सत्यमेव जयते

Government of India
Central Drugs Standard Control Organisation(Headquarter)
(Directorate General of Health Services)
FDA Bhavan, ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail: dci@nic.in

File No. BIO/CT/24/000083 Dated 26-12-2024

To

M/s Serum Institute of India Pvt. Ltd.,
212/2, Off. Soli Poonawala Road,
Hadapsar, Pune – 411 028,
Maharashtra, India.

Subject: Application for grant of permission to conduct Phase III Clinical trial titled –"A Phase III, Double-Blind, Randomized, Placebo-Controlled, Multicentric Study of Dengue Monoclonal Antibody in Children ≥5 Years and Adults with Dengue" vide Protocol No. Dengue-mAb-03; Version 1.0 dated 04.07.2024 - regarding.

Ref.: Your Application No BIO/CT04/FF/2024/44455 dated 22-07-2024.

Sir,

With reference to your Application No. BIO/CT04/FF/2024/44455 dated 22-07-2024, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019. Further the Insurance certificate mentioning the protocol number and number of subjects should be submitted to CDSCO before initiating the trial.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

(I) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licensing Authority under rule 8;

(II) Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

(III) In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

(IV) The Central Licensing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;

(V) Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;

(VI) Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;

(VII) Status of enrolment of the trial subjects shall be submitted to the Central Licensing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

(VIII) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority electronically in the SUGAM portal;

(IX) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination;

(X) Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licensing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;

(XI) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter;

(XII) In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter;

(XIII) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorised by the Central Licensing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;

(XIV) The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;

(XV) The Central Licensing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;

(XVI) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(XVII) where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified.

(XVIII) It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

(XIX) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of two years from the date of its issue, unless extended by the Central Licencing Authority.

(XX) The firm should submit Clinical study report (CSR) to this office after completion of trial.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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Date: 2024.12.26 14:58:58 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

File. No. BIO/CT/24/000083

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 Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawala Road, Hadapsar, Pune – 411 028, Maharashtra, India** to conduct clinical trial of the new drug or investigational new drug study titled –"A Phase III, Double-Blind, Randomized, Placebo-Controlled, Multicentric Study of Dengue Monoclonal Antibody in Children ≥5 Years and Adults with Dengue" vide Protocol No. Dengue-mAb-03; Version 1.0 dated 04.07.2024 in the below mentioned clinical trial sites.

2. Details of 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.

Place: New Delhi
Date: 26.12.2024

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Annexure:

Details of new drug or investigational new drug:

<table>
<tr><td>Name of the new drug or investigational new drug</td><td>Dengue Monoclonal Antibody (Recombinant)</td></tr>
<tr><td>Therapeutic class</td><td>Monoclonal Antibody (Recombinant)</td></tr>
<tr><td>Dosage form:</td><td>Solution for intravenous infusion</td></tr>
<tr><td>Composition:</td><td>
<table>
<tr><th>Name of Ingredient</th><th>Quantity per ml</th><th>Reference to Pharmacopoeial Standards</th><th>Function</th></tr>
<tr><td>Dengue Monoclonal Antibody</td><td>25 mg</td><td>In-house</td><td>Active ingredient</td></tr>
<tr><td>L-Histidine</td><td>0.67 mg</td><td>BP/Ph.Eur.</td><td>Buffering Agent</td></tr>
<tr><td>L-Histidine Monohydrochloride</td><td>4.33 mg</td><td>BP/Ph.Eur.</td><td>Buffering Agent</td></tr>
<tr><td>L-Arginine</td><td>2.26 mg</td><td>BP/Ph.Eur.</td><td>Stabilizer</td></tr>
<tr><td>L-Arginine Hydrochloride</td><td>13.06 mg</td><td>BP/Ph.Eur.</td><td>Stabilizer</td></tr>
<tr><td>Sodium Chloride</td><td>5.90 mg</td><td>IP/ BP/Ph.Eur.</td><td>Tonicity Enhancer</td></tr>
<tr><td>Sucrose</td><td>5.00 mg</td><td>BP/Ph.Eur.</td><td>Stabilizer</td></tr>
<tr><td>Polysorbate-80</td><td>0.20 mg</td><td>IP/ BP/Ph.Eur.</td><td>Surfactant</td></tr>
<tr><td>Water for Injection</td><td>q.s.</td><td>IP/ BP/Ph.Eur./ USP</td><td>Vehicle</td></tr>
</table>
</td></tr>
<tr><td>Indications:</td><td>For treatment of Dengue</td></tr>
</table>

