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India's first mRNA-based vaccine moves into Phase II/III trial

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Developed in partnership with DBT-BIRAC under Mission COVID Suraksha



Gennova Biopharmaceuticals, the Pune-based biotechnology company, working on the nation's first mRNA-based COVID-19 vaccine, submitted the interim clinical data of the Phase I study to the Central Drugs Standard Control Organisation (CDSCO), the Government of India's National Regulatory Authority (NRA).

Vaccine Subject Expert Committee (SEC) reviewed the interim Phase I data and found that HGCO19 was safe, tolerable, and immunogenic in the participants of the study.

Gennova submitted the proposed Phase II and Phase III study entitled "A Prospective, Multicentre, Randomized, Active-controlled, Observer-blind, Phase II study seamlessly followed by a Phase III study to evaluate the Safety, Tolerability, and Immunogenicity of the candidate HGCO19 (COVID-19 vaccine) in healthy subjects" which was approved by the office of the DCG(I), CDSCO.

The study will be conducted in India at approximately 10-15 sites in Phase II and 22-27 sites in Phase III. Gennova plans to use the DBT-ICMR clinical trial network sites for this study.

Gennova's mRNA-based COVID-19 vaccine development program was partly funded by the Department of Biotechnology (DBT), Govt. of India under Ind CEPI, way back in Jun 2020. Later on, the DBT further supported the program under the Mission COVID Suraksha- The Indian COVID-19 Vaccine Development Mission, implemented by BIRAC.