सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services) Ministry of Health & Family Welfare
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. CT/24/000016

To,

M/s Parexel International Clinical Research Private Limited,
CoWrks, RMZ Eco world, Ground Floor, Bay Area –Adjacent to Building 6A,
Outer Ring Road, Devarabeesanahalli Village, BENGALURU, INDIA -560103

Sir,

With reference to your application No. GCT/CT04/FF/2024/41452 dated 23-JAN-2024, please find enclosed herewith the permission in Form CT-06 for conduct of **Phase III** clinical trial titled, **"A randomized, double-blind, parallel-group study to compare efficacy, safety, and immunogenicity of GME751 (proposed pembrolizumab biosimilar) and EU-authorized Keytruda® in adult participants with untreated metastatic non-squamous non-small cell lung cancer (NSCLC)" Protocol No. CGME751A12301, Version 1.0 dated 24-Jul-2023 with a total of up-to 91 subjects from India** under the provisions of New Drugs and Clinical Trial Rules, 2019

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

1) **More Govt. sites shall be included.**
2) **PI shall be Medical Oncologist only.**
3) **Human biological samples i.e. Human blood (whole) and tumor tissue related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO. Further, ICMR/DHR permission shall be obtained for export of optional biological samples as per DGFT notification number 72/2023 dated 11.03.2024.**
4) 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;
5) 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;
6) 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;

7) 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;

8) 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;

9) 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;

10) 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;

11) 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 electronically in the SUGAM portal;

12) 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;

13) 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;

14) 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 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;

15) 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 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;

16) 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 authorised 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;

17) 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;

18) 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;

19) 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;

20) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

21) Merely granting permission to conduct the **clinical trial** with the Investigational Drug Product does not convey or imply that, based on the **clinical trial study data** generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;

22) 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.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

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

FORM CT-06
(See rules 22,25,26,29 and 30)

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

1. The Central Licensing Authority hereby permits **M/s. Parexel International Clinical Research Private Limited, CoWrks, RMZ Eco world, Ground Floor, Bay Area –Adjacent to Building 6A, Outer Ring Road, Devarabeesanahalli Village, BENGALURU, INDIA -560103 Telephone No.: 8067723000 FAX: 80 67723001 E-Mail : PAREXELINDIA@PAREXEL.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No. CGME751A12301, Version 1.0 dated 24-Jul-2023** in the below mentioned clinical trial sites [As per Annexure].-

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.

Place: New Delhi
Date _____

RAJEEV SINGH RAGHUVANSHI

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

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	GME751 (pembrolizumab) concentrate for solution for infusion 25 mg/mL (100 mg/vial)
Therapeutic class:	Antineoplastic agents PD 1 and PDL 1 inhibitors
Dosage form:	Concentrate for solution for infusion
Composition:	GME751 =25.0000 mg/ml In House Specification Active
Indications:	It is indicated for the treatment metastatic non-squamous non-small cell lung cancer (NSCLC)

Annexure:

Details of clinical trial site:

S.No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Healthcare Global Enterprises Limited#. 8, P Kalinga Rao Road, HCG Towers, Sampangi Ram Nagar, Bengaluru, Karnataka-560027, India	HCG Central Ethics Committee No. 8, P Kalinga Rao Road, HCG Towers, Sampangi Ram Nagar, Bengaluru, Karnataka-560027, India ECR/386/Inst/KA/2013/RR-19	Dr. Satheesh C T
2.	Dr. B. L. Kapur Memorial Hospital, Pusa Road, New Delhi-110005, India	Dr. B. L. Kapur Memorial Hospital Ethics CommitteeDr. B.L.Kapur Memorial Hospital, Pusa Road, New Delhi-110005, India ECR/3/BLK/Inst/DL/2013/RR-19	Dr. Chandragouda Dodagoudar
3.	Nizam's Institute of Medical Sciences, Department of Medical Oncology Panjagutta, Hyderabad, Telangana-500082, India	NIMS-Institutional Ethics Committee 2nd floor, SRC, NIMS old block, Panjagutta, Hyderabad, Telangana-500082, India ECR/303/Inst/AP/2013/RR-19	Dr. Sadashivudu Gundeti
4.	LMMF's Deenanath Mangeshkar Hospital and Research center Erandawane, Pune, Maharashtra-411004, India	Institutional Ethics Committee, Deenanath Mangeshkar Hospital & Research Centre, off Karve Road, Erandawane, Pune, Maharashtra-411004, India ECR/15/Inst/Maha/2013/ RR-22	Dr. Chetan Dilip Deshmukh
5.	The Gujarat Cancer & Research Institute (M.P. Shah	GCRI/GCP Ethics Committee The Gujarat Cancer & Research	Dr. Harsha Suryakant

