



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/22/000177

To,

M/s Kashiv BioSciences Private Limited,
27/2 & 43, Mauje Sarkhej At Building Block B Paiki,
Opposite Applewood Township, Sarkhej,
Ahmedabad (India) – 382210.

Sir,

With reference to your application No. GCT/CT04/FF/2022/35345 (GCT/177/22) dated 23-12-2022, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Randomized, Multicenter, Double-Blind, 4-Arm, Parallel-Group, Active-Controlled, Phase 3 Study to Compare Efficacy, Safety and Immunogenicity of ADL-018 150 mg and 300 mg with US-Licensed Xolair® 150 mg and 300 mg Administered Through Subcutaneous Route Every 4 Weeks in Patients with Chronic Idiopathic Urticaria (CIU) who Remained Symptomatic Despite Treatment with Approved Doses of H1 Antihistamines”**, Protocol No. **KBS/OMA/01, Version 4.0 dated 6/March/2023 with a total of up-to 200 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) **The use of anti-histaminic should be narrowed down to the use of levocetirizine only. Subject who failed to respond to the double dose of the levocetirizine should only be qualified for the inclusion in the proposed biosimilar trial;**
- 2) **Inclusion criteria for the age of proposed trial subject should be 18years to 60 years;**
- 3) **The firm should only recruit a maximum of up to 200 subjects from the country;**
- 4) **There should be 50% site from Govt. hospitals;**
- 5) **The Investigator at all proposed trial sites should be well-experienced dermatologists;**
- 6) **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;**

- 7) 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;
- 8) 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;
- 9) 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;
- 10) 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;
- 11) 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;
- 12) 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;
- 13) 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;
- 14) 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;
- 15) 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;
- 16) 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;
- 17) 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;
- 18) 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;
- 19) 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;

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- 20)** 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;
- 21)** 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;
- 22)** the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- 23)** 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;
- 24)** 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 Licencing 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 **M/s Kashiv BioSciences Private Limited , 27/2 & 43, Mauje Sarkhej At Building Block B Paiki, Opposite Apple wood Township, Sarkhej, Ahmedabad (India) - 382210 Telephone No.: 079-68183800 079-68183801 FAX: 079-68183975 E-Mail : PARVA.PUROHIT@KASHIVBIO.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No. KBS/OMA/01, Version 4.0 dated 6/March/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 _____

(Dr. Rajeev Singh Raghuvanshi)
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 | Omalizumab (r-DNA origin) Injection 150 mg/ml |
| Therapeutic class: | Anti IgE Monoclonal Antibody |
| Dosage form: | rDNA (Liquid) |
| Composition: | Water for Injection = 1.0000 ml U.S.P. Inactive Poloxamer 188 = 0.4000 mg/ml U.S.P., E.P. Inactive L-Arginine Hydrochloride (Food Chemical Codex) = 42.1300 mg/ml U.S.P., E.P., J.P. Inactive Sodium Phosphate dibasic heptahydrate = 1.3400 mg/ml U.S.P., E.P., J.P. Inactive Sodium Phosphate monobasic monohydrate = 2.0700 mg/ml B.P. U.S.P., E.P., J.P. Inactive Omalizumab (r-DNA Origin) (ADL-018) = 150.0000 mg/ml In House Specification Active |

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|---------------------|--|
| Indications: | Chronic Idiopathic Urticaria Asthma and Nasal Polyps |
|---------------------|--|

Annexure:

Details of clinical trial site:

| S. No. | Name and address of clinical trial site | Ethics Committee Details | Name of Investigator |
|---------------|--|--|-----------------------------|
| 1. | Chennai Meenakshi Multi Speciality Hospital Limited, Old # 