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	M.V. Hospital and Research Centre, 1st Floor, 314/30, Mirza Mandi, Chowk Lucknow Uttar Pradesh - 226003	Institutional Ethics Committee M.V. hospital and research Centre, 1st floor, 314/30, Mirza Mandi, Chowk, Lucknow – 226003, Uttar Pradesh, India ECR/13/Inst/UP/2023/RR-24	Dr. Sandeep Gupta, MD

2	Seth G. S. Medical College and KEM Hospital, Acharya Donde Marg, Parel east, Parel, Mumbai -400 012, Maharashtra, India	Institutional Ethics Committee-1, Ground Floor, UG-PG hostel, Seth G S Medical College and KEM Hospital, Mumbai -400012 ECR/229/Inst/MH/2013/RR-24	Dr. Nithya Gogtay, MD
3	Swami Harshankaranand Ji Hospital and Research Center, Newada, Sundepur, Varanasi – 221 005, India	Independent Ethics Committee Namaste Integrated Services 3rd Floor, B-31/80-23B, Bhogabeer, Lanka, Varanasi – 221005, Uttar Pradesh, India ECR/340/Indt/UP/2021	Dr. Indraneel Basu, MD
4	Atharva Multispecialty Hospital and Research Center, H-4/Comm -2 construction Div -21, Avas Vikas Pari shad Sector –E, Lucknow-226 003, Uttar Pradesh, India	Institutional Ethics Committee Atharva Multispeciality Hospital & Research Centre, H-4/Comm-2, construction Div-21, UP Avas Vikas Parishad Sector –E, Lucknow-226 003, Uttar Pradesh India, ECR/1241/Inst/UP/2019	Dr. Vineet Shukla, MD
5	Radiant Superspecialty Hospital Research Department, 3rd Floor Rehab Building, Near Kalyan Nagar Square, Sabnis Plot, Amravati – 444 606, Maharashtra, India	Radiant Superspeciality Hospital Ethics Committee Sabnis Plot, Near Kalyan Nagar square, Amravati -444 606 Maharashtra, (India) ECR / 997 / Inst. / MH / 2017 / RR -21	Dr. Ganesh Bansod, MD
6	Department of Pharmacology, 2nd Floor, College Building, Lokmanya Tilak Municipal Medical College and General Hospital, Dr Babasaheb Ambedkar Road, Sion, Mumbai – 400 002, Maharashtra, India	Institutional Ethics Committee Room No. 17, 2nd floor, College Building, Lokmanya Tilak Municipal Medical College and General Hospital, Dr Babasaheb Ambedkar Road, Sion, Mumbai – 400 002, India ECR/266/Lokmanya/Inst/MH/2013/RR -19	Dr. Sudhir Pawar, MD

7	Clinical Research Centre – HIMSAR with SAS Hamdard Institute of Medical Sciences and Research (HIMSR) with Society for Applied Studies (SAS), Hakeem Abdul Hameed Centenary Hospital (HAHCH), Guru Ravidas Marg, Hamdard Nagar, New Delhi – 110 062, India	Institutional Ethics Committee HIMSR And Associated HAH Centenary Hospital, Guru Ravidas Marg Hamdard Nagar South West Delhi, South West Delhi Delhi - 110062 India ECR/1597/Inst/DL/2021	Dr. Vineet Jain, MD