

COVAXIN exhibits 100% efficacy against severe COVID-19 disease

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



Bharat Biotech has 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 per cent (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.

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."

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.”