variants.

Dr. Krishna Ella, Chairman & Managing Director, Bharat Biotech, said, "We are proud to announce the approval of iNCOVACC, a global game changer in Intra Nasal vaccines technology and delivery systems. Despite the lack of demand for COVID-19 vaccines, we continued product development in intra nasal vaccines to ensure that we are well prepared with platform technologies for future infectious diseases. We thank the Ministry of Health, the CDSCO, Dept of Biotechnology Govt of India, and Washington University St. Louis for their support and guidance. iNCOVACC has been designed for efficient distribution and easy administration."

iNCOVACC was evaluated to determine its impact on safety. The reactogenic events and adverse events that were documented during the trial were highly comparable to published data from other covid-19 vaccines. Product development data will be submitted to peer reviewed journals and will be made available in the public domain.

iNCOVACC 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. It promises to become an important tool in mass vaccinations during pandemics and endemics. With the receipt of approval today, the product will be launched and available for use in due course of time.

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 16 vaccines, 4 bio-therapeutics, registrations in more than 123 countries, and the World Health Organization (WHO) Prequalifications. 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 4 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[®].

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