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DCGI approves India’s first indigenous mRNA vaccine for Ph I/II trial

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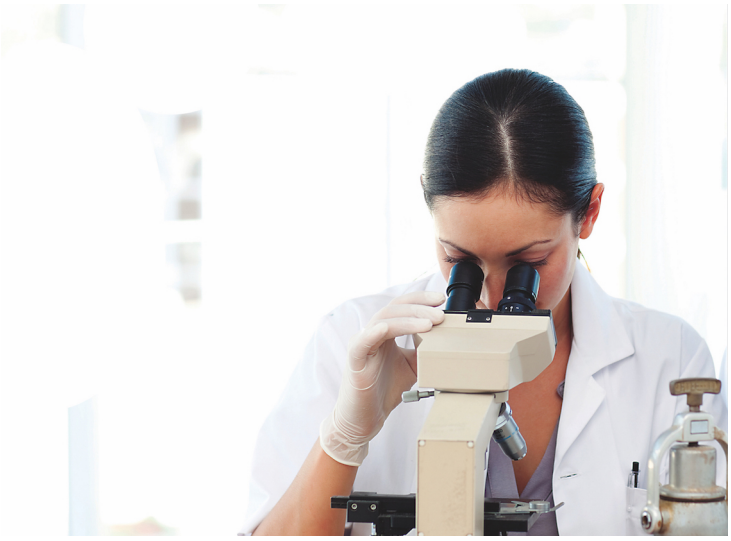

India’s first indigenous mRNA vaccine candidate has received approval from Indian drug regulators to initiate Phase I/II human clinical trial. The novel mRNA vaccine candidate, HGCO19 has been developed by Gennova, Pune and supported with seed grant under the Ind-CEPI mission of Department of Biotechnology.

mRNA-based vaccines are scientifically the ideal choice to address a pandemic because of their rapid developmental timeline. The mRNA vaccine is considered safe as is non-infectious, non-integrating in nature, and degraded by standard cellular mechanisms. They are expected to be highly efficacious because of their inherent capability of being translatable into the protein structure inside the cell cytoplasm.

Gennova, in collaboration with HDT Biotech Corporation, Seattle, USA, has worked together to develop an mRNA vaccine candidate. HGCO19 has already demonstrated safety, immunogenicity, neutralisation antibody activity in animals. The neutralising antibody response of the vaccine in mice and non-human primates was comparable with the sera from the convalescent patients of COVID-19. Gennova’s vaccine candidate uses the most prominent mutant of spike protein (D614G) and also uses the self-amplifying mRNA platform, which gives the advantage of a low dosing regimen compared with the non-replicating mRNA or traditional vaccines. HGCO19 uses the adsorption chemistry so that the mRNA is attached on the surface of the nano-lipid carrier to enhance the release kinetics of the mRNA within the cells compared to the encapsulation chemistry.

HGCO19 is stable at 2-8°C for two months. Gennova has completed all preliminary work and should be initiating the Phase I/II Human clinical trial soon since the approval from the DCGI office has been received.