File No: BIO/CT/20/000071
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 Mr. Varma B S S S Bhupathiraju of 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@biological.com to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: BECT061/PCV-Phase-III/CTP-01, Version No.: 1.0 Final dated 14.05.2020 in the below mentioned clinical trial sites.

CT No.: CT- 05/2021

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.

VENUGOPAL GIRDHARILAL SOMANI

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

Place: New Delhi
Date: 05-MAR-2021

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent)	
Therapeutic class:	Vaccine	
Dosage form:	Suspension for Intramuscular injection	
Composition:	Each dose of 0.5 ml contains	
	Name of Active ingredient	**Quantity**
	Pneumococcal Polysaccharide Serotype 1	3.0 µg
	Pneumococcal Polysaccharide Serotypes 3, 4, 5, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F	2.2 µg
	Pneumococcal Polysaccharide Serotype 6B	4.4 µg
	Name of Inactive ingredients	
	Adsorbed onto Aluminum Phosphate, as Al+++	0.5 mg
	Succinic Acid	295 µg
	Polysorbate 20	0.35 mg
	0.6% w/v Sodium Chloride Solution	q.s.
	2-Phenoxyethanol	4 mg
	1 N Sterile Hydrochloric Acid Solution	q.s.
	1 N Sterile Sodium Hydroxide Solution	q.s.
	*Polysaccharides conjugated to 20 –50 µg of CRM197	
Indications:	For active immunization for the prevention of disease caused by Streptococcus pneumonia serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33 F in infants ages 6-8 weeks at first dose.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	King George Hospital, Andhra Medical College, Visakhapatnam –530 002.	Institutional Ethics Committee, King George Hospital, Maharani pet, Collector Office Junction, Visakhapatnam-530 002, India.	Dr. P. Venugopal
2	Guru Teg Bahadur Hospital, Dilshad Garden, North East Delhi –110 095, India.	Guru Teg Bahadur Ethics Committee,Guru Teg Bahadur Hospital,Dilshad Garden, North East Delhi -110 095.	Dr. Manish Narang
3	Mysore Medical College and Research Institute and Associate Hospitals, Irwin Road, Mysore - 570 001, Karnataka.	Institutional Ethics Committee, MMC and RI and Associated Hospitals,Mysore Medical college and Research Insitute, Irwin Road, Mysuru, Karnataka - 570 001.	Dr. S. Prashanth
4	KLEs Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar Belagavi – 590 010	Institutional Ethics Committee, KLE University KLE Dr.PK Hospital and MRC, Nehru Nagar Belagavi (Belgaum)	Dr. N. S. Mahantashetti

		Karnataka - 590010 India	
5	St. Theresa's Hospital, Erragadda, Santhanagar, Hyderabad - 500 018, Telangana India.	Ethics Committee, ST. Theresa's Hospital, Sanath Nagar, OPP Erragadda Raitu Bazar, Hyderabad Telangana - 500018	Dr. G. Bala Kishor

In addition to point 3, the permission is subject to following conditions:

I. The clinical trial should be conducted as per approved protocol titled " A single blind randomised active-controlled Phase-III study to evaluate safety and immunogenicity of a candidate 14-valent pneumococcal polysaccharide conjugate vaccine administered to 6-8 weeks old healthy Indian Infants in 6-10 -14 weeks dosing schedule" vide Protocol No.: BECT061/PCV-Phase-III/CTP-01, Version No.: 1.0 Final dated 14.05.2020".
II. The firm is required to constitute a DSMB to review the safety data.
III. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures.
IV. To submit the copy of Insurance Certificate (Certificate Only) before initiation of subject trial.
V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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