COVAXIN™ clinical trials cross 23,000 subjects, and forges ahead, India’s largest Phase III trials

The product development and clinical trial data thus far has generated 5 publications, 4 of which have been accepted by international peer reviewed journals 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.

Hyderabad, January 02, 2021: Bharat Biotech has announced successful recruitment of 23,000 volunteers, and continued progress towards achieving the goal of 26,000 participants for Phase-3 clinical trial of COVAXIN™ across multiple sites in India.

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.

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.

Ms. Suchitra Ella, Joint Managing Director of Bharat Biotech said, “We thank every volunteer who has taken the time to participate in this trial. Their volunteering spirit is a great morale boost for India and the world. We thank all the Principle Investigators, Doctors, medical staff & the hospitals for their cooperation & support in taking the phase III trials forward in 26,000 volunteers in India. We continue our progress towards achieving the goal of 26,000 participants for Phase-3 clinical trials of COVAXIN™” Mrs. Ella added.
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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