



GOVERNMENT OF INDIA  
CENTRAL DRUGS STANDARD CONTROL  
ORGANISATION (Headquarter)  
(Directorate General of Health  
Services) Ministry of Health & Family  
Welfare  
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**File No. CT/25/000082**

To,

M/s. Novartis Healthcare Private Limited,  
Inspire BKC, Part of 601 & 701,  
BKC Main Road Bandra Kurla Complex,  
Bandra (East), Mumbai (India) – 400051, Maharashtra.

Sir,

With reference to your application No. GCT/CT04/FF/2025/50212 dated 17-Jun-2025, please find enclosed herewith the permission in Form CT-06 for conduct of **phase IIIb** clinical trial titled, “**A single arm, multicenter, open-label extension (OLE) trial to evaluate long-term safety and tolerability of pelacarsen (TQJ230) in participants who completed the parent Lp(a)HORIZON trial**” Protocol No.: **CTQJ230A12301E1 Version No. 00 dated 19-Dec-2024 with a total of up-to 460 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:-

- (i) **Human biological samples i.e. Whole blood, serum and plasma 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.**
- (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 Licencing 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;
- (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 Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing 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;
- (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. 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. Novartis Healthcare Private Limited, Inspire BKC, Part of 601 & 701, BKC Main Road Bandra Kurla Complex Bandra (East), Maharashtra (India) - 400051 Telephone No.: 912250243588 FAX: 912250243010 E-Mail: NHPL.DRASUGAM@NOVARTIS.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: CTQJ230A12301E1 Version No. 00 dated 19-Dec-2024** with 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. 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:

<b>Names of the new drug or investigational new drug</b>	TQJ230
<b>Therapeutic class:</b>	Antisense oligonucleotide ASO
<b>Dosage form:</b>	Solution for injection in in pre filled pen
<b>Composition:</b>	TQJ230 =80.0000 mg/zero point 8 ml In House Specification Active
<b>Indications:</b>	lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease

**Annexure:**

Details of clinical trial site:

<b>Sr. No.</b>	<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
1.	Apollo Hospitals, Apollo Hospitals, Enterprises Limited, 21, Greams Lane, Off Greams Road Chennai Tamil Nadu -600006	Institutional Ethics Committee-Clinical Studies, Apollo Hospitals enterprise limited, No. 21, greams lane, off greams road, Chennai – 600006, India  ECR/37/Inst/TN/2013/RR-19	Dr Abraham Oomman
2.	Fortis Escorts Heart Institute, Okhla Road New Delhi Delhi -110025	Institutional Ethics Committee, Academics and Research Department, Room no 23A, 2nd floor, Residential Tower, Fortis Escorts Heart Institute, Okhla Road, New Delhi-110025  ECR/261/Inst/DL/2013/RR-24	Dr Vishal Rastogi
3.	Kovai Diabetes Speciality Center and Hospital, 15, Vivekananda Road, Ram Nagar Coimbatore Tamil Nadu -641009	Institutional Ethics Committee of Kovai Diabetes Speciality Centre & Hospital, #15, Vivekananda Road, Ram Nagar, Coimbatore 641009, Tamil Nadu, India  ECR/233/Inst/TN/2013/RR-24	Dr Balamurugan Ramanathan

