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iNCOVACC®, World's first Intranasal Vaccine to receive both Primary series and Heterologous booster approval.

- iNCOVACC® recently received approval under Restricted Use in Emergency Situation for ages 18 and above for heterologous booster doses.
- In heterologous boosting, a person administered a different vaccine from the one that was used for the primary dose series.
- iNCOVACC® is the world's first Intranasal vaccine for COVID to receive approval for the primary 2-dose schedule, and heterologous booster dose.
- iNCOVACC® had earlier received approval under Restricted Use in Emergency Situation for ages 18 and above for primary 2-dose schedule. Phase III trials were conducted for safety, immunogenicity in ~3100 subjects, at 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 at 9 trial sites across India.

Hyderabad, Nov 28, 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 from the Central Drugs Standard Control Organisation (CDSCO) under Restricted Use in Emergency Situation for ages 18 and above, in India, for heterologous booster doses.

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.

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.

Dr. Krishna Ella, Chairman & Managing Director, Bharat Biotech, said, "iNCOVACC®, is an intranasal vaccine for the primary 2-dose schedule, and heterologous booster dose. This is a great achievement for us and the global scientific community to enable nasal administration of COVID vaccines. Despite the lack of demand for COVID vaccines, we continued product development in intranasal vaccines to ensure that we are well-prepared with platform technologies for future infectious diseases. 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. iNCOVACC® has been designed for efficient distribution, easy and pain-free administration. We have also initiated development of variant-specific vaccines for COVID for future preparedness."

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.

Immunogenicity was evaluated through serum neutralizing antibodies by PRNT assays and serum IgG's through ELISA's. To evaluate vaccine, 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. Rajesh S. Gokhale, Secretary, DBT, and Chairperson, BIRAC, lauded the efforts of the scientific community and said, "DBT is fostering biotech enterprises & innovation ecosystem and strategically strengthening Indian bioeconomy. DBT, along with BIRAC, is dedicated to the development of effective and safe COVID-19 vaccines under Mission COVID Suraksha. The DCGI's approval of Bharat Biotech's intranasal vaccine iNCOVACC® (BBV154) to be used as a heterologous booster dose against currently available COVID-19 vaccines is a moment of great pride for our country. This move will further strengthen our collective fight against the pandemic and broaden vaccine coverage."

"We are excited by the expansion of the EUA for iNCOVACC® as a booster, which enables this intranasal vaccine to be used by many more people, and hopefully curtail transmission," said Michael S. Diamond, MD, PhD, of Washington University in St. Louis, who co-developed the nasal vaccine technology with Washington University colleague David Curiel, MD, PhD. "This approval will increase the options for people to get vaccinated and protected against the SARS-CoV-2 virus during the ongoing pandemic."

Washington University licensed the vaccine technology to Bharat Biotech in 2020 for further development.

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 this approval, launch dates, pricing and availability will be announced 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 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).

More about COVAXIN® - https://www.bharatbiotech.com/covaxin.html

For more information, please contact:
Sheela Panicker: enright@enrightpr.com; +91 984 980 9594