

COVAXIN™ clinical trials cross 13,000 subjects, the half way mark and forges ahead, India's largest Phase III trials

Bharat Biotech thanks the trial participants and their sprit of volunteerism

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Hyderabad, December 22, 2020: Bharat Biotech has announced successful recruitment of 13,000 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.

Speaking on the occasion, Ms. Suchitra Ella, Joint Managing Director of Bharat Biotech said, "This is an unprecedented vaccine trial ever to take place in India, and we are overwhelmed with the steady rise in participation. We sincerely thank all the 13000 volunteers across the country for their support in enabling us to bring out a safe and efficacious Indian vaccine for COVID-19. This pro-vaccine public health volunteerism is a morale booster for us to achieve our milestone target of 26,000 soon – Thank you volunteers Thank you India."

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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