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Bharat Biotech's intranasal vaccine iNCOVACC receives heterologous booster approval

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World’s first Intranasal vaccine for COVID-19 to receive approval for the primary 2-dose schedule, and heterologous booster dose

Hyderabad-based Bharat Biotech has 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. The vaccine 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. Washington University licensed the vaccine technology to Bharat Biotech in 2020 for further development.

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-19 vaccines in India.

Dr Rajesh S. Gokhale, Secretary, DBT, and Chairperson, BIRAC, said, “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.”