



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/20/000017

To,

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

Sir,

With reference to your application No GCT/CT04/FF/2020/18697 (GCT/17/20) dated 26-02-2020, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease”** **Protocol Number: CTQJ230A12301 Version No. 01 dated 23/September/2019** 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) 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;
- (ii) 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;
- (iii) 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;
- (iv) 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;
- (v) 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;
- (vi) 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;

- (vii) 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;
- (viii) 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;
- (ix) 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;
- (x) 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;
- (xi) 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;
- (xii) 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;
- (xiii) 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;
- (xiv) 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;
- (xv) 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;
- (xvi) 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;
- (xvii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xviii) 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,

VENUGOPAL  
L SOMANI

Date: 2020.06.19 12:05:46 +05'30'

(Dr. V. G. Somani)  
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, Bandra Kurla Complex, Bandra (East), Mumbai (India) – 400051** to conduct clinical trial of the new drug or investigational new drug as per protocol no: **CTQJ230A12301 Version No. 01 dated 23/September/2019** 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 \_\_\_\_\_

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI  
DN: cn=VENUGOPAL GIRDHARILAL SOMANI, o=MINISTRY OF HOME AFFAIRS, ou=Ministry of Home Affairs, email=VENUGOPAL.GIRDHARILAL.SOMANI@nic.in, c=IN  
VENUGOPAL GIRDHARILAL SOMANI  
Date: 2020.09.19 12:05:51 +05'30'

(Dr. V. G. Somani)  
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 Licensing 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                                                                                                  |
| <b>Composition:</b>                                      | TQJ230 = 80.0000 mg/0.8 ml in House Specification Active                                                                |
| <b>Indications:</b>                                      | Lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease |

Details of clinical trial site:

| <b>Names and address of clinical trial site</b>                                                                                                                 | <b>Ethics committee details</b>                                                                                                                                                                                                | <b>Name of investigator</b>     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Lisie Hospital, P.O Box No. 3053 Kochi. Kerala, India- 682018                                                                                                   | Institutional Ethics Committee, Lisie Hospital, P.O Box No. 3053 Kochi. Kerala, India - 682018<br><br>ECR/40/Inst/KL/2013/RR-20                                                                                                | Dr. Jabir Abdullakutty          |
| Vijan Hospital & Research Centre (Vijan Cardiac & Critical Care Centre), Dr. Vijan Hospital Marg, College Road, Nashik-422005, Maharashtra, India               | Vijan Hospital Ethics Committee, Vijan Cardiac & Critical Care Centre, Dr. Vijan Hospital Marg, College Road, Nashik-422005, Maharashtra, India<br><br>ECR/406/Inst/MH/2013/RR-19                                              | Dr. Vikrant Vinod Vijan         |
| Department of Cardiology, Government Medical College and Super Specialty Hospital, Tukdoji Square, Nagpur-440009, Maharashtra, India                            | Government Medical College and Hospital, Medical Square, Hanuman Nagar, Nagpur-440003, Maharashtra, India<br><br>ECR/43/Inst/MH/2013/RR-19                                                                                     | Dr. Sunil Nilkanthrao Washimkar |
| Apollo Hospitals International Limited, Gandhinagar, Apollo Hospitals International Limited, Plot No. 1A, BHAT GIDC Estate, Gandhinagar-382428, Gujarat, India  | Institutional Ethics Committee- Clinical Studies, Office of Institutional Ethics Committee, Site Office Building, Apollo Hospitals International Ltd, Bhat, Gandhinagar, Gujarat-382428<br><br>ECR/30/Inst/GJ/2013/RR-19       | Dr. Subir Ghosh                 |
| Acharya Vinoba Bhave Rural Hospital, JNMC,DMIMS Sawangi (Meghe), Wardha-442004, Maharashtra, India                                                              | Institutional Ethics Committee, Besides Food Court, JNMC,DMIMS Sawangi (Meghe), Wardha-442004<br><br>ECR/440/Inst/MH/2013/RR-19                                                                                                | Dr. Gajendra Agrawal            |
| New Era Institute and Research Center, Near Jalaram Mandir, Queta Colony, Near Telephone exchange square Center, Avenue Road, Nagpur, Maharashtra, India-440008 | New Era Hospital Ethics Committee, New Era Institute and Research Center, Near Jalaram Mandir, Queta Colony, Near Telephone exchange square, Center Avenue Road, Nagpur, Maharashtra, India-440008<br><br>ECR/896/Inst/MH/2016 | Dr. Nidheesh Mishra             |
| Shrikrishna Hrudayalaya and Critical Care Centre, Tikekar Road, Congress Nagar Square, Dhantoli, Nagpur-440012                                                  | Virtuous Institutional Medical Research Ethics Committee, IVth Floor, Shrikrishna Hrudayalaya and Critical Care Centre, Tikekar Road, Congress Nagar Square, Dhantoli, Nagpur-440012<br><br>ECR/548/Inst/MH/2014/RR-17         | Dr. Mahesh Fulwani              |