4.	Sengupta Hospital and Research Institute, Ravinagar Square, Nagpur Nagpur Maharashtra - 440033	Sengupta Hospital & Research Institute Ethics Committee, Ravinagar Square, Nagpur 440033, Maharashtra, India  ECR/675/Inst/MH/2014/RR-24	Dr Shantanu Pradeep Sengupta
5.	Shri Guru Ram Rai Institute of Medical and Health Sciences and Shri Mahant Indiresht Hospital, Patel Nagar, Dehradun Dehradun Uttarakhand - 248001	Institutional Ethics Committee- SGRRI&HS, Admin Block, Shri Guru Ram Rai Institute of Medical and Health Sciences and Shri Mahant Indiresht Hospital, Patel Nagar, Dehradun-248001, Uttarakhand, India  ECR/710/Inst/UK/2015/RR-21	Dr Tanuj Bhatia
6.	Galaxy Hospital A Unit of Galaxy Lifecare Services Pvt Ltd., Plot No- 4 to 7, Dayal Enclave, Mahmoorganj Varanasi Uttar Pradesh -221010	Galaxy Hospital Ethics Committee, Galaxy Life Care Services Pvt. Ltd. Plot No. 4-7 Dayal Enclave, Mahmoorganj Varanasi-221010, Uttar Pradesh  ECR/877/Inst/UP/2016/RR-20	Dr Ajay Kumar Pandey
7.	G Kuppuswamy Naidu Memorial Hospital, P Box No 6327, Nethaji Road, Paappanaic kenpalayam Coimbatore Tamil Nadu - 641037	Institutional Ethics Committee, G Kuppuswamy Naidu Memorial Hospital, P Box No 6327, Nethaji Road, Paappanaickenpalayam, Coimbatore-641037, Tamil Nadu, India  ECR/209/Inst/TN/2013/RR-24	Dr Rajpal Kanaklal Abhaichand
8.	Lalitha Super Specialities Hospital Pvt. Ltd., Kothapet, Guntur Guntur Andhra Pradesh - 522001	Lalitha Superspecialities Hospital Ethics Committee, Lalitha Super Specialities Hospital Pvt. Ltd, Kothapet, Guntur- 522001, Andhra Pradesh  ECR/437/Inst/AP/2013/RR-24	Dr Polavarapu Veera Raghava Sarma
9.	Aster Medcity, Kuttisahib Road, South Chittoor. Kochi Kochi Kerala - 682027	Institutional Ethics Committee, Aster Medcity Kuttisahib Road, South Chittoor Po, Kochi-682027, Kerala, India  ECR/737/INST/KL/2015/RR-21	Dr Anil Kumar
10.	KLES Dr Prabhakar Kore Hospital and MRC, G plus 2, OPD number 29, Nehru Nagar Belagavi Karnataka - 590010	Institutional Ethics Committee, KLE University (KAHER), KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi-590010, Karnataka, India  ECR/211/INST/KA/2013/RR-24	Dr Prasad M R
11.	Yashoda Hospitals, Raj Bhavan Road, Somajiguda, Hyderabad Hyderabad	Yashoda Academy of Medical Education and Research, Yashoda Hospitals, Behind Hari Hara Kala Bhavan, S.P.Road, Secunderabad, Hyderabad,	Dr Rohith P Reddy

		Telangana-500003, India ECR/49/Inst/AP/2013/RR-22	
12.	Yenepoya Medical College Hospital, A Constituent College of Yenepoya, Deemed to be University Road, Deralakatte Mangalore. Mangalore Karnataka - 575018	Yenepoya Ethics committee-1, Yenepoya (Deemed to be University), University Road, Deralakatte, Dakshina Kannada, Mangalore- 575018, Karnataka, India ECR/521/Inst/KA/2014/RR-20	Dr Prashanth R M
13.	New Era Hospital, Central Avenue Road, Near Telephone Exchange Chowk Queta Colony, Nagpur Maharashtra - 440008	New Era Hospital Ethics Committee, New Era Hospital, Near Queta Colony Telephone Exchange Square, Central Avenue Road, Nagpur-440008 ECR/896/inst/MH/2016/RR-20	Dr Nidheesh Vyanktesh Mishra
14.	Manipal Hospital Pvt Ltd, Sr.No111-11-1 Mahalunge Baner Road Opp D-Mart, Baner Pune.Pune Maharashtra - 411045	Manipal Hospital Baner Pune, Institutional Ethics Committee, Manipal Hospital Pvt Ltd, Sr.No 111/11/1 Mahalunge Baner, Road Opp D-Mart, Baner pune, Maharashtra 411045 India ECR/1825/Inst/MH/2023	Dr Abhijit Bhaskar Joshi
15.	WMFs Viloo Poonawalla Memorial Hospital, S.No. 156, Pune Solapur road, Hadapsar, Pune. Pune Maharashtra -411028	Institutional Ethics Committee, WMF's Viloo Poonawalla Memorial Hospital, WMF's Viloo Poonawalla Memorial Hospital, S.No. 156, Plot no.1/3A, 3B, 1, 2/3, Pune Solapur Road, Hadapsar, Pune, Maharashtra 411028, India ECR/1642/Inst/MH/2022	Dr Hemant Kokane
16.	Rhythm Heart Institute- A Unit of Synergy Lifecare Pvt. Ltd., Near Siddharth Bungalows, Sama- Savli Road Vadodara. Vadodara Gujarat - 390022	Rhythm Heart Institute Ethics Committee, Near Siddharth Bungalows, Sama- Savli Road, Vadodara- 390022, Gujarat ECR/224/Inst/GJ/2013/RR-24	Dr Nirav Chandulal Bhalani
17.	Marengo CIMS Hospital Pvt. Ltd., Opp. Panchamrut Bungalows, Nr. Shukan mall, Off. Science City Road, Sola, Ahmedabad. Ahmedabad Gujarat - 380060	Ethics Committee of Care Institute of Medical Sciences. Marengo CIMS Hospital Pvt. Ltd., Opp. Panchamrut Bungalows, Nr. Shukan mall, Off. Science City Road, Sola, Ahmedabad- 380060, Gujarat, India. EC/206/Inst/2013/RR-24	Dr Shah Urmil Girishbhai

