File No: BIO/CT/22/000034

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. Sathyan Kuppusamy of M/s Tergene Biotech Private Limited ,Suite 121 & 122, Building 450, Genome Valley, Turkapally (V), Shamirpet (M), RR Dist, HYDERABAD (India) - 500078 Telephone No.: 9959013131 FAX: 40-23480075 E-Mail: ks@tergene.com to conduct clinical trial of the new drug or investigational new drug as per Protocol no.: CBCC/2021/029, Version no.:2.0, Dated 30.06.2022 in the below mentioned clinical trial sites.

CT No.: CT- 21/2022

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.

VENUGOPAL G SOMANI

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

Date: 15-SEPT-2022
Place: New Delhi

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed), I.P. (15 valent)	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for Injection for Intramuscular (IM) route of administration	
Composition:	Each dose of 0.5 mL vaccine contains:	
	*Pneumococcal polysaccharide for serotypes 1, 2, 3, 4, 5, 6A, 7F, 9V, 12F, 14, 18C, 19A, 19F & 23F and for serotype 6B	2.2 µg
	*Pneumococcal polysaccharide for serotype 6B	4.4 µg
	*Conjugated to CRM_{197} carrier protein (~35 µg) and adsorbed on aluminium phosphate (0.125 mg aluminium)	
	2-Phenoxyethanol	5 mg
	Polysorbate 80	0.1 mg
	Sodium chloride	4.5 mg
	Water for injection	q.s to 0.5ml
Indications:	For Active immunization against Pneumonia and Invasive Disease caused by Streptococcus pneumoniae serotypes 1, 2, 3, 4,5, 6A, 6B, 7F, 9V,12F, 14, 18C, 19A, 19F and 23F in infants and children from 6 weeks up to 5 years of age.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	KLE'S Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum 590010, Karnataka.	Institutional Ethics Committee, KLE University, Belgaum Karnataka - 590010 [ECR/211/Inst/KA/2013/RR-19]	Dr. Mahantesh Patil
2	Suyog Hospital, Nashik 2nd Floor, B-Wing, Krushi Utpanna Bazar, Samiti Sankul, Dindori Rd, Panchavati, Nashik - 422003, Maharashtra.	Institutional Ethics Committee, Suyog Hospital, 2nd Floor, B-Wing Krushi Utpanna Bazar Samiti Sankul, Dindori Road Panchavati Maharashtra-422003 [ECR/965/Inst/MH/2017/RR-2020]	Dr. Reena Rathi
3	Cheluvamba Hospital, Mysore Department of Paediatrics Mysore, Irwin Road, Mysore-570001, Karnataka	Institutional ethics committee, Mysore Medical college and Research Institute and Associate Hospitals, Irwin Road, Myosre– 570001, Karnataka [ECR/134/Inst/KA/2013/RR-19]	Dr. Pradeep. N
4	Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar,	Institutional Ethics Committee, Yashwantrao Chavan Memorial	Dr. Deepali

	Pimpri, Pune-411018, Maharashtra.	Hospital, Sant Tukaram Nagar, Pimpri, Pune-411018, Maharashtra, India [ECR/1236/Inst/MH/2019]	Ambike
5	Niloufer Hospital, Red Hills, Lakdikapul, Hyderabad-500004, Telangana.	Institutional Ethics Committee, Niloufer Hospital, Red Hills, Lakdikapul, Hyderabad-500004, Telangana, India [ECR/300/Inst/AP/2013/RR-19]	Dr. N. Ravi Kumar

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

I. The Phase III clinical trial should be conducted as per title “A Phase 3, Observer blind, Randomized, Active-Controlled Trial Evaluating the Immunologic Non-inferiority, Safety and Tolerability of a 15-valent Pneumococcal Conjugate Vaccine Compared to a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given in a Reduced Dosing Schedule with Routine Pediatric Vaccinations” vide Protocol no.: CBCC/2021/029, Version no.:2.0, Dated 30.06.2022.
II. The firm is required to constitute a DSMB to review the safety data of clinical trial.
III. Copy of Ethics committee approval for conduct of proposed Phase III clinical trial
IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and using validated procedures.
V. Only CDL, Kasauli certified0020batches shall be used in the clinical trial.

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

Date: 15-SEPT-2022
Place: New Delhi