**File No. CT/17/20-DCG(I)**

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| Bhaktivedanta Hospital and Research Institute, Srishti Complex, Bhaktivedanta Swami Marg, Mira Road(E), Thane-401107                               | Bhaktivedanta Hospital Ethics Committee, 6 <sup>th</sup> Floor, Bhaktivedanta Hospital and Research Institute, Srishti Complex, Bhaktivedanta Swami Marg, Mira Road(E), Thane-401107<br><br>ECR/396/Inst/MH/2013/RR-19                                     | Dr. Sandeep Patil            |
| Bhanubhai & Madhuben Patel Cardiac Centre, Shree Krishna Hospital and Medical Research Centre, Gokal Nagar, Karamsad-388325, Gujarat, India        | Institutional Ethics Committee, H.M. Patel Centre for Medical Care and Education, (Managed by Charutar Arogya Mandal), Gokal Nagar, Karamsad, Gujarat-388325, India<br><br>ECR/331/Inst/GJ/2013/RR-19                                                      | Dr. Sunil Kumar Karna        |
| Sahyadri Super Speciality Hospital, 30C-Erandwane, Karve Road, Pune-411004, Maharashtra, India                                                     | Sahyadri Hospitals Ltd Ethics Committee, Sahyadri Clinical Research & Development Centre, A unit of Sahyadri Hospitals Limited, 33/34B, Makarand Bhawe Path, Erandawane, Pune-411004, Maharashtra, India<br><br>ECR/493/Inst/MH/2013/RR-19                 | Dr. Sunil Vasant Sathe       |
| Niramaya Hospitals Pvt Ltd., S. No.4742, Behind Jai Hind Petrol Pump, Next to Chinchwad (E) Post Office, Chinchwad Pune-411019                     | 5 <sup>th</sup> Floor, Niramaya Hospitals Pvt Ltd., Ethics Committee, S. No.4742, Behind Jai Hind Petrol Pump, Next to Chinchwad (E) Post Office, Chinchwad Pune-411019, Maharashtra, India<br><br>ECR/438/Inst/ MH/2013/RR-16                             | Dr. Abhijit Bhaskar Joshi    |
| Department of Cardiology, B.J.G.M.C and Sassoon General Hospital, Near Pune Railway Station, Pune-411001, MH, India                                | Institutional Ethics Committee, B.J. Govt. Medical College and Sassoon General Hospital, Department of Pharmacology, B.J. Govt. Medical College and Sassoon General, Near Pune Railway Station, Pune-411001, MH, India<br><br>ECR/280/Inst/Maha/2013/RR-19 | Dr. Kokane Hemant Trimbak    |
| M S Ramaiah Medical College and Hospitals, M S Ramaiah Clinical Research Centre, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka, India | Ethics Committee, M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka, India<br><br>ECR/215/Inst/KA/2013/RR-19                                                                                           | Dr. Nagamalesh U. M          |
| Mahatma Gandhi Mission Medical College & Hospital, N-6 Cidco , Aurangabad- 431003, Maharashtra, India                                              | Ethics Committee for Research on Human Subject ,Pharmacology Department, Mahatma Gandhi Mission Medical College & Hospital, N-6, Cidco-Aurangabad- 431003 , Maharashtra, India<br><br>ECR/581/Inst/MH/2014/RR-17                                           | Dr.Prashant Prabhakar Udgire |