18.	EPIC Hospital - A Unit of Vatsalya Healthcare LLP, Rajpath Rangoli Road, Opp. Pandit Dindayal Hall, Bodakdev, Ahmedabad. Ahmedabad Gujarat - 380054	EPIC Hospital Ethics Committee, EPIC Hospital [Unit of Vatsalya Healthcare LLP], Rajpath Rangoli Road, Opp. Pandit Dindayal Hall, Bodakdev, Ahmedabad-380054, Gujarat, India  ECR/1372/Inst/GJ/2020	Dr Anil Ranjeetmal
19.	S.P. Medical College and AG Hospitals, Dept. of Cardiology, S.P. Medical College and AG Hospitals, Bikaner. Bikaner Rajasthan - 334003	Institutional Ethics Committee, SP Medical College & AG Hospitals, Bikaner-334003  ECR/27/SP/Inst/RJ/2013/RR-19	Dr Devendra Kumar Agarwal
20.	Department of Cardiology, King Georges Medical University, Dept Of Cardiology, King Georges Medical University, Lucknow. LucknowUttar Pradesh - 226003	King George's Medical University, Institutional Ethics Committee, Office of Research Cell, Luknow, Uttar Pradesh-226003, India  ECR/262/Inst/UP/2013/RR-24	Dr Rishi Sethi
21.	Sir Ganga Ram Hospital, SGRH Marg, Rajinder Nagar, New Delhi. New Delhi Delhi -110060	Ethics Committee, Sir Ganga Ram Hospital, Room Number 1643, 6th Floor, Casualty Building, Rajinder Nagar, New Delhi-110060, India  ECR/20/Inst/DL/2013/RR-24	Dr Manish Kumar Sharma
22.	Kasturba Medical College and Hospital, Kasturba Medical College and Hospital, Madava Nagar, Post Box No.- 7, Manipal. Manipal Karnataka -576104	MAHE Ethics committee, Mezzanine floor of OLD KMC library building, Near KMC Dean Office, Kasturba Medical College and Hospital, Manipal - 576104, Karnataka, India  ECR/191/Inst/KL/2013/RR-24	Dr Tom Devasia
23.	Manipal Hospital Mysore, No.85-86, Bangalore-Mysore Ring Road Junction, Bannimantapa A layout, Siddique Nagar, Mandi Mohalla, Mysuru. Mysuru Karnataka - 570015	Institutional Ethics Committee Columbia Asia Hospital - Mysore, No. 85-86, Bangalore-Mysore Ring Road Junction, Bannimantapa 'A' layout, Siddique Nagar, Mandi Mohalla, Mysuru, Karnataka 570015  ECR/1106/Inst/KA/2018/RR-21	Dr CB Keshavamurthy
24.	Max Super Speciality Hospital Vaishali - A Unit of Crosslay Remedies Ltd, W-3, Sector-1, Vaishali , Ghaziabad. Ghaziabad Uttar Pradesh -201012	Institutional Ethics Committee, Max Super Specialty Hospital Vaishali (A Unit of Crosslay Remedies Limited), Max Super Speciality Hospital Vaishali (A Unit of Crosslay Remedies Ltd), W-3, Sector-1, Vaishali, Ghaziabad -201012, Uttar Pradesh, India  ECR/360/Inst/UP/2013/RR-24	Dr Gaurav Minocha

