

Bharat Biotech's 'COVAXIN™' Emergency Use Authorization approval by DCGI-CDSCO, MoH&FW, a significant landmark in India's Scientific Discovery, and Scientists Capability

Hyderabad, January 03, 2021:

Expressing delight about Ministry of Health & Family Welfare announcement today from the statement from DCGI - Central Standards Control Organization (CDSCO) Grant of permission for emergency use of its Covid-19 Vaccine, **the Chairman and Managing Director of Bharat Biotech Dr. Krishna Ella said** *"The approval of COVAXIN™ for emergency use is a giant leap for Innovation and novel product development in India. It is a proud moment for the nation and a great milestone in India's scientific capability, a kickstart to the innovation ecosystem in India. While this vaccine addresses an unmet medical need during this pandemic, our goal is to provide global access to populations that need it the most. COVAXIN™ has generated excellent safety data with robust immune responses to multiple viral proteins that persist."*

Dr. Ella added, *On behalf of the Board, & all my colleagues at Bharat Biotech, we thank the Secretary MOH&FW Shri. Rajesh Bhushan, DCGI Dr. V G. Somani, member Niti Ayog, Dr. Vinod Paul, Principal Scientific Advisor Dr. Vijay Raghavan, Secretary Dept of Biotechnology Dr. Renu Swarup and the Government of India, for the grant of EUA for COVAXIN™.*

The development of COVAXIN™ was truly a public private partnership between ICMR, NIV and Bharat Biotech, we sincerely thank the Director General ICMR, Dr. Balram Bhargava for his visionary leadership in this project." **Dr. Ella further added.**

The Subject Expert Committee (SEC) of Central Drugs Standards Control Organization (CDSCO) makes recommendations in respect of Accelerated Approval Process request. The Subject Expert Committee of CDSCO met on 1st and 2nd January, 2021 and made the recommendations for the consideration and final decision of the Drugs Controller General of India.

COVAXIN™ is a highly purified and inactivated 2 dose SARS-CoV2 vaccine, manufactured in a Vero cell manufacturing platform with an excellent safety track record of more than 300 million doses.

The Phase III human clinical trials of COVAXIN™ began mid-November, targeted to be done in "26,000" volunteers across India, this is India's first and only Phase III efficacy study for a COVID-19 vaccine, and the largest phase III efficacy trial ever conducted for any vaccine in India. COVAXIN™ has been evaluated in approximately 1000 subjects in Phase I and Phase II clinical trials, with promising safety and immunogenicity results, with acceptance in international peer reviewed scientific journals.

COVAXIN™, India's indigenous COVID-19 vaccine by Bharat Biotech is developed in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV). This indigenous, inactivated vaccine is developed and manufactured in Bharat Biotech's BSL-3 (Bio-Safety Level 3) bio-containment facility, one of its kind in the world.

The evaluation of COVAXIN™ has resulted in several unique product characteristics including long term persistence of immune responses to multiple viral proteins, as opposed to only the spike protein, and

has demonstrated broad spectrum neutralizing capability with heterologous SARS-CoV2 strains, thus potentially reducing or eliminating escape mutants. It has also shown to generate memory T cell responses, for its multiple epitopes, indicating longevity and a rapid antibody response to future infections. Its most critical characteristic is the demonstrated safety profile, which is significantly lower than several other vaccines with published data.

The product development and clinical trial data thus far has generated 5 publications, which have been submitted to international peer reviewed journals, 4 of which have been accepted and will be published soon. The publication of phase II trial data is undergoing the peer review process. As a part of our regulatory guidelines, all data has been submitted to the DCGI and CDSCO.

COVAXIN™ Publications: 5 publications in 8 months.

<https://www.medrxiv.org/content/10.1101/2020.12.21.20248643v1>

<https://www.medrxiv.org/content/10.1101/2020.12.11.20210419v1>

<https://www.biorxiv.org/content/10.1101/2020.09.09.285445v2>

<https://www.researchsquare.com/article/rs-76768/v1>

<https://www.researchsquare.com/article/rs-65715/v1>

About Bharat Biotech

Bharat Biotech has established an excellent track record of innovation with more than 140 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 116 countries and WHO Pre-qualifications.

Located in Genome Valley, the hub for the global biotech industry, the company 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 4 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis, Rabies, Chikungunya, Zika and the world's first tetanus-toxoid conjugated vaccine for Typhoid.

The company is proficient in conducting extensive multi-centre clinical trials, having completed more than 75 trials enrolling more than ~ 700,000 participants globally. Our commitment to global social innovation programs and public-private partnerships resulted in the introduction of path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC® and Typbar TCV® combating Polio, Rotavirus and Typhoid infections respectively. Bharat Biotech has successfully partnered with NIV-ICMR having developed JENVAC®, a licensed Japanese Encephalitis vaccine.

The 2019 acquisition of Chiron Behring (CHIRORAB®), has positioned Bharat Biotech as the largest Rabies vaccine manufacturer in the world.

To learn more about Bharat Biotech visit www.bharatbiotech.com

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