



Ministry of Science & Technology

# First Nasal Vaccine Developed by Bharat Biotech supported by DBT-BIRAC gets nod of regulator for Phase 2 Trial

Posted On: 13 AUG 2021 5:57PM by PIB Delhi

The Department of Biotechnology (DBT) and its PSU, Biotechnology Industry Research Assistance Council (BIRAC) have been at the forefront in the fight against the prevailing global crisis. They together have strategized to fast-track R & D efforts especially for vaccine development, diagnostics, drug repurposing, therapeutics and testing. The development of vaccines has been the top priority of the Department of Biotechnology.

This Mission COVID Suraksha was launched to reinforce and accelerate COVID-19 vaccine development efforts as part of the third stimulus package, Atmanirbhar 3.0. The focus of this mission is to consolidate and streamline available resources towards a warpath for accelerated vaccine development in order to bring a safe, efficacious, affordable and accessible COVID-19 Vaccine to the citizens at the earliest with a focus on Atmanirbhar Bharat.

Bharat Biotech's intranasal vaccine is the first nasal vaccine that has received the regulatory approval for Phase 2 trials. This is the first of its kind COVID-19 jab to undergo human clinical trials in India. BBV154 is an intranasal replication-deficient chimpanzee adenovirus SARS-CoV-2 vectored vaccine. BBIL has in-licensed technology from Washington University in St Louis, USA.

Phase 1 Clinical trial has been completed in age groups ranging  $\geq 18$  to  $\leq 60$  years. The Company reports that the doses of the vaccine administered to healthy volunteers in the Phase I clinical trial, has been well tolerated. No serious adverse events reported. Previously, the vaccine was found to be safe, immunogenic and well tolerated in the pre-clinical toxicity studies. The vaccine was able to elicit high level of neutralizing antibodies in animal studies.

The regulatory approval has been received for conducting "A Phase 2 randomized, multi-centric, Clinical Trial of Heterologous Prime-Boost Combination of SARS-CoV-2 Vaccines to evaluate the immunogenicity and safety of BBV152 (COVAXIN®) with BBV154 (Adenoviral Intranasal COVID-19 vaccine) in Healthy Volunteers."

Dr Renu Swarup, Secretary, DBT and Chairperson, BIRAC speaking on the subject said that "the Department through Mission COVID Suraksha, is committed to development of safe and efficacious COVID-19 vaccines. Bharat Biotech's BBV154 Covid Vaccine is the first intranasal vaccine being developed in the country entering into late-stage clinical trials."

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For Further Information: Contact Communication Cell of DBT/ BIRAC

## **About DBT**

**f** The Department of Biotechnology (DBT), under the Ministry of Science & Technology, promotes and accelerates the **t** development of biotechnology in India, including **g** growth and application of **in**

*biotechnology in the areas of agriculture, healthcare, animal sciences, environment and industry.*

### **About BIRAC**

*The Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit Section 8, Public Sector Enterprise, set up by DBT, Government of India as an Interface Agency to strengthen and empower the emerging biotech enterprises to undertake strategic research and innovation for globally competitive product development to address unmet needs.*

### **About BBIL**

*Bharat Biotech 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) Pre-qualifications. Having delivered more than 4 billion doses of vaccines worldwide, Bharat Biotech 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. Bharat's commitment to global social innovation programs and public-private partnerships resulted in introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively.*

*SNC/TM/RR*

(Release ID: 1745509) Visitor Counter : 713

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