25.	Aakash Healthcare Pvt. Ltd., Hospital Plot, Road No-201, Sector -3, Dwarka, New Delhi. New Delhi Delhi - 110075	Aakash Healthcare Institutional Ethics Committee, Aakash Healthcare Super Specialty Hospital, Hospital Plot, Road No. 201 Sector 3, Dwarka, New Delhi-110075  ECR/1265/Inst/DL/2019/RR-24	Dr Ashish Agrawal
26.	Vijan Hospital and Research Center, Vijan Cardiac and Critical Care, Dr. Vijan Hospital Marg, College Road, Nashik. Nashik Maharashtra - 422005	Vijan Hospital Ethics Committee, Vijan Cardiac & Critical Care Centre, Dr. Vijan Hospital Marg, College Road, Nashik-422005, Maharashtra, India  ECR/406/Inst/MH/2013/RR-24	Dr Vikarant Vijan
27.	Sahyadri Super Speciality Hospital and Sahyadri Clinical Research and Development Center, A Unit of Sahyadri Hospitals Pvt Ltd., Sahyadri Super Speciality Hospital, Plot No 30C, Erandwane, Karve Road, Pune and Sahyadri Clinical Research and Development Center, A Unit of Sahyadri Hospitals Pvt Ltd, 33 -34B Makarand Bhave Path, Erandwane, Pune. Pune Maharashtra - 411004	Sahyadri Hospitals Private Limited Ethics Committee, Sahyadri Clinical Research and Development Centre, 33/34B, Makarand Bhave Path, Erandwane, Pune - 411004, Maharashtra India  ECR/493/Inst/MH/2013/RR-24	Dr Sunil Vasant Sathe
28.	Lisie Hospital, Lisie Hospital, Kochi, Kerala 682018 Kochi Kerala - 682018	Institutional Ethics committee, Lisie Hospital, Kochi-682018, Kerala  ECR/40/INST/KL/2013/R R-20	Dr Jabir Abdullakutty
29.	Shrikrishna Hrudayalaya and Critical Care Centre, Shrikrishna Hrudayalaya and Critical Care Centre, Tikekar Road, Congress Nagar Square, Dhantoli, Nagpur. Nagpur Maharashtra - 440012	Virtuous Institutional Medical Research Committee, IVth Floor, Shrikrishna Hrudayalaya and Critical Care Centre; Tikekar Road, Congress Nagar Square, Dhantoli, Nagpur-440012  ECR/548/Inst/MH/2014/RR-20	Dr Mahesh Fulwani
30.	Amrita Institute of Medical Sciences and Research Centre, Amrita Institute of Medical Sciences and Research Centre, AIMS-Ponekkara. P.O, Kochi-682041, Kerala, India Kochi Kerala - 682041	Institutional Ethics Committee, Amrita Institute of Medical Sciences, AIMS-Ponekkara.P.O, Kochi, Edappally, Ernakulam, Kerala-682041, India.  ECR/129/Inst/KL/2013/RR-24	Dr Navin Mathew
31.	Central India Cardiology Hospital and Research Institute, Plot no-1, Pioneer Co-Op Housing Society, Gawande Lay-Out, Khamla Ring Road, Opps. Sawarkar	Virtuous Institutional Medical Research EC, Shrikrishna Hrudayalaya and Critical Care Centre; Tikekar Road, Congress Nagar Square, Dhantoli, Nagpur-440012,	Dr Sunil Nillkanthrao Washimkar

	Garden, Khamla, Nagpur, Maharashtra -440015 Nagpur Maharashtra - 440015	Maharashtra, India ECR/548/Inst/MH/2014/RR-20	
32.	Krishna Institute of Medical Sciences Ltd, KIMS Hospitals, Krishna Institute of Medical Sciences Ltd, KIMS Hospitals,1 8 31-1, Minister Road, Secunderabad-500003, Hyderabad. Hyderabad Telangana - 500003	KIMS ETHICS COMMITTEE, Krishna Institute of Medical Sciences Ltd, Address: 1-8- 31/1, Minister Road, Secunderabad-500003, Hyderabad, Telangana ECR/142/Inst/AP/2013/RR-24	Dr Rajendra Kumar Premchand

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