File No: BIO/CT/20/000137

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 Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078, Telephone No.: nil, Fax: nil, E-Mail:dra@bharatbiotech.com, to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: BBIL/CHIKV/II-III/2019 Protocol Version 1.0 Dated 30 Jul 2020** in the below mentioned clinical trial sites.

CT No.: CT- 17/2021

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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Date: 2021.06.04 17:49:11 +05'30'

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

Place: New Delhi
Date: 04/06/2021

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CDSCO CDSCO CENTRAL DRUGS STANDARD CONTROL ORGANISATION MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

Annexure:
Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Chikungunya vaccine (Inactivated)
Therapeutic class:	Vaccine
Dosage form:	Suspension for Injection for Intramuscular administration
Composition:	Each dose of 0.5 ml contains:

Name of Active ingredient	**Quantity**	**Quantity**
Purified, inactivated Chikungunya virus protein	NLT 20 µg	NLT 40 µg
Name of Inactive ingredients	**Quantity**	**Quantity**
Aluminium hydroxide gel equivalent to Al^{+++}	0.25mg	0.25mg
2-phenoxyethanol IP	2.5mg	2.5mg
Phosphate buffer saline (PBS)	qs to 0.5mL	qs to 0.5mL

Indications:	Active immunization for prevention of Chikungunya virus infection

Details of clinical trial sites:

S. No.	**Name and Address of Clinical Trial Site**	**Ethics Committee details**	**Name of Principal Investigator**
1	KEM Hospital Research Center, Vadu Rural Health program, Vadu Budruk, Tal : Shirur, Dist.: Pune 412216 Maharashtra	KEM Hospital Research Center Ethics committee, Sardar Moodliar Road, Rasta Peth Pune, Maharashtra 411011 ECR/272/Inst/MH/2013/RR-19	Dr. Anand Shantaram Kawade
2	Kasturba Medical College, Manipal Academy of Higher education, Madhav nagar, Manipal 576104, Karnataka	Manipal Academy of Higher education ethics commitee, Mezzanine floor, KMC old library building , Madhav nagar, Manipal 576104, Karnataka ECR/191/Inst/KL/2013/RR-19	Dr. Veena Ganesh Kamath
3	Hamdard Institute of medical sciences and research (HIMSR & associated Hakeem Abdul Hameed centenary Hospital (HAHCH), Hamdard Nagar, new Delhi, 110062	Jamia Hamdard institutaional ethics committee, Basement, Biotechnology building, Jamia Hamdard, Hamdard Nagar, New Delhi, 110062 ECR/48/Inst/DL/2013/RR-19	Dr. Sunil Kohli
4	King George Hospital, KGH Down Rd, Opp KGH OP Gate, Maharani Peta, Visakhapatnam, Andhra Pradesh 531011	Ethics Committee King George Hospital , Opp KGH OP Gate, Maharani Peta, Visakhapatnam, Andhra Pradesh 531011	Dr R Vasudev
5	BJ Medical College & Hospital, Asarva, Ahmedabad, Gujarat 380016	Institutional Ethics Committee, BJ Medical College & Hospital, Asarva, Ahmedabad, Gujarat 380016 ECR/72/Inst/GJ/2013/RR-19	Dr.KartikeyaParmar
6	Institute of Medical Sciences (IMS) & SUM Hospital, K 8, Kalinga Nagar, Ghatikia, Bhubaneshwar -751003, Odisha	Institutional Ethics Committee, IMS & SUM Hospital, K 8, Kalinga Nagar, Ghatikia, Bhubaneshwar 751003, Odisha ECR/627/Inst/OR/2014/RR-20	Dr. E. Venkata Rao

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

I. The Phase II/III clinical trial should be conducted as per protocol titled “A Seamless Phase II/III, Double-blind, Multi-centre, Randomized Clinical Trial to Evaluate Immunogenicity and Safety of BBV87, an Inactivated Chikungunya Virus Vaccine in Healthy Subjects 12-65 Years of Age” vide Protocol No: BBIL/CHIKV/II-III/2019 Version No: 1.0 Date: 30-07-2020.
II. Firm is required to submit Phase II clinical trial report for further evaluation as per SEC recommendations
III. DSMB to be constituted for assessment of safety.
IV. Firm is required to submit
    a. Risk assessment, Change over procedures to be followed for campaign based manufacturing & cleaning validation protocol and report.
    b. Manufacturing Process Validation of Drug substance & drug product before commencing of Phase III studies.
    c. Validation of Analytical Method procedures before commencing of Phase III studies
V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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(Dr. V. G. Somani)
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