File No: BIO/CT/20/000180
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 Licensing Authority hereby permits M/s Indian Immunological Limited, Rakshapuram, Gachibowli post Hyderabad Rangareddi Hyderabad-500032, India, Telephone No.: 04023000211, FAX no.: 04023000512, E-mail: msrs@indimmune.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol no.: HBI/Deng/I/2020/003.01.02 Version 1.0 Amendment 02 Dated: 21 June 2022** in the below mentioned clinical trial sites.

CT No.: CT- 19/2022

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.

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 vaccine in the country will automatically be granted to you.

VENUGOPAL G SOMANI

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

Place: New Delhi
Date: 09-SEP-2022

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Live Attenuated Tetravalent Recombinant Dengue Vaccine</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Lyophilized powder for subcutaneous injection</td></tr>
<tr><td>Composition:</td><td>Each dose of 0.5 ml reconstituted vaccine contains:
<table>
<tr><th>Name of Active ingredient</th><th>Quantity</th></tr>
<tr><td>rDENV-1</td><td>$\geq 3\ log_{10}$PFU</td></tr>
<tr><td>rDENV-2</td><td>$\geq 4\ log_{10}$PFU</td></tr>
<tr><td>rDENV-3</td><td>$\geq 3\ log_{10}$PFU</td></tr>
<tr><td>rDENV-4</td><td>$\geq 3\ log_{10}$PFU</td></tr>
<tr><td>Human Albumin</td><td>25 mg</td></tr>
<tr><td>Maltose</td><td>22.5 mg</td></tr>
<tr><td>MEM with Hanks'salts(HMEM)</td><td>q.s. to 0.5 mL</td></tr>
</table>
to be reconstituted with sterile water for injection</td></tr>
<tr><td>Indications:</td><td>Prophylaxis against Dengue.</td></tr>
</table>

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Bharati Vidyapeeth (Deemed to be University) Medical College & Hospital, Pune-Satara Road, Katraj-Dhankawadi, Pune-411043, Maharashtra	Ethics Committee - Bharati Vidyapeeth Medical College & Hospital, , Pune-Satara Road, Katraj-Dhankawadi, Pune-411043, Maharashtra ECR/313/Inst/MH/2013/RR-1	Dr. Sonali Palkar
2	JSS Medical College &Hospital, Mahatma Gandhi Road, Mysuru-570 004,Karnataka	Ethics Committee -JSS Medical College & Hospital, ECR/387/Inst/KA/2013/RR-19	Dr. Prathibha Pereira

In addition to point 4, the permission is subject to following conditions:

I. The clinical trial should be conducted as per approved protocol titled "A phase I single blind randomized placebo controlled study to evaluate the safety and immunogenicity of live attenuated tetravalent recombinant Dengue Vaccine of HBI in healthy adults of 18 to 50 years of age." Protocol Number: HBI/Deng/I/2020/003.01.02 Version, 1.0, Amendment 02, Dated: 21 June 2022.
II. Firm is required to obtain permission in Form CT-11 to manufacture live attenuated tetravalent recombinant Dengue vaccine for clinical trial purpose.
III. Firm is required to submit copy of the Insurance Certificate before initiation of the trial.
IV. DSMB shall be constituted for assessment of safety.
V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability programme.
VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA),
pseudonym=112046a34e21727bacb255748732c456d249073e55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba41522525ffca0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.09.12 11:16:53 +05'30'

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

Place: New Delhi
Date: 09-SEP-2022