



File No. BIO/CT/23/000100

Dated 10-01-2024

To,

M/s GSK Pharma India Private Limited,
C/o GlaxoSmithKline Pharmaceuticals Limited,,
Dr. Annie Besant Road, Worli, Mumbai ,
Maharashtra (India) - 400030

Subject: Application for grant of permission to conduct Phase IV clinical trial entitled – "Phase 4, open label, non-comparative, interventional, multicenter study to evaluate the safety of Dostarlimab in adult patients in India with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regime" vide Protocol No. 221460 dated 25.07.2023. - regarding

Ref. No.: Your Application No. BIO/CT04/FF/2023/38948 dated 31.07.2023

Sir,

With reference to your application No.: BIO/CT04/FF/2023/38948 dated 31.07.2023, 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) Total evaluable patients in the study should be minimum 30.
- (II) You are required to submit the Clinical study report after completion of study.
- (III) 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
- (IV) 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;
- (V) 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;
- (VI) 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;
- (VII) 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.

- (VIII) 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.
- (IX) 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;
- (X) 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.
- (XI) 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.
- (XII) 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.
- (XIII) 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.
- (XIV) 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.
- (XV) 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.
- (XVI) 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.
- (XVII) 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.
- (XVIII) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

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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. GSK Pharma India Private Limited, C/o GlaxoSmithKline Pharmaceuticals Limited, Dr. Annie Besant Road, Worli, Mumbai, Maharashtra (India) - 400030 to conduct Phase IV clinical trial entitled **“Phase 4, open label, non-comparative, interventional, multicenter study to evaluate the safety of dostarlimab in adult patients in India with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen”** as per Protocol No. 221460 dated 25.07.2023 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: 10-Jan-2024

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

Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Dostarlimab concentrate for solution for infusion 500mg/10 ml	
Therapeutic class	Monoclonal Antibody	
Dosage form:	One vial of 10 mL concentrate for solution for infusion contains 500 mg of dostarlimab	
Composition:	Each vial contains:	
	Name of Ingredients	Quantity (per vial)
	Dostarlimab IH	500 mg
	Citric Acid monohydrate Ph.Eur	4.80 mg
	Tri-sodium citrate Dihydrate Ph.Eur	66.80mg
	L-Arginine hydrochloride Ph.Eur	210.66 mg
	Sodium chloride Ph.Eur	18.11 mg
	Polysorbate 80 Ph.Eur	2.0 mg
	Water for Injection Ph.Eur	q.s to 10ml
Indications:	Dostarlimab is indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen	

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	Narayana Superspeciality Hospital, 120/ 1, Andul Rd, Howrah-711103, West Bengal, India	NSH Ethics Committee Narayana Superspeciality Hospital 120/1 Andul Road Near Nabanna Howrah Howrah West Bengal – 711103 EC Reg. No.: ECR/1006/Inst/WB/2018/RR-21	Dr. Chandrakanth MV
2.	All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar-751019, Odisha, India	Institutional Ethics Committee, All India Institute of Medical Sciences, Sijua, Patrapada, Dum Duma, Bhubaneswar-751019, Odisha, India EC Reg. No.: ECR/534/Inst/OD/2014/RR-20	Dr. Sourav Kumar Mishra

3.	Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomtinagar, Lucknow-226010, Uttar Pradesh	Institutional Ethics Committee Dr. Ram Manohar Lohia Institute of Medical Sciences, Research Cell Office, Room No. 35, 2nd Floor, Administrative Block, RMLIMS Lucknow- 226010, Uttar Pradesh, India EC Reg. No.: ECR/913/Inst/UP/2017/RR-20	Dr. Ashish Singhal
4.	Rajiv Gandhi Cancer Institute and Research Centre, Sector -5, Rohini, New Delhi- 110085, India	Institutional Review Board Rajiv Gandhi Cancer Institute and Research Centre, Sector -5, Rohini, New Delhi-110085, India EC Reg. No.: ECR/10/Inst/DC/2013/RR-19	Dr. Sumit Goyal
5.	Noble Hospital Pvt.Ltd., 153, Magarpatta City Road, Hadapsar, Pune-411013, Maharashtra, India	Noble Hospital Institutional Ethics Committee Noble Hospitals Pvt. Ltd., Room No 5, Clinical Research Department, Noble Annex, 153 A, Magarpatta City Road, Hadapsar, Pune –411013, Maharashtra, India EC Reg. No. ECR/259/Inst/MH/2013/RR-19	Dr. Minish Mahendra Jain
6.	MGM Medical College and Hospital, N-6, CIDCO, Aurangabad- 431003, Maharashtra, India	MGM ETHICS COMMITTEE FOR RESEARCH ON HUMAN SUBJECT MGM Medical College and Hospital N-6, CIDCO Aurangabad, Aurangabad, Maharashtra, 431003 India EC Reg No. ECR/581/Inst/MH/2014/RR-20	Dr. Prakash Narayanrao Devde
7.	Nirmal Hospital Pvt. Ltd. Ring Road, Surat-395002, Gujarat, India	Nirmal Hospital Ethics Committee Nirmal Hospital Pvt. Ltd. 2/1423-8- 6 Sagrampura Ring Road, Near Centre Point Surat-395002, Gujarat, India EC Reg No. ECR/390/Inst/GJ/2013/RR-19	Dr. Jayantilal Govindji Patel
8.	Regional Cancer Centre, Medical College Campus, Thiruvananthapuram-695011, Kerala, India	Human Ethics Committee Regional Cancer Centre Medical College Campus Thiruvananthapuram- 695011, Kerala, India EC Reg No. ECR/21/Inst/Ker/2013/RR-19	Dr. Aswin Kumar

9.	Government Royapettah Hospital, No. 1, West Cott Road, Royapettah, Chennai, Tamil Nadu-600014, India	IEC GKMCGovt Kilpauk Medical College and Hospital, Kilpauk, Chennai, Tamil Nadu 600010 EC Reg No. ECR/1385/Inst/TN /2020	Dr. Raja Gopal
10.	Government Rajaji Hospital and Madurai Medical College, Alwarpuram, Tamil Nadu, India-625020	Institutional Ethics Committee Madurai Medical College and Govt. Rajaji Hospital Government Rajaji Hospital & Madurai Medical College Panagal Road, Madurai Tamil Nadu – 625020, India EC Reg No. ECR/1365/Inst/TN/2020	Dr. Jebasingh Joseph Dhanaraj
11.	Amala Institute of Medical Science Amala Nagar, Thrissur-680555, Kerala, India	Institutional Ethics Committee Amala Institute of Medical Science AmalaNagar, Thrissur, Kerala-680555, India EC Reg No. ECR/653/Inst/KL/2014/RR-22	Dr. Sunu Lazar Cyriac