

Bharat Biotech's COVID-19 intranasal vaccine gets 'emergency use' approval

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World's first intranasal vaccine to receive approval for primary 2 dose schedule

Bharat Biotech has 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 pre-fusion 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 and clinical trials were funded in part by the Government of India through the Department of Biotechnology's, COVID Suraksha programme.

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.

Dr Krishna Ella, Chairman & Managing Director, Bharat Biotech, said, "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."