**File No. CT/17/20-DCG(I)**

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| Rhythm Heart Institute- A Unit of Synergy Lifecare Pvt. Ltd., Near Siddharth Bungalows, Sama- Savli Road, Vadodara- 390022, Gujarat                                              | Rhythm Heart Institute Ethics Committee, Near Siddharth Bungalows, Sama- Savli Road, Vadodara- 390022<br><br>ECR/224/Inst/GJ/2013/RR-19                                                                                                 | Dr. Nirav Bhalani                 |
| CIMS Hospital Pvt. Ltd., Opp. Panchamrut Bungalows, Nr. Shukan mall, Off. Science City Road, Sola, Ahmedabad- 380060, Gujarat, India                                             | Ethics Committee of Care Institute of Medical Sciences Hospital, CIMS Hospital Pvt. Ltd., Opp. Panchamrut Bungalows, Nr. Shukan mall, Off. Science City Road, Sola, Ahmedabad- 380060, Gujarat, India<br><br>ECR/206/Inst/GJ/2013/RR-16 | Dr. Shah Urmil Girishbhai         |
| Chopda Medicare and Research Centre Pvt. Ltd. Magnum Heart Institute, 3/5, Patil Lane No 1, Laxmi Nagar, Near K.B.H. Vidyalaya, Canada Corner, Nashik-422005, Maharashtra, India | Magna-Care Ethics Committee, C/o Chopda Medicare and Research Centre Pvt. Ltd., Magnum Heart Institute, Patil Lane No 1, Near K.B.H. Vidyalaya, Canada Corner, Nashik- 422005, Maharashtra, India<br><br>ECR/79/Inst/MH/2013/RR-19      | Dr. Manojkumar Bhavarilal Chopada |
| EPIC Hospital (Unit of Vatsalya Healthcare LLP), Empire Doctor House, Opp. Kargil Petrol Pump, S. G. Highway, Ahmedabad- 380060, Gujarat, India                                  | Ethics committee of Shreeji Hospital, 1, Saraswati Shopping Centre, Near Visat Petrol Pump, Opposite O.N.G.C. Avanibhavan, Sabarmati, Ahmedabad- 380005, Gujarat, India<br><br>ECR/1220/Inst/GJ/2019                                    | Dr Anil Ranjeetmal Jain           |
| Dept. of Cardiology, S.P. Medical College & A.G. Hospitals, Bikaner-334003                                                                                                       | Ethics Committee, S.P. Medical College & A.G. Hospitals, Bikaner- 334001<br><br>ECR/27/SP/Inst/RJ/2013/RR-19                                                                                                                            | Dr. D. K. Agrawal                 |
| Dept of Cardiology, King George's Medical University, Lucknow                                                                                                                    | King George's Medical University, U.P., Institutional Ethics Committee, Office of the Ethics Committee, Luknow - 226003, (UP) India<br><br>ECR/262/Inst/UP/2013/RR-19                                                                   | Dr. S.K. Dwivedi                  |
| Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi- 110060                                                                                           | Sir Ganga Ram Hospital Ethics Committee, Room Number 1496, 4th Floor, Old Building, Sir Ganga Ram Hospital, Old Rajinder Nagar, New Delhi-110060<br><br>ECR/20/Inst/DL/2013/RR-19                                                       | Dr. Ashwani Mehta                 |

**File No. CT/17/20-DCG(I)**

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| Kasturba Hospital, Madava Nagar, Post Box No. 7, Manipal- 576104                                                     | MAHE, Ethics committee, Mezzanine floor, KMC Old library building, Manipal – 576104<br><br>ECR/191/Inst/KL/2013/RR-19                                                                                                                                       | Dr. Tom Devasia        |
| Department of General Medicine, Government Medical College, Kozhikode, 673008                                        | Institutional Ethics Committee, Government Medical College Kozhikode, 4th Floor, Golden Jubilee Annex, Institute of Maternal & Child Health, Medical College Kozhikode- 673008<br><br>ECR/395/Inst/KL/2013/RR-16<br>Application-<br>EC/RENEW/INST/2019/4433 | Dr. Neeraj Manikath    |
| Columbia Asia Hospital, 85-86 Mysore- Bangalore Ring Road, Junction, Bannimantap 'A' Layout, Mysore-570015 Karnataka | Institutional Ethics Committee, 85-86 Mysore- Bangalore Ring road, Junction, Bannimantap 'A' Layout, Mysore-570015<br><br>ECR/1106/Inst/KA/2018                                                                                                             | Dr. C.B. Keshavamurthy |