File No: BIO/CT/22/000004

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits M/s Gennova Biopharmaceuticals Limited ,T-184 Emcure House Bhosari MIDC Pune Maharashtra (India) - 411026 Telephone No.: 020-39821300 FAX: 020-39821300 E-Mail : rajeshkumar.singh@gennova.co.in to conduct clinical trial of the new drug or investigational new drug as per protocol no. GBL/GEMCOVAC-19/2022/01 Version 3.0 Dated 10 Feb 2022 in the below mentioned clinical trial sites.

CT No.: CT- 09/2022

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

4. It may kindly be noted that merely granting permission to conduct Clinical trial with the vaccine does not convey or imply that, based on the Clinical trial data generated with the vaccine, permission to market this vaccine in the country will automatically be granted to you.

Place: New Delhi
Date: 29.03.2022

VENUGOPAL G SOMANI

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Date: 2022.03.29 17:12:19 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

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Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	HGCO19 Lyophilized mRNA Vaccine for Injection (COVID-19)	
Therapeutic class:	Vaccine	
Dosage form:	Lyophilized powder for Injection by Intramuscular route	
Composition:	Each 5 dose vial Contains:	
	Ingredients	**Quantity**
	m-RNA	50 mcg
	DOTAP	1.5 mg
	Squalene	1.88 mg
	Sorbitan Monostearate	1.86mg
	Polysorbate 80 Ph.Eur.	1.86 mg
	Sucrose IP	250 mg
	Citric acid monohydrate IP	5.25 mg
	Sterile Water for Injection IP (For reconstitution)	6 ml
Indications:	For active immunization against SARS-CoV-2 (COVID-19)	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Meditrina Institute 278, Central bazar road, Ramdaspeth, Nagpur, Nagpur - 440010,Maharashtra, India	Meditrina Institute Ethics Committee Meditrina Institute of Medical Sciences, 278, Central bazar road, Ramdaspeth, Nagpur, Nagpur - 440010,Maharashtra, India ECR/608/Inst/MH/2014/RR-20	Dr. Sandeep Mogre
2	JSS Medical College and Sri Shivarathreeshwara Nagar Mysuru (Mysore) Karnataka - 570015, India, Institutional	Institutional Ethics Committee JSS Medical College and Sri Shivarathreeshwara Nagar Mysore Mysuru (Mysore) Karnataka - 570015, India ECR/387/Inst/KA/2013/RR-19	Dr. M D Ravi
3	All India Institute of Medical Sciences (AIIMS), Tatibandh, GE Road, Raipur	Institute Ethics Committee, Room no. 2103, 2nd Floor, South Wing, Medical College Complex, Gate No. 5, AIIMS, Tatibandh, GE Road, Raipur, 492099 Chhattisgarh, India ECR/714/Inst/CT/2015/RR-21	Dr. Atul Jindal
4	Institute of Child Health, Dr. Biresh Guha Street Kolkata West Bengal-700017 India	Institutional Ethics Committee, ICH 11, Dr. Biresh Guha Street Kolkata West Bengal-700017 India ECR/359/Inst/WB/2013/RR-19	Dr. Kheya Ghosh Uttam
5	KEM Hospital, Rasta Peth Pune, Maharashtra - 411011 India	KEM Hospital Research Centre Ethics Committee and TDH building Rasta Peth IIIRD FLOOR. 303 Pune, Pune Maharashtra - 411011 ECR/272/Inst/MH/2013/RR-19	Dr. Amita Sapru

6	Maharaja Agrasen Hospital and Central Spine, Agrasen Aspatal Marg Sector 7, Vidhyadhar Nagar, Jaipur Jaipur Rajasthan - 302039 India	Institutional Ethics Committee, Maharaja Agrasen Hospital and Central Spine, Agrasen Aspatal Marg Sector 7, Vidhyadhar Nagar, Jaipur Jaipur Rajasthan - 302039 India. ECR/1222/Inst/RJ/2019	Dr. Vinay Kumar Gill
7	Mankar Hospital, Pune	Ethics Committee of Pulse Multispecialty Hospital Pulse Multispecialty Hospital, Survey No. 51/7/B/1 Vishwa Arcade, Mumbai Bangalore Highway, At Post Narhe, Pune, Maharashtra-411041 India ECR/1339/Inst/MH/2020	Dr. Sanjay Mankar
8	St. Theresa's hospital sanathnagar, opposite erragadda raitu bazar, Hyderabad, Hyderabad – 500018, Telangana, India	Ethics committee, st. Theresa's hospital sanathnagar, opposite erragadda raitu bazar, Hyderabad, Hyderabad – 500018, Telangana, India	ECR/230/Inst/AP/2013/RR-19
9	Kasturba Medical College, Manipal	MAHE Ethics Committee Manipal Academy of Higher Education, manipal Education building Madhav Nagar, Manipal, Udupi, Udupi – 576104, Karnataka ECR/191/Inst/KL/2013/RR-19	Dr. Dinesh M Nayak

In addition to point 4, the permission is subject to following condition(s):

I. The Phase II/III clinical trial should be conducted as per protocol titled "A Prospective, Multicentre, Randomized, Phase II study seamlessly followed by a Phase III study to evaluate the Safety, Tolerability and Immunogenicity of the candidate GEMCOVAC-19 (COVID-19 vaccine) in healthy pediatric subjects of 5 to less than 18 years" vide protocol no. GBL/GEMCOVAC-19/2022/01 Version 3.0 Dated 10 Feb 2022.
II. DSMB should be constituted for review of the safety data in the clinical trial for both the age groups >12 to <18 & >5 to <12 years at all the study time points.
III. Firm is required to submit immunogenicity data of Phase II part of both the age groups (>12 to <18 years & >5 to <12 years) before proceeding to Phase III part of trial in both age groups.
IV. Firm is required to submit report for Reference Standard Validation.
V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Date: 29-MAR-2022
Place: New Delhi

VENUGOPAL G SOMANI

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Digitally signed by VENUGOPAL G SOMANI
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