File No: BIO/CT/21/000097

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. BECT073/MRV-PI/CTP-01, version no: 01, dated 10-JULY-2021in the below mentioned clinical trial sites.

CT No.: CT- 41/2021

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.

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 drug in the country with automatically be granted.

VENUGOPAL G SOMANI

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Date: 2021.12.28 17:29:06 +05'30'

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

Date: 28-DEC-2021
Place: New Delhi

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Measles (Edmonston Zagreb) and Rubella (RA27/3) Vaccine Live, Attenuated (Freeze Dried), IP	
Therapeutic class:	Vaccine	
Dosage form:	Lyophilized powder for Subcutaneous injection upon reconstitution with sodium chloride-0.9% w/v	
Composition:	Each reconstituted dose of 0.5mL contains:	
	Name of Active ingredient	**Quantity**
	Measles virus (Edmonston-Zagreb), propagated in MRC 5 cells	≥ 1000 $CCID_{50}$
	Rubella virus (Wistar RA 27/3 strain), propagated in MRC 5 cells	≥ 1000 $CCID_{50}$
	Name of Inactive ingredients	
	Citric acid	0.175mg
	Disodium Hydrogen phosphate	0.935mg
	Hydrolyzed Gelatin	25mg
	Sorbitol Solution	22.5mg
	Trehalose Dihydrate	25mg
	Human Albumin Solution	0.31mg
	L-Histidine	1mg
	L-Alanine	0.5mg
	L-Arginine Monohydrochloride	4mg
	L-Proline	8.5mg
	Glycine	5.63mg
	Magnesium Sulphate Heptahydrate	3.08mg
	Water for Injection	q.s. to 0.5mL
Indications:	For active immunization against infection Measles and Rubella Viruses.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Cheluvamba Hospital, Mysore Medical College and Research Institution, Irwin Road, Mysore.	Institutional Ethics Committee, Mysore Medical College and Research Institute Irwin Road Mysuru, Karnataka–570001,India. [ECR/134/Inst/KA/2013/RR-19)]	Dr. Prashanth S.

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

I. The Phase I clinical trial should be conducted as per approved protocol titled "A Phase I Open Label Study to Evaluate the Safety, Tolerability and Immunogenicity of Biological E's Live, Attenuated Measles Rubella Vaccine (MR) in 4-5 year Old Healthy Children" vide protocol no. BECT073/MRV-PI/CTP-01, version no: 01, dated 10/07/2021.

II. The firm is required to comply & submit following data/documents:

a. Constitute a DSMB to review the safety data of Phase I 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. The EC approval for the proposed Phase I study of MR vaccine as per New Drugs and Clinical Trials Rules, 2019.

III. Firm is required to obtain Form CT-11 for clinical trial as per New Drugs and Clinical Trials Rules, 2019.
IV. The details of manufacturing site that will be used for clinical batches and commercial manufacturing along with technology transfer plan, if any.
V. The reconstituted stability data of MR vaccine with diluent (sodium chloride-0.9% w/v) before start of clinical trial.
VI. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability programme.
VII. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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