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COVAXIN shows 80.6 per cent efficacy in Ph 3 trials

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Bharat Biotech has announced the first interim analysis of its BBV152 (COVAXIN®). The whole virion inactivated COVID-19 vaccine candidate demonstrated an interim vaccine efficacy of 81 per cent in its Phase 3 clinical trial. The trials involved 25,800 subjects, the largest ever conducted in India, in partnership with the Indian Council of Medical Research.

“With today’s results from our Phase 3 clinical trials, we have now reported data on our COVID-19 vaccine from Phase 1, 2, and 3 trials involving around 27,000 participants,” said Dr Krishna Ella, Chairman & Managing Director, Bharat Biotech.

“I want to thank every one of the participants, who volunteered to participate in this vital clinical trial, our partners, principal investigators across 25 study sites, and our team at Bharat Biotech who dedicated their time to this vaccine discovery,” said Suchitra Ella, Joint Managing Director, Bharat Biotech.

The Phase 3 study enrolled 25,800 participants between 18-98 years of age, including 2,433 over the age of 60 and 4,500 with comorbidities. The primary endpoint of Phase 3 clinical trial is based on the first occurrence of PCR-confirmed symptomatic (mild, moderate, or severe) COVID-19 with onset at least 14 days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline.

The first interim analysis is based on 43 cases, of which 36 cases of COVID-19 were observed in the placebo group versus seven cases observed in the BBV152 (COVAXIN®) group, resulting in a point estimate of vaccine efficacy of 80.6 per cent.

Analysis from the National Institute of Virology indicates that vaccine-induced antibodies can neutralise the UK variant strains and other heterologous strains, which has been published in bioRxiv.

Bharat Biotech expects to share further details of the trial results as additional data become available. An additional interim analysis is planned for 87 cases, and the final analysis is planned for 130 cases.