

## Bharat Biotech launches iNCOVACC®: World's 1<sup>st</sup> intranasal COVID vaccine for Primary series and Heterologous booster

- **iNCOVACC® is the world's first Intranasal vaccine for COVID to receive approval for the primary 2-dose schedule, and as a heterologous booster dose, administered as nasal drops.**
- **iNCOVACC® is a cost effective COVID vaccine which does not require syringes, needles, alcohol wipes, bandage, etc, saving costs related to procurement, distribution, storage, and biomedical waste disposal, that is routinely required for injectable vaccines.**
- **iNCOVACC® utilizes a vector-based platform, which can be easily updated with emerging variants leading to large-scale production, within a few months. These rapid response timelines combined with the ability of cost-effective and easy intranasal delivery, makes it an ideal vaccine to address future infectious diseases.**
- **A rollout of iNCOVACC® is expected to begin in private hospitals that have placed advance orders. Initial manufacturing capacity of several million doses per annum has been established, this can be scaled up to a billion doses as required. iNCOVACC® is priced at INR 325/dose for large volume procurement by State Governments and Govt of India.**
- **Phase III trials (as a 2-dose regimen) were conducted for safety, immunogenicity in ~3100 subjects, in 14 trial sites across India.**
- **Heterologous booster dose studies were conducted for safety and immunogenicity in ~875 subjects, with BBV154 intranasal vaccine administered in those previously completing a regimen of the commonly administered COVID vaccines. The trials were conducted in 9 trial sites across India.**
- **iNCOVACC® recipients demonstrated significant levels of Mucosal IgA antibody levels (measured in the saliva). Mucosal IgA antibodies in the upper respiratory tract may provide benefits in reducing infections and transmission.**

**New Delhi/Hyderabad, Jan 26, 2023:** Bharat Biotech International Limited (BBIL), a global leader in vaccine innovation and developer of vaccines for infectious diseases, today dedicated iNCOVACC® (BBV154) to the nation, world's 1<sup>st</sup> COVID intranasal vaccine for Primary series and Heterologous booster. iNCOVACC® was launched by Dr. Mansukh Mandaviya, Hon'ble Minister for Health and Family Welfare, in the presence of Dr. Jitendra Singh, Hon'ble Minister for Science & Technology, on the occasion of Republic Day.

Product development and clinical trials for iNCOVACC® were funded in part by the Government of India, through the Department of Biotechnology's, COVID Suraksha Program.

Bharat Biotech received approval from the Central Drugs Standard Control Organization (CDSCO) for iNCOVACC® to be administered for primary series and as heterologous booster doses. Amid growing COVID-19 cases and emerging variants of the highly transmissible virus, a booster dose of the vaccine becomes imperative. iNCOVACC® is now available on CoWIN, and priced at INR 800 for private markets and INR 325 for supplies to Govt of India and State Governments.

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.



This 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. As a needleless vaccination, Bharat Biotech's iNCOVACC® will be the world's first such booster dose. India will now have more options when it comes to third doses or precautionary doses.

Clinical trials and extensive humoral and cell mediated responses 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. The intranasal vaccine is stable at 2-8°C for easy storage and distribution and has been designed for efficient distribution and easy pain free administration.

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. The Technology Development Board, Govt of India, has been instrumental in debt financing for commercial scale manufacturing facilities.

Despite the lack of demand for COVID-19 vaccines, Bharat Biotech continued product development in intranasal vaccines, to be well-prepared with platform technologies for future infectious diseases. Bharat Biotech has also initiated development of variant-specific vaccines for COVID in an attempt to be future ready.

Dr. Mansukh Mandaviya, Hon'ble Minister for Health and Family Welfare, said, "The launch of iNCOVACC® vaccine is an important milestone in Atma Nirbhar Bharat vision. Today, India contributes 65% of the vaccine need of the world, saving lives of children, adolescents and adults. It is also great to note that, in global dialogue, India's manufacturing, research and innovation capabilities are admired. India will not be just known as the pharmacy of the world, but will be known for its research and innovation in vaccines."

Dr. Jitendra Singh, Hon'ble Minister for Science & Technology, said, "Bharat Biotech and the Department of Science and Technology are Natural Collaborators, and we owe this vaccine innovation to the world. India has taken the lead in vaccine innovation, as we have a legacy of dealing with communicable diseases. He added, iNCOVACC® nasal vaccine launched today will be a huge success, with Bharat Biotech's expertise, and diligence it will be a success story."

Dr. Krishna Ella, Executive Chairman, said, "With the rollout of iNCOVACC® today, we have achieved our goal of establishing a novel vaccine delivery platform for intranasal delivery. It proves that India can innovate for itself and for the world. We and the country are well prepared for future COVID-19 variants and future infectious diseases. We reaffirm our commitment to India, to lead innovation & develop novel vaccine technologies for combating infectious diseases & public health globally. We have proven these capabilities and expertise time and again with innovator vaccines such as TYPBAR TCV®, ROTAVAC®, JENVAC®, COVAXIN® and others. Bharat Biotech is a leading global developer and manufacturer of vaccines with more than 7 billion doses manufactured till date."

Ms. Suchitra Ella, MD, said, "It is exemplary that India has not only served herself during the pandemic challenges, but also a strong provider to the global platform in distributing vaccines & medicines to over 150 countries. With iNCOVACC® - the world's 1<sup>st</sup> intranasal COVID vaccine, we are privileged to defend the nation's health with global quality and scale."

"It is exciting to see the deployment of iNCOVACC® in India as a nasally-delivered vaccine and booster," said Dr. Michael S. Diamond, MD, PhD, of Washington University in St. Louis, who co-developed the nasal vaccine technology with Washington University colleague Dr. David T. Curiel, MD, PhD. "The continued waves of COVID-19 infection necessitate new strategies to overcome transmission. By generating immunity



in the upper respiratory tract at the portal of entry of the virus, this vaccine has the potential to better limit spread of the virus than other approaches. Washington University licensed the vaccine technology to Bharat in 2020 for further development.”

#### **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<sup>®</sup>), 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<sup>®</sup>, ROTAVAC<sup>®</sup>, ROTAVAC<sup>®</sup> 5D, and Typbar TCV<sup>®</sup> 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<sup>®</sup> and Indirab<sup>®</sup>. Bharat Biotech’s COVAXIN<sup>®</sup>, India's indigenous COVID-19 vaccine was developed in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV).

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