	Cancer Hospital) Civil Hospital Campus, Asarwa, Ahmedabad 380016 Gujarat India	Institute M.P. Shah Cancer Hospital, Civil Hospital Campus, Asarwa, Ahmedabad 380016 Gujarat India ECR/41/Inst/GJ/2013/RR-19	Pancha
6.	Apex Wellness Hospital, Survey No. 799, Plot No. 187, behind Prakash Petrol Pump, Govind Nagar, Nasik 422009, Maharashtra, India	Apex Wellness Ethics Committee C/O Apex wellness hospital, Survey No. 799, Plot No. 187, behind Prakash Petrol Pump, Govind Nagar, Nasik 422009, Maharashtra, India ERC/1500/ Inst/MH/2021	Dr. Shailesh Bondarde
7.	National Cancer Institute Khasar No. 25, outer Hingna Ring Road, Mouza, Jamtha, Nagpur, Maharashtra-441108, India	National Cancer Institute Ethics Committee Khasar No. 25, outer Hingna Ring Road, Mouza, Jamtha, Nagpur, Maharashtra-441108, India ECR/1130/Inst/MH/2018/RR-21	Dr. Anand Bhaskarrao Pathak
8.	Tata Memorial Centre11th floor, Homi Bhabha block, Tata Memorial Hospital, Dr. Ernest Borges Road, Parel Mumbai-400012, Maharashtra, India	IEC I & II: Institutional Ethics Committee, Clinical Research Secretariat, 3rd Floor, Main Building, Tata Memorial Hospital, Dr. Ernest Borges Road, Parel, Mumbai –400012, Maharashtra, India IEC I:- ECR/170/Inst/MH/2013/RR-22, IEC II:- ECR/414/Inst/MH/2013/RR-19	Dr. Kumar Prabhash
9.	Noble Hospital Pvt Ltd, Ground Floor, OPD-Room No. 18, 153 Magarpatta City Road, Hadapsar Pune-411013, Maharashtra, India	Noble Hospital Institutional Ethics committee, Noble Hospital Pvt. Ltd Room no. 5, Clinical Research Department, Noble Annex, 153 Magarpatta city road, Hadapsar, Pune-411013, Maharashtra, India ECR/259/Inst/MH/2013/RR-19	Dr. Minish Jain
10.	Sir Ganga Ram Hospital,Sir Ganga Ram Marg Rajinder Nagar, New Delhi-110060, India	Ethics Committee Sir Ganga Ram Hospital Room No-1643, 6thfloor, old building, Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi-110060, India.	Dr. Shyam Aggarwal

		ECR/20/INST/DL/2013/RR-19	
11.	HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka, Nashik, Maharashtra-422002, India	Manavata Clinical Research Institute Ethics Committee, HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka, Nashik, Maharashtra-422002, India ECR/500/Inst/MH/2013/RR-20	Dr. Raj Nagarkar
12.	Department of Pulmonary Medicine, S.P. Medical College and AG of Hospitals, Bikaner, Rajasthan-334003, India	Ethics Committee, S.P. Medical College and AG of Hospitals, Pawanpuri, Bikaner, Rajasthan-334003, India ECR/27/SP/Inst/RJ/2013/RR-19	Dr. Manak Gujrani
13.	KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi, Karnataka-590010, India	Institutional Ethics Committee, KLE Academy of Higher Education and Research (KAHER), JNMC Campus, Nehru Nagar, Belagavi, Karnataka-590010, India. ECR/211/Inst/KA/2013/RR-19	Dr. Mahesh kumar Kalloli
14.	P.D Hinduja Hospital and Medical Research Centre Marvella 724, 11th Road, Khar West, Mumbai, Maharashtra-400052, India.	Institutional Ethics Committee, PD Hinduja Hospital and Medical Research Centre,Veer Savarkar Marg, Mahim, Mumbai, Maharashtra-400016, India. ECR/61/Inst/MH/2013/RR-19	Dr. Vijay Patil
15.	Apollo Hospitals, 154/11, Opp. IIM, Bannerghatta road, Bangalore, Karnataka-560076, India.	Institutional Ethics Committee-Clinical Studies, Apollo Hospitals, 154/11, Opp. IIM, Bannerghatta road, Bangalore, Karnataka-560076, India. ECR/320/Inst/KA/2013/RR-20	Dr. Vijay Agarwal
16.	Sparsh Hospital and Critical Care (P) Ltd., A/407, Saheed Nagar, Bhubaneswar, Odisha-751007, India	Institutional Ethics Committee, Sparsh Hospital, & Critical Care (P) Ltd, A/407, Saheed nagar, Bhubaneswar, Odisha-751007, India ECR/68/Inst/OR/2013/RR-22	Dr. Ghanashyam Biswas
17.	State Cancer Institute, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna, Bihar-800014, India	Institutional Ethics Committee, Indira Gandhi Institute of Medical Sciences, Sheikhpura Raja Bazar, Patna Bihar-800014, India.	Dr. Dinesh Kumar Sinha

		ECR/640/Inst/BR/2014/RR-20	
18.	Mahamana Pandit Madan Mohan Malaviya Cancer Centre, Department of Medical Oncology, Sundar Bagiya, Near Nariya Gate, Banaras Hindu University Campus, Varanasi, Uttar Pradesh-221005 India	Institutional Ethics Committee, MPMMCC & HBCH, Varanasi, Mahamana Pandit Madan Mohan Malaviya Cancer Centre, Sundar Bagiya, Near Nariya Gate, Banaras Hindu University Campus, Varanasi, Uttar Pradesh-221005. India ECR/1501/Inst/UP/2021	Dr. Akhil Kapoor
19.	Sujan Surgical Cancer Hospital and Amravati Cancer Foundation, 52/B Shankar Nagar, Main Road, Amravati, Maharashtra-444605, India	Amravati Ethics Committee, Sujan Surgical Cancer Hospital and Amravati Cancer Foundation,52/B Shankar Nagar, Main Road, Amravati, Maharashtra-444605, India ECR/432/Inst/MH/2013/RR-19	Dr. Rajendersingh Arora
20.	Hemato Oncology Clinic Ahmedabad Pvt. Ltd., Vedanta Institute of Medical Science, Ground floor and First floor, Near Samved Hospital, Stadium Commerce College Road, Navrangpura, Ahmedabad, Gujarat-380009, India	Ethics Committee of CIMS, Care Institute of Medical Science, Opp. Panchamrut Bunglows, Nr. Shukan Mall, off Science City Road, Sola, Ahmedabad, Gujarat-380060, India	Dr. Sandip Abhaykumar Shah
21.	Max Super Speciality Hospital, Saket (A Unit of Devki Devi Foundation) 2, Press Enclave Road, Saket, New Delhi - 110017, India	Institutional Ethics Committee (IEC), Devki Devi Foundation Service Floor, Office of Ethics Committee, East block, Next to Conference Room, Max Super Speciality Hospital, Saket (A Unit of Devki Devi Foundation) 2, Press Enclave Road, Saket, New Delhi – 110017, India ECR/110/Inst/DL/2013/RR-19	Dr. Sandeep Batra
22.	Marathwada Regional Cancer Center and Research Institute, G.M.C.H., Near Jama masjid, Front of aam khas maidan, Aurangabad, Maharashtra-431001, India.	Institutional Ethics committee, (IMC-GMCA), Department of Pharmacology, Government medical college, Aurangabad, Maharashtra-431001, India. ECR/314/Inst/MH/2013/RR-19	Dr. Balaji Keshavrao Shewalkar

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