File No: BIO/CT/20/000158

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 Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078, Telephone No.: nil, Fax: nil, E-Mail:varma.bhupathiraju@biologicale.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol no. BECT062/Covid-19-phase-I&II/CTP-01 Version No.: 1.1 dated 07.10.2020** in the below mentioned clinical trial sites.

CT No.: CT- 25/2020

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.

VENUGOPAL GIRDHARILAL SOMANI

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

Date : 29.10.2020
Place: New Delhi

Stamp

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Covid-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 (RBD antigen of SARS CoV-2 (Covid-19))				
Therapeutic class:	Vaccine (recombinant RBD subunit vaccine)				
Dosage form:	Solution for Injection by Intramuscular route				
Composition:	Each dose of 0.5 mL Contain				
	Name of Active ingredient	**Quantity**			
		BECOV2A	**BECOV2B**	**BECOV2C**	**BECOV2D**
	RBD antigen of SARS CoV-2 (Covid-19)	50 µg	25 µg	25 µg	15 µg
	Name of Inactive ingredients				
	Aluminium Hydroxide gel as Al++	750 µg	750 µg	500 µg	750 µg
	CpG 1018	500 µg	500 µg	250 µg	500 µg
	Buffer (Tris and NaCl in WFI)	q.s to 0.5 mL	q.s to 0.5 mL	q.s to 0.5 mL	q.s to 0.5 mL
Indications:	For active immunization of at-risk persons to prevent COVID-19				

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	All India Institute of Medical Sciences, Sri Aurobindo Marg, Ansari Nagar East New Delhi –110029, India	All India Institute of Medical Sciences, Sri Aurobindo Marg, Ansari Nagar East New Delhi – 110029, India ECR/538/Inst/DL/2014/RR-20	Dr. Puneet Misra
2	UCMS & Guru Teg Bahadur Hospital Dilshad Garden, Shahdara Delhi -110095, India	Guru Teg Bahadur Hospital Ethics Committee, Guru Teg Bahadur Hospital, Dilshad Garden, East Delhi -110095 India ECR/510/Inst/DL/2014/RR-20	Dr. Shiva Narang
3	All India Institute of Medical Sciences Phulwari Sharif Patna –801507, Bihar, India.	Institutional Ethics Committee, All India Institute of Medical Sciences, Phulwarisharif, Patna Bihar -801507 India ECR/1387/Inst/BR/2020	Dr. Chandramani Singh
4	King George Hospital Collectorate Junction, Maharanipeta Visakhapatnam –530002 Andhra Pradesh, India	Institutional Ethics Committee, King George Hospital, Visakhapatnam–530002, Andhra Pradesh, India ECR/197/Inst/KGH/2013/RR-20	Dr. P. Venugopal

5	St. Theresa's Hospital Erragadda Main Road Czech Colony Sanath Nagar Hyderabad -500038, Telangana, India.	Ethics Committee, St. Theresa's Hospital, Sanath Nagar OPP Erragadda Raitu Bazar, Hyderabad Telangana - 500018 India ECR/230/Inst/AP/2013/RR-19	Dr. A. Venkateshwar Rao

In addition to point 3, the permission is subject to following condition(s):

I. The Phase I/II clinical trial should be conducted as per approved protocol titled " A prospective open label randomized phase-I seamlessly followed by phase-II study to assess the safety, reactogenicity and immunogenicity of Biological E's novel Covid-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 for protection against Covid-19 disease when administered intramuscularly in a two dose schedule (0, 28D) to healthy volunteers.." vide Protocol no. BECT062/Covid-19-phase-I&II/CTP-01 Version No.:1.1 dated 07.10.2020.
II. To submit DSMB safety evaluation data of Phase I study before proceeding to Phase II trial.
III. To submit Copy of the Insurance Certificate.
IV. To submit Ethics Committee approvals.
V. To submit Details of the contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator.
VI. To submit animal challenge study reports as and when completed preferably before initiation of Phase II clinical trial.
VII. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability programme.
VIII. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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(Dr. V. G. Somani)
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