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Bharat Biotech to initiate Ph 1 & 2 trials for COVID-19 vaccine

30 June 2020 | News

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Bharat Biotech, has successfully developed COVAXIN™ï¸•, India's 1st vaccine candidate for COVID-19, in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV).

The SARS-CoV-2 strain was isolated in NIV, Pune and transferred to Bharat Biotech. The indigenous, inactivated vaccine developed and manufactured in Bharat Biotech's BSL-3 (Bio-Safety Level 3) High Containment facility located in Genome Valley, Hyderabad, India.

The Drug Controller General of India - CDSCO, Ministry of Health & Family Welfare granted permission to initiate Phase I & II Human clinical trials after the company submitted results generated from preclinical studies, demonstrating safety and immune response. Human clinical trials are scheduled to start across India in July 2020.

Announcing the vaccine development milestone, Dr. Krishna Ella, Chairman and Managing Director said: "We are proud to announce COVAXIN™ï¸•, India's first indigenous vaccine against COVID-19.The collaboration with ICMR and NIV was instrumental in the development of this vaccine. The proactive support and guidance from CDSCO has enabled approvals to this project. Our R&D and Manufacturing teams worked tirelessly to deploy our proprietary technologies towards this platform."

Expedited through national regulatory protocols , the company accelerated its objective in completing the comprehensive pre-clinical studies. Results from these studies have been promising and show extensive safety and effective immune responses.