

Bharat Biotech and ICMR Announce Interim Results from Phase 3 trials of COVAXIN®; Demonstrates overall Interim Clinical Efficacy of 78% and 100% efficacy against Severe COVID-19 disease

- The second interim results showed India's First COVID-19 Vaccine had demonstrated strong primary efficacy against severe COVID-19 disease

Hyderabad, India, April 21, 2021: Bharat Biotech, a global leader in vaccine innovation, developing vaccines for infectious diseases, announced phase 3 interim analysis results of COVAXIN®. The second interim analysis is based on accruing more than 87 symptomatic cases of COVID-19. Due to the recent surge in cases, 127 symptomatic cases were recorded, resulting in a point estimate of vaccine efficacy of 78% (95%CI: 61-88) against mild, moderate, and severe COVID-19 disease.

The efficacy against severe COVID-19 disease was 100% (95%CI: 60-100), with an impact on reduction in hospitalizations. The efficacy against asymptomatic COVID-19 infection was 70%, suggesting decreased transmission in COVAXIN® recipients.

Safety and Efficacy results from the final analysis will be available in June, and the final report will be submitted to a peer-reviewed publication. Based on the achievement of the success criteria, placebo recipients have now become eligible to receive two doses of COVAXIN®.

The Phase 3 study enrolled 25,800 participants between 18-98 years of age, including 10% over the age of 60, with analysis conducted 14 days post 2nd dose. COVAXIN® was developed with seed strains received from the National Institute of Virology, and the phase 3 clinical trial was co-funded by the Indian Council of Medical Research, making it a true public, private partnership towards public health.

Dr. Krishna Ella, Chairman & Managing Director, Bharat Biotech, said, "Efficacy against SARS-Cov-2 has been established. COVAXIN® has demonstrated an excellent safety record in human clinical trials and in usage under emergency use. COVAXIN® is now a global innovator vaccine derived from Research & Development from India. The efficacy data against severe COVID-19 and asymptomatic infections is highly significant, as this helps reduce hospitalizations and disease transmission, respectively."

The protocols for manufacturing, testing and release of inactivated vaccines have been tried, tested and validated across several of our vaccines; these also meet the requirements of WHO, Indian and other regulatory authorities. These protocols have delivered consistent results over a 15-year period with more than 300 million doses supplied globally, with excellent safety and performance record.

Prof. Balram Bhargava, Secretary Dept. of Health Research & Director General, Indian Council of Medical Research, said, “I am very pleased to state that COVAXIN[®], the first indigenous COVID-19 vaccine developed by ICMR and BBIL, has shown the efficacy of 78% in the second interim analysis. The tireless efforts of our scientists at ICMR and BBIL have resulted in a truly effective international vaccine of the highest standards and efficacy. I am also happy to note that COVAXIN[®] works well against most variants of SARS-CoV-2. These findings together consolidate the position of our indigenous vaccine in the global vaccine landscape.”

Several million doses of COVAXIN[®] have been supplied and administered in India and several other countries with an excellent safety record, evident by the minimal or lack of adverse events post-immunization. COVAXIN[®] was approved and introduced initially through Emergency Use Authorization under the clinical trial mode, resulting in robust safety data in real-life conditions.

The company’s efforts to further develop COVAXIN[®] continues, with clinical trials planned in India and globally to evaluate its safety and immunogenicity in younger age groups, the impact of booster doses, and protection against SARS-CoV-2 variants.

Mrs. Suchitra Ella, Joint Managing Director, Bharat Biotech, said, “COVAXIN[®]’s evidence-based development has proved its suitability for global access, with excellent efficacy results against symptomatic, asymptomatic, and severe disease. The interest from countries worldwide has quietly validated our efforts. We thank our Volunteers, Principal Investigators, Partners and team Bharat Biotech for their contribution to this project towards improving Global Public Health.”

More than 60 countries globally have expressed their interest in COVAXIN[®]. These countries are highly satisfied with the safe, inactivated vaccine technology and robust data package for safety and immunogenicity across the whole SARS-CoV-2 virus. Emergency Use Authorizations have been received from several countries.

The company’s development efforts have been transparent and published in 6 peer-reviewed journals, with additional publications in process.

The capacity expansion has been implemented across multiple facilities in Hyderabad and Bangalore to reach ~ 700 million doses/year, one of the largest production capacities for Inactivated viral vaccines worldwide.



About Bharat Biotech

Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 123 countries, and the World Health Organization (WHO) Pre-qualifications. Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution.

Having delivered close to 5 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis (JENVAC®), Rabies, Chikungunya, Zika, Cholera, and the world's first tetanus-toxoid conjugated vaccine for Typhoid. Bharat's commitment to global social innovation programs and public-private partnerships resulted in introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The acquisition of Chiron Behring Vaccines, has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer with Chirorab® and Indirab®. To learn more about Bharat Biotech, visit www.bharatbiotech.com.

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