



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/22/000041

To,

M/s. Raptim Research Pvt. Ltd.,
A-242, T.T.C., Industrial Area, Mahape M.I.D.C.,
Navi Mumbai, Maharashtra (India) – 400710.

Sir,

With reference to your application No. GCT/CT04/FF/2022/31863 (GCT/41/22) dated 28-04-2022, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase 2, Double-Blind, Placebo-Controlled, Multicenter Clinical Trial Comparing Chemoimmunotherapy (Paclitaxel-Carboplatin-Oregovomab) versus Chemotherapy (Paclitaxel-Carboplatin-Placebo) as Neoadjuvant Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Peritoneal Carcinoma”, Protocol Number: QPT-ORE-006 Protocol Version 1.0 dated 14-April-2022** 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:-

- (i) The applicant should adhere to the condition for SAEs reporting as stipulated under ND & CT Rules 2019 and all SAEs including death irrespective of its cause shall be reported as SAE to Central Licensing Authority.
- (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;

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- (v) 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;
- (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 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;
- (ix) 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;
- (x) 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;
- (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 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;
- (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 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;
- (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 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;
- (xiv) 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;
- (xv) 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;
- (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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
- (xvii) 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;
- (xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xix) 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;

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(xx) 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
Stamp

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

1. The Central Licensing Authority hereby permits **M/s Raptim Research Pvt. Ltd., A-242, T.T.C. Industrial Area Mahape M.I.D.C., Navi Mumbai Navi Mumbai (India) – 400701** to conduct clinical trial of the new drug or investigational new drug as per **Protocol Number: QPT-ORE-006 Protocol Version 1.0 dated 14-April-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 Licencing 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	Oregovomab (MAbB43.13)
Therapeutic class:	Monoclonal Antibody
Dosage form:	Lyophilized powder for solution for infusion
Composition:	Oregovomab = 2.0000 milligram (mg) In House Specification Active
Indications:	To be used in Chemolmmunotherapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Peritoneal Carcinoma

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Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	King George Hospital/ Andhra Medical college, Department of Medical Oncology, Maharani-peta, Visakhapatnam-530002, Andhra Pradesh, India	Institutional Ethics Committee, King George Hospital, Maharani-peta, Collector's Office Junction, Visakhapatnam, Andhra Pradesh-532002, India ECR/197/Inst/KGH/2013/RR-20	Dr. Shilpa Kandipalli
2	Omega hospitals, Plot no4, Chinagadhili, Hanumanthawaka, Visakhapatnam, A.P, India-530040	Institutional Ethics Committee, Omega hospitals, Omegahospit Ala Vizag Speciality Hospitals, Plot.N04, Chinnagadali, Arilova Section , Visakhapatnam, Andhra Pradesh -530040 India ECR/1486/Inst/AP/2020	Dr. B. Ravi Shankar
3.	Bhaktivedanta Hospital & Research Institute, Srishti Complex, Bhaktivedanta Swami Marg, Mira Road (East), Thane-401107, Maharashtra, India.	Bhaktivedanta Hospital Ethics Committee, 6th Floor, Bhaktivedanta Hospital & Research Institute, Srishti Complex, Bhaktivedanta Swami Marg, Mira Road (East), Thane-40 1107, Maharashtra, India ECR/396/Inst/MH/2013/RR-19	Dr. Nirmal Raut
4.	Regional Cancer Centre, Medical College Campus, Thiruvananthapuram- 695011, Kerala, India	Human Ethics Committee, Regional Cancer Centre, 151 Floor, P.O. Box No.2417, Medical College Campus, Trivandrum- 695011, Kerala ECR/21/Inst/Ker/2013/RR-19	Dr. Aswin kumar
5.	Nil Ratan Sircar Medical College and Hospital, 138 Acharya Jagdish Chandra Bose Road, Kolkata- 700014, West Bengal, India	Ethics Committee, NRS Medical College, Nil Ratan Sircar Medical College and Hospital, 138 Acharya Jagdish Chandra Bose Road, City Kolkata, Pin-700014, West Bengal, India ECR/609/Inst/WB/2014/RR-20	Dr. Srikrishna Mandal
6.	Amrita Institute of Medical Sciences, AIMS Ponekkara P O, Kochi - 682041, Kerala, India	Institutional Ethics Committee Amrita Institute of Medical Sciences AIMS-Ponekkara Kochi Edappally Emakulam Kerala - 682041 India ECR/129/Inst/KL/2013/RR-19	Dr. K. Pavithran

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7.	Wockhardt Super Speciality Hospital, 1643, North Ambazari Road, Nagpur- 440033, Maharashtra, India.	Institutional Ethics Committee, Wockhardt Hospital Limited Nagpur, 1643, Shankar Nagar, North Ambazari Road, Nagpur, Maharashtra, India ECR/1541/Inst/MH/2021	Dr. Chaudhary Vaibhav Gangaram
8.	KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India	Institutional Ethics Committee, KLE Academy of Higher Education and Research (KAHER) Belagavi, JNMC Campus, Nehru Nagar, Belagavi-590010 Karnataka, India ECR/211/Inst/KA/2013/RR-19	Dr. Maheshkumar Kalloli
9.	Himalaya Cancer Hospital and Research Institute, 4, Vinod Baugh, Railway Station, Jetalpur Bridge, Alkapuri, Vadodara-390007, Gujarat, India	Institutional Ethics Committee, Himalaya Cancer Hospital and Research Institute, 4, Vinod Baugh, B/H Railway Station, Jetalpur Bridge, Alkapuri, Vadodara-390007, Gujarat, India ECR/980/Inst/GJ/2017/RR-22	Dr. Kartikeya Jain
10.	Apex Hospital. N-7/2A-5D.Bhikharipur. DL W Hydell Road, Varanasi-221004, Uttar Pradesh	Institutional Ethics Committee, Apex Hospital, N-7/2A-5D, Bhikharipur. DLW Hydell Road, Varanasi-221 004 Uttar Pradesh ECR/462/Inst/UP/2013/RR-21	Dr. Neha Gupta
11.	Department of Surgical Oncology, 3 rd Floor, Shatabdi Phase 2, King Georges Medical University, Lucknow-226003, Uttar Pradesh, India	Institutional Ethics Committee, King George Medical University, Office of Research Cell, Lucknow-226003, Uttar Pradesh, India ECR/262/Inst/UP/2013/RR-19	Dr. Vijay Kumar
12.	Kailash Cancer Hospital and Research Centre, Muni Seva Ashram, Goraj - 391760, Waghodiya, Vadodara, Gujarat, India	Institutional Ethics Committee Kailash Cancer Hospital and Research Centre, Mun.i Seva Ashram, Goraj - 391760, Waghodiya, Vadodara, Gujarat, India ECR/49/Inst/GJ/2013/RR-19	Dr. Niraj Bhatt
13.	1 st Floor, CRF Department, Saveetha Medical College and Hospital, Saveetha Nagar, Thandalam, Chennai – 602105, Tamil Nadu, India	Saveetha Medical College and Hospital–Institutional Ethics Committee (SMCH - IEC) Saveetha Nagar, Thandalam, Chennai- 602105, Tamil Nadu, India ECR/724/Inst/TN/2015/RR-19	Dr. Anita Ramesh