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/23/000143 Dated 21.03.2025

To,

M/s Roche Products (India) Private Limited,
146 B, 166 A, Unit No 7,8,9, 8th floor, R city office, R City Mall
Lal Bahadur Shastri Marg, Ghatkopar (West)
Mumbai (India) – 400086

Subject: Application for grant of permission to conduct Phase IV clinical trial entitled – " A Phase IV, open label, study evaluating the safety and efficacy of polatuzumab vedotin in combination with Rituximab and CHP(RCHP) in previously untreated adult patients with diffuse large B-Cell Lymphoma (DLBCL) vide Protocol No ML45360, version 2 dated 02.05.2024- regarding

Ref. No.: Your Application No. BIO/CT04/FF/2023/40827 dated 05.12.2023

Sir,

With reference to your application No.: BIO/CT04/FF/2023/40827 dated 05-DEC-2023, 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.

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

(I) You are required to submit the Clinical study report after completion of study to this office.
(II) 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
(III) 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;

(IV) 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;
(V) 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;
(VI) 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.

(VII) 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.

(VIII) 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;

(IX) 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.

(X) 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.

(XI) 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.

(XII) 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.

(XIII) 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.

(XIV) 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 authorized 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.

(XV) 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.

(XVI) 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.

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

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

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

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 Roche Products (India) Private Limited, 146 B, 166 A, Unit No 7,8,9, 8th floor, R city office, R City Mall Lal Bahadur Shastri Marg, Ghatkopar (West) Mumbai (India) – 400086 Telephone No.: 22-33941443, 22-33941415, 22-33941413 FAX: 22-33941054 E-Mail : VIPUL.GUPTA@ROCHE.COM to conduct Phase IV clinical trial entitled **"A Phase IV, open label, study evaluating the safety and efficacy of polatuzumab vedotin in combination with Rituximab and CHP(RCHP) in previously untreated adult patients with diffuse large B-Cell Lymphoma (DLBCL)"** vide Protocol No ML45360, version 2 dated 02.05.2024 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: 21-March-2025

RAJEEV SINGH RAGHUVANSHI

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Date: 2025.03.21 17:52:07 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Annexure:

Details of new drug or investigational new drug:

<table>
<tr><td>Names of the new drug or investigational new drug:</td><td>Polatuzumab Vedotin for Injection, 30mg/vial and 140 mg/vial (r-DNA origin)</td></tr>
<tr><td>Therapeutic class</td><td>Anti-cancer</td></tr>
<tr><td>Dosage form:</td><td>Powder for concentrate for solution for infusion</td></tr>
<tr><td>Composition:</td><td>
<table>
<tr><th>Name of Ingredients</th><th>Specifications</th><th>Nominal amount (per vial) 140mg/vial</th><th>Nominal amount (per vial) 30mg/vial</th></tr>
<tr><td>Polatuzumab vedotin</td><td>IH</td><td>140 mg</td><td>30 mg</td></tr>
<tr><td>Succinic acid</td><td>USPNF/JPE</td><td>8.27 mg</td><td>1.77 mg</td></tr>
<tr><td>Sodium hydroxide</td><td>USPNF/Ph.Eur/JP</td><td>3.80 mg</td><td>0.82 mg</td></tr>
<tr><td>Sucrose</td><td>USPNF/Ph.Eur/JP</td><td>288 mg</td><td>62 mg</td></tr>
<tr><td>Polysorbate 80</td><td>USPNF/Ph.Eur/JPE</td><td>8.4 mg</td><td>1.8 mg</td></tr>
</table>
Target concentration after reconstitution with 7.2ml (for 140 mg/vial drug
product) or 1.8ml (for 30mg/vial) of SWFI yielding approximately 7.52ml (140mg/vial drug product) or 1.88 ml (30mg/vial drug product) of solution respectively
Amount to obtain a pH of 5.3</td></tr>
<tr><td>Indications:</td><td>Polatuzumab vedotin in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP) is indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL)</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.	Rajiv Gandhi Cancer Institute & Research Center (RGCIRC)Rajiv Gandhi Cancer Institute and Research Center, Sector-5, Rohini, New Delhi -110085 - India	Institutional Review Board Rajiv Gandhi Cancer Institute and Research Centre Rohini Sector V Rohini west Metro station Delhi South West Delhi Delhi -110085 India EC Reg. No.: ECR/10/Inst/DC/2013/RR-19 EC	Dr. Dinesh Bhurani
2.	National Cancer Institute Khasara No. 25, Outer Hingna Ring Road, Mouza Jamtha, Nagpur-441 108, Maharashtra, India	National cancer Institute Ethics Committee National Cancer Institute Khasara No. 25 Outer Hingna Ring Road Jamtha Nagpur Maharashtra -441108 India EC Reg. No.: ECR/1130/Inst/MH/2018/RR-21	Dr. Anand Pathak

3.	Tata Memorial Centre, Tata Memorial Hospital, 81, ground floor, main building E Borges road, Mumbai 400012, Mumbai	TMH, Institutional Ethics Committee I/IITata Memorial Hospital, Main Building, IIIrdFloor, Dr Ernest Borges Road, Parel, Mumbai, Mumbai City, Maharashtra –400012 EC Reg. No. 1: ECR/170/Inst/MH/2013/RR-22 EC Reg. No. 2: ECR/414/Inst/MH/2013/RR-19	Dr. Hasmukh Jain
4.	Mazumdarshaw Medical Center, A unit of Narayana Health 258/A, Bommasandra Industrial Area, Hosur Road, Anekkal Taluk, Bangalore - 560099	NARAYANA HEALTH MEDICAL ETHICS COMMITTEE NARAYANA HEALTH HOSPITAL HEALTH CITY, NO. 258/A, BOMMASANDRA INDUSTRIAL AREA ANEKAL TALUK Bengaluru Bengaluru (Bangalore) Rural Karnataka - 560099 India EC Reg No.: ECR/390/Inst/KA/2013/RR-19	Dr. Sharat Damodar
5.	Basavatarakam Indo American Cancer Hospital & Research Institute, 10, Banjara Hills, Hyderabad-500034, Telangana -India	Basavatarakam Indo-American Cancer Hospital and RI, Road No 10, Banjara Hills, Hyderabad, Telanaga -500034 EC Reg. No. ECR/7/Inst/AP/2013/RR-20	Dr. MVT Krishna Mohan