



सत्यमेव जयते

**GOVERNMENT OF INDIA**  
CENTRAL DRUGS STANDARD CONTROL  
ORGANISATION (Headquarter)  
(Directorate General of Health Services)  
Ministry of Health & Family Welfare  
FDA Bhawan, Kotla Road,  
New Delhi – 110002  
Phone No.: 91-11-23216367  
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File No. CT/22/000059

To

M/s. Parexel International Clinical Research Private Limited.,  
CoWrks, Coworking Spaces Pvt. Ltd–RMZ Eco World,  
Ground Floor, Bay Area-Adjacent to Building 6A, Outer Ring Road,  
Devarabeesanahalli Village, Bengaluru-560103, Karnataka, India.  
Tel.: 80 67723000; Fax: 80 67723001  
E-Mail: parexelindia@parexel.com

Sir,

With reference to your SUGAM application no. GCT/CT04/FF/2022/32828 (GCT/59/22) dated 01-JUL-2022, please find enclosed herewith the permission in Form CT-06 for conduct of Phase 3 clinical trial titled, “ **A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib Plus Durvalumab Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations, and Whose Disease Has Progressed On or After Prior Anti-PD-(L)1 Therapy and Platinum-based Chemotherapy: LATIFY**” vide Protocol no. **D533BC00001, Version 1.0 dated 21-MAR-2022 and Protocol Addendum IND-1 Version 1.0 dated 17-NOV-2022** with a total of up to 19 subjects 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, specifically that: -

- 1) **SAEs irrespective of its causality are to be reported to CDSCO as per the provisions of New Drugs and Clinical Trial Rules 2019 during the study and its follow up period;**
- 2) **the PI of the study site(s) should be experienced Medical Oncologist and also to include more number of Govt. sites in the study;**
- 3) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Institutional Ethics Committee of that site, registered with the Central Licencing Authority under Rule 8;
- 4) 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;

- 5) 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 Licencing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;
- 6) 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;
- 7) 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;
- 8) 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;
- 9) 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;
- 10) 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;
- 11) 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;
- 12) 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;
- 13) 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;
- 14) 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;
- 15) 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;

- 16)** 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;
- 17)** 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;
- 18)** 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;
- 19)** the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- 20)** 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;
- 21)** 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,

(Dr. V. G. Somani)  
Drugs Controller General (India) &  
Central Licencing Authority

**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 Ecoworld, Ground Floor Bay Area Adj. to Building 6A, ORR, Devarabeesanahalli, Bengaluru – 560103, India, Tel.: 80 67723000; Fax: 80 67723001, E-Mail: PAREXELINDIA@PAREXEL.COM** to conduct clinical trial of the new drug or investigational new drug as per **LATIFY Protocol no. D533BC00001, Version 1.0 dated 21-MAR-2022 and Protocol Addendum IND-1 Version 1.0 dated 17-NOV-2022** 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 \_\_\_\_\_

(Dr. V. G. Somani)  
Drugs Controller General (India) &  
Central Licensing Authority

**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:

<b>Names of the new drug or investigational new drug</b>	A) CERALASERTIB (AZD6738) and B) DURVALUMAB (MEDI4736)
<b>Therapeutic class:</b>	A) Anti tumour agent (ATR Inhibitor) and B) Anti PD L1 MAB
<b>Dosage form:</b>	A) Tablets (80 mg & 120 mg) and B) Concentrate solution for infusion (50 mg/ ml)
<b>Composition:</b>	Ceralasertib = 120.00mg In House Specification Active Ceralasertib = 80.00mg In House Specification Active and Durvalumab = 50.00 mg/ml In House Specification Active
<b>Indication:</b>	Advanced or Metastatic Non-Small Cell Lung Cancer

**Annexure:**

Details of clinical trial site:

S.No.	Names and address of clinical trial site	Ethics committee details	Name of Investigator
1.	Apex Hospitals Pvt. Ltd, SP-4&6, Malviya Nagar Industrial Area, Malviya Nagar, Jaipur-302017, Rajasthan	Institutional Ethics Committee, Apex Hospitals Pvt. Ltd, SP-4&6, MIA, Malviya Nagar- Jaipur-302017, Rajasthan	Dr. Priti Agarwal
2.	Somani Hospital, 277-278, Shri Gopal Nagar, 80 ft, Road Gopalpura Bypass Jaipur 302019 Rajasthan	Somani Hospital Ethics Committee, Somani Hospital, 277, Shri Gopal Nagar, 80 ft, Road, Gopalpura Bypass Jaipur 302019 Rajasthan	Dr. Naresh Somani
3.	Grant Medical Foundation, Ruby Hall Clinic, 40, Sassoon Road, Pune-411001, Maharashtra	Institutional Ethics Committee, Poona Medical Research Foundation, E-4 C to E-4 F, 4 <sup>th</sup> Floor, Fifth Avenue Condominium, Dhole Patil Road, Pune-411001, Maharashtra	Dr. Jain Minish Mahendra
4.	Unique Hospital – Multispeciality and Research Institute, Opp. Kiran Motor, Near Canal, Civil Hospital Char Rasta-Sosyo Circle Lane, Off Ring Road, Surat-395002, Gujarat  Unique Hospital Corporate Office, B-9 Shivkrupa Society, Ambanagar, Behind Unique Hospital, Surat-395002, Gujarat	Ethics Committee, Unique Hospital – Multispeciality & Research Institute, Opp. Kiran Motors, Near Canal, Civil Hospital Char Rasta-Sosyo Circle Lane, Off Ring Road, Surat-395002, Gujarat	Dr. Maksud Tanveer Mohibbhai
5.	Tata Memorial Centre, 304 OPD, 3 <sup>rd</sup> Floor, Homi Bhabha Block, Dr. Ernest Borges Road, Parel, Mumbai-400012, Maharashtra	Institutional Ethics Committee Tata Memorial Hospital, 3 <sup>rd</sup> Floor, Main Building, Dr. Ernest Borges Road, Parel, Mumbai-400012, Maharashtra	Dr. Vanita Noronha

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