

Bharat Biotech completes clinical development for ph III trials of intranasal COVID-19 vaccine

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Data from both Phase III human clinical trials have been submitted for approval to National Regulatory Authorities

Bharat Biotech International Limited (BBIL) has announced that BBV154 (intra nasal vaccine) has proven to be safe, well-tolerated, and immunogenic in subjects in controlled clinical trials.

BBV154 is a recombinant replication-deficient adenovirus vectored vaccine with a pre-fusion stabilized spike protein. This vaccine candidate was evaluated earlier in phase I and II clinical trials with successful results. BBV154 has been specifically formulated to allow intranasal delivery. In addition, the nasal delivery system has been designed and developed to be cost-effective in low and middle-income countries.

It 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.

Suchitra K. Ella, Joint Managing Director, Bharat Biotech, said, "If approved, this intranasal vaccine will make it easier to deploy in mass immunization campaigns with an easy to administer formulation and delivery device. Vectored vaccines also enable faster development of targeted vaccines in response to emerging variants of concern. We hereby thank the volunteers, principle investigators, and clinical trial personnel for all their efforts."

BBV154 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.