



Bharat Biotech starts Phase III trials for COVAXIN™ .

Hyderabad, India, November 16, 2020: Bharat Biotech has announced commencement of Phase III trials of COVAXIN™ today. **The Phase III trials will involve 26,000 volunteers across India**, conducted in partnership with ICMR. It is the largest clinical trial conducted for a COVID-19 vaccine in India.

This is India's first phase 3 efficacy study for a COVID-19 vaccine, and the largest phase III efficacy trial ever conducted in India. **The trial has been registered at www.ctri.nic.in (CTRI/2020/11/028976) and approved by the Drugs Controller General of India.**

Trial volunteers will receive two intramuscular injections approximately 28 days apart. Participants will be randomly assigned to receive COVAXIN™ or placebo. The trial is double blinded, such that the investigators, the participants and the company will not be aware of who is assigned to which group.

COVAXIN has been evaluated in ~ 1000 subjects in Phase I and Phase II clinical trials, with promising safety and immunogenicity data. Volunteers who wish to participate in this trial should be adults over 18 years of age.

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**. COVAXIN™ is a highly purified and inactivated vaccine, manufactured in a vero cell manufacturing platform with an excellent safety track record of more than 300 million doses supplied.

Speaking on the occasion, **Mrs. Suchitra Ella** Joint Managing Director of Bharat Biotech added, **“The development and clinical evaluation of COVAXIN™ marks a significant milestone for vaccinology in India, for a novel vaccine. It is important for Indian companies to innovate and develop indigenous vaccines, especially during a pandemic. COVAXIN™ has garnered interest from several countries worldwide for supplies and introduction.”**

This multicenter phase III study is conducted at the following sites across India. Participating Volunteers who undergo vaccination in the Phase III trials, will be monitored to detect occurrence of COVID-19 disease.

S#	City / State	Medical Center / Site
1.	Bhubaneswar	IMS SUM hospital
2.	New Delhi	Guru Tej Bahadur Hospital
3.	Mumbai	Grant Government Medical College and Sir J.J. Group of Hospitals
4.	Guntur	Guntur Medical College
5.	Bhopal	Gandhi Medical College
6.	Ahmedabad	Gmers Medical College and Civil Hospital
7.	Uttar Pradesh	Aligarh Muslim University
8.	Hyderabad	Nizams Institute of Medical Sciences
9.	Rohtak	Pandit Bhagwat Dayal Sharma University of Health Sciences
10.	Goa	Redkar Hospital and Research Centre

11.	Guwahati	Guwahati institute of medical sciences
12.	Faridabad	ESIC hospital
13.	New Delhi	AIIMS
14.	Mumbai	Lokmanya Tilak Municipal General Hospital And Medical College (Sion Hospital)
15.	Nagpur	Rahate hospital
16.	Patna	AIIMS
17.	Pondicherry	MG Medical College, Sri Balaji Vidyapeeth
18.	Bangalore	Vydehi institute of medical sciences
19.	Vizag	King Gorge Hospital
20.	Bhopal	People's University
21.	Kolkata	ICMR-National Institute of Cholera and Enteric Diseases
22.	Chennai	Directorate of Public Health and Preventive Medicine, Teynampet

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 300,000 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® combatting 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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