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F. No. ND/CT/25/000068
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-11 0002

To

M/s Glenmark Pharmaceuticals Ltd.,
7 D Atmaram House, 1 Tolstoy Marg,
Delhi (India) – 110001

Subject: Grant of permission to conduct Phase-IV Clinical trial of drug Zanubrutinib Capsules 80 mg vide protocol titled "An Open Label, Phase IV, Single Arm, Multicentric, Prospective Study to Evaluate the Safety and Efficacy of Zanubrutinib In Patients with B-Cell Lymphomas (ZAP-BCL)" Protocol Number: GPL ZANU-401, Version No. 2.0 dated 29-Dec-2025. -regarding.

Sir,

With reference to your application no. **ND/CT04/FF/2025/50536 dated 02.07.2025,** please find enclosed herewith the permission in **Form CT-06 vide No. CT/ND/07/ 2026** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

This permission is subject to the conditions as mentioned below.

Yours faithfully

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.03.13 17:44:13 +05'30'

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

Conditions of permission

(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 Licencing 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 Licencing 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 Licencing 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 Licencing Authority;

(ix) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing 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 Licencing 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 of the New Drugs and Clinical Trials Rules, 2019;

(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 the Chapter VI of the said Rules and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing 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 the Chapter VI and details of compensation provided in such cases shall be

intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing 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 Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorized by the Central Licencing 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) 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;

(xv) The Laboratory owned by any person or a company or any other legal entity and utilized 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 Licencing 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.

(xviii) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG ~~OR INVESTIGATIONAL NEW DRUG~~

CT Permission No: CT/ND/ 07/2026

The Central Licensing Authority hereby permits, **M/s Glenmark Pharmaceuticals Ltd., B/2, MAHALAXMI CHAMBERS 22, BHULA BHAI DESAI ROAD MUMBAI (India) - 400026 Telephone No.: 2240189999 FAX: 2240189988 E-Mail: KISHANSINGH.KAIRA@GLENMARKPHARMA.COM** to conduct clinical trial of the new drug as per **Protocol Number: GPL ZANU-401, Version No. 2.0 dated 29-Dec-2025** in the below mentioned clinical trials sites.

2. Details of new drug ~~or investigational new drug~~ and clinical trial site:

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Names of the new drug ~~or investigational new drug:~~		**Zanubrutinib Capsules 80 mg**
Therapeutic class:		Anticancer
Dosage form:		Capsules
Composition:		Zanubrutinib =80.0000 milligram (mg) In House Specification Active
Indications:		It is indicated for the treatment of adult patients with: 1. Mantle cell lymphoma (MCL) who have received at least one prior therapy. 2. Waldenström's macroglobulinemia (WM). 3. Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti CD20- based regimen. 4. Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). 5. Relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy.
Details of clinical trial sites-		
Sr. No.	**Name of Principal Investigator & Trial Sites**	**Ethics Committee Name/ Registration Number**
1.	Dr. Ajay Gogia All India Institute of Medical Sciences, New Delhi, Ansari Nagar East. New Delhi Delhi -110029	Institute Ethics Committee All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29 New Delhi South Delhi - 110029 India **ECR/538/Inst/DL/2014/RR-20**
2	Dr. Naresh Somani Somani Hospital, Jaipur, 277-278, Shri Gopal Nagar, 80-ftRoad	Somani Hospital Ethics Committee 277-278, shri Gopal Nagar, 80-ft Road Gopalpura byepass Jaipur-302019

	Gopalpura byepassJaipur Rajasthan - 302019	**EC/1531/Inst/RJ/2021**
3	Dr. Mukesh Kumar SMS Medical College & Hospital, SMS Medical College and Hospital Department of medical Oncology, R.K Birla cancer center, Room No. 11,JLN Marg, Jaipur Rajasthan -302004	SMS Medical College and Attached Hospitals SMS Medical College, JLN College. Marg, Jaipur, Rajasthan302004, India **ECR/26/Inst/RJ/2013/RR-24**
4	Dr. Shailendra Prasad Verma King George's Medical University, King Georges Medical University, King Georges Medical University, Shahimina Road Chowk, Lucknow Uttar Pradesh	Institutional Ethics Committee, Research Cell Administrative Block King George's Medical University, Shahmina Shah Chowk Lucknow 226003. **ECR/262/Inst/UP/2013/RR-24**
5	Shuvra Neel Baul NRS Medical College, Kolkata, 138, AJC Bose Road, Kolkata West Bengal - 700014	Ethics Committee, N.R.S. Medical College NRS Medical College And Hospital NRS Medical College138, A.J.C Bose Road Kolkata West Bengal - 700014 India **ECR/609/Inst/WB/2014/RR-20**
6	Dr. Sandeep Nemani Horizon Multispeciality Hospital, Sangli, 1st floor, Clinical Research DepartmentS.No.90 2B 1A 2A 1, Plot No. 1plus 3, Dhamani Road, .Sangali Maharashtra - 416416	EC-Horizon Multispeciality Hospital, Sangli. 1592, 3rd Lane, Ganesh Nagar Sangli Maharashtra - 416416 India **ECR/1864/Inst/MH/2023**
7	Dr. Kalpesh Prajapati Matis Hospital, Ahmedabad, Adani CNG gas station opp. Motera cross road, near motera bus stop, motera Ahmedabad, Gujarat - 380005	Shakti Hospital Ethics Committee Shakti General Hospital A116,117,118 And A 102,103,105 FF Krishna Complex Nr Shahwadi Bus Stand, Narol Ahmedabad Gujarat - 382405 India **ECR/1766/Inst/GJ/2023**
8	Dr. Riya Ballikar, KIMS Kingsway Hospitals, Nagpur, 44, Parwana Bhawan, Kingways Nagpur Maharashtra - 440001	KIMS kingsway hospitals Ethics Committee KIMS kingsway hospitals 44, Parwana bhawan kingsway Nagpur **ECR/1269/Inst/MH/2019**
9	Dr. Kulkarni Uday Prakash, CMC, Vellore, , Department of	Institutional review board Christian Medical college thorapadi post Bagayam Vellore Tamil Nadu - 632012 India

	Haematology, A Block, 6thFloor,Christian Medical College, Vellore - Ranipet Campus Kilminnal Village Vellore TamilNadu - 632517	**ECR/326/Inst/TN/2013/RR-24**

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.

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority
Stamp

New Delhi