Ministry of Science & Technology

Department of Biotechnology provides under Mission COVID Suraksha for Gennova Biopharmaceuticals Ltd.'s novel mRNA-based COVID 19 Vaccine candidate –HGCO19.

HGCO19: starting the enrolment for the PhaseI/II human clinical trials

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Vaccine Discovery Programme supported by the Department of Biotechnology, Govt. of India under the Mission COVID Suraksha- The Indian COVID-19 Vaccine Development Mission, implemented by BIRAC, moves into clinical trials

The Department of Biotechnology (DBT), Ministry of Science & Technologyhas announced that it has approved additional funding towards clinical studies of India's'first of its kind' mRNA-based COVID-19 vaccine - HGCO19, developed by Pune-based biotechnology company Gennova Biopharmaceuticals Ltd.

This funding has been awarded under the'Mission COVID Suraksha- The Indian COVID-19 Vaccine Development Mission'by DBT's dedicated Mission Implementation Unit at BiotechnologyIndustry Research Assistance Council (BIRAC) after multiplerounds of evaluation of all the applications that were submitted in response to the 'Request for Expression of Interest (REOI)'under Mission COVID Surakshafor the'Development of COVID-19 vaccine candidate(s)'.

DBT has been hand-holding Gennova's right from the start and has facilitated establishing Gennova's mRNA-based next-generation vaccine manufacturing platform by providing seed funding for the development of HGCO19. Gennova, in collaboration with HDT Biotech Corporation, USA,has developed theCOVID-19mRNA vaccine – HGCO19.

HGCO19 has already demonstrated safety, immunogenicity, neutralization antibody activityin the rodent and non-human primate models. The neutralizing antibody response of the vaccine in mice and non-human primates was comparable with the sera from the convalescent patients of COVID-19.Gennova has completed two preclinical toxicity studies as per theDrugs and Cosmetics (Ninth Amendment) Rules - 2019,to establish the safety of the vaccine candidate and got regulatory clearance from the Review Committee on Genetic Manipulation (RCGM) and office of the Drugs Controller General of India (DCGI), Central Drugs Standard Control Organization (CDSCO), Government of India, to conduct clinical trials. Gennova has initiated the process to enroll healthy volunteers from the Phase I/II clinical trials.

mRNA vaccines are considered safe as mRNA is non-infectious, non-integrating in nature, and degraded by standard cellular mechanisms. They are highly efficacious because of their inherent capability of being translatable into the protein structure inside the cell cytoplasm. Additionally,

mRNA vaccines are fully synthetic and do not require a host for growth, e.g., eggs or bacteria. Therefore, they can be quickly manufactured inexpensively under cGMP conditions to ensure their "availability" and "accessibility" for mass vaccination on a sustainable basis.

The establishment of such atechnology platform will empower India to handle the COVID-19 pandemic and ensure the preparedness for any future pandemic or endemic stage that will follow (mutation in the virus, unvaccinated low-risk population, newborns,etc.)by utilizing its rapid development path. Speed of this platform technology has been already proven during the COVID-19 outbreak as mRNA candidate was the first to enter the human trails globally

Dr. Renu Swarup, Secretary, DBT, and Chairperson, BIRAC, said, "At the onset of COVID-19, DBT backed many vaccine development programs, including the mRNA-based COVID-19 vaccine. A year back, this was a new technology and never used for vaccine manufacturing in India. However, believing in the potential of this technology, DBT provided seed funding to Gennova to develop this technology platform amenable to scale-up and production.We are very proud that India's first mRNA-based COVID-19 vaccine is going to the clinics."

She also mentioned that, "DBT is committed to fostering technological innovation in biotechnology in India .Through the Mission COVID Suraksha program provided support also towards scale-up and clinical studies. I wish Gennova grand success as this technology can address the mutant forms of the virus."

Speaking on the development, CEO of Gennova Biopharmaceuticals Ltd, Dr. Sanjay Singh, said, We conducted all required safety assessments of the HGCO19 as per well-defined norms and regulations before the start of the human clinical trial designed to establish the safety and efficacy of the HGCO19. Today, the problem of the SARS-CoV2 illness and the associated appearance of new variants made this disease a moving target. We believe the mRNA-based cutting-edge technology will play an important role in evolving effective solutions."

About DBT

The Department of Biotechnology (DBT), under the Ministry of Science & Technology, promotes and accelerates the development of biotechnology in India, including growth and application of biotechnology in the areas of agriculture, healthcare, animal sciences, environment, and industry.

About BIRAC:

Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit Section 8, Schedule B, Public Sector Enterprise, set up by the Department of Biotechnology (DBT), Government of India as an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.

About Gennova

Gennova Biopharmaceuticals Ltd., headquartered in Pune, India, is a biotechnology company dedicated to the research, development, production, and commercialization of biotherapeutics to address life-threatening diseases across various indications. To find out more, visit https://gennova.bio

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