

File No: BIO/CT/21/000004
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

From:

The Drugs Controller General, India
Directorate General of Health Services,

FDA Bhawan Kotla Road,
New Delhi-110002
Dated: 04-MAY-2021

To

M/s JSS Medical Research India Pvt. Ltd.,
Plot 12/2, 6th Floor, Vatika Mindscapes Tower- B,
Sarai Khwaja Metro Station, NH-2 Mathura Road, Sector 27- D,
Faridabad, Haryana- 121003, India

Subject: Permission for conducting a clinical trial titled "A prospective, randomized, multicentric, comparative Phase I/ Phase II clinical trial to evaluate the clinical safety, efficacy and tolerability of Equine Anti Covid Antibody Fragments F(ab')₂ as an add on therapy to Standard of Care (SOC) in comparison to SOC alone in hospitalized adult subjects with COVID-19 infection, with moderate severity", protocol no. VBP-EAF-001 version 4.0 dated 27 Apr 2021- regarding.

Reference: Your Application No. BIO/CT04/FF/2020/23478 dated 02-JAN-2021 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2020/23478 dated 02-JAN-2021 received by this office on the above subject. In this regard, please find enclosed herewith permission to conduct a Phase I/II clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

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

File No: BIO/CT/21/000004
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
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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 JSS Medical Research India Private Limited, Plot No. 12/2, 6th Floor, Vatika Mindscapes, Tower-B, Sector-27 D, Faridabad (India) -121003, Telephone No.: 9810979215 FAX: 1296613520 E-Mail: shariq.anwar@jssresearch.com to conduct clinical trial of the new drug or investigational new drug as per protocol no. VBP-EAF-001 version 4.0 dated 27 Apr 2021 in the below mentioned clinical trial sites.

CT No.: CT- 10/2021

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.

Date: 04-MAY-2021

Place: New Delhi

VENUGOPAL
GIRDHARILA
L SOMANI

(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:	Equine Anti Covid Antibody Fragments F(ab') 2	
Therapeutic class:	COVID Antisera	
Dosage form:	Solution for Injection	
Composition:	Each mL contains:	
	Equine COVID Antibody fragments F(ab')2	Neutralizing antibodies NLT 10000
	Sodium acetate	1.65 mg
	Sodium chloride	9 mg
	m-cresol	0.0015 mL
	Polysorbate-80 (Tween-80)	0.0005 mL
Indications:	For the treatment of COVID-19 infected patients with moderate severity.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	St. George Hospital, PD Mello Road, CST-Mumbai 400001 Maharashtra	Institutional Ethics Committee, GGMC, MUMBAI Grant Govt Medical College JJ Road, JJ Hospital compound Mumbai Central Mumbai Mumbai City Maharashtra - 400008 India. ECR/382/Inst/MH/2013/ RR-19	Dr. Darnule Rahul Ashok
2	Medanta Medicity, Sector 38, Gurugram Haryana-122001	Medanta Institutional Ethics Committee Medanta-The Medicity Medanta- The Medicty Sector 38, Gurugram Haryana-122001 ECR/282/Inst/HR/2013/ RR-20	Dr. Sushila Kataria
3	DIMHANS, S.P. Medical College & AG of Hospitals, Bikaner 334003, Rajasthan	Ethics Committee, S.P. Medical College, Bikaner S.P. Medical College, Bikaner S.P. Medical College, Bikaner Pawanpuri, Bikaner Bikaner Rajasthan - 334003 ECR/27/SP/Inst/RJ/2013 /RR-19	Dr. Sanjay Kumar Kochar
4	KLE Dr. Prabhakar Kore Hospital & MRC Site Management Office, 2ndfloor, KLE Dr. Prabhakar Kore Hospital, Belgavi-590010	Institutional Ethics Committee, KLE University KLE University KLE Dr. PK Hospital and MRC Nehru Nagar Belagavi Belgavi (Belgaum) Karnataka - 590010 India ECR/211/Inst/KA/2013/ RR-19	Dr. Madhav Prabhu
5	Sarojjini Naidu. Medical College, Raja Mandi, Near Agra College, central Liabrary, Moti	Institutional Ethics Committee S.N. Medical College, SN Medical College, Raja Mandi, Near Agra College, central Liabrary, Moti Katra, MantolaAgra Uttar Pradesh 282003 ECR/1409/Inst/UP/2020	Dr. Prabhat Agarwal

Katra, Mantola-Agra Uttar Pradesh-282003		
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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 title "A prospective, randomized, multicentric, comparative Phase I/ Phase II clinical trial to evaluate the clinical safety, efficacy and tolerability of Equine Anti Covid Antibody Fragments F(ab')₂ as an add on therapy to Standard of Care (SOC) in comparison to SOC alone in hospitalized adult subjects with COVID-19 infection, with moderate severity", protocol no. VBP-EAF-001 version 4.0 dated 27 Apr 2021.
- II. The firm is required to constitute a DSMB to review the safety data.
- III. The firm is required to submit the following documents:
 - a. Insurance certificate before initiation of clinical trial.
 - b. 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.
 - c. Principal investigator's undertaking as per the revised protocol.
 - d. Investigator's brochure as per the revised protocol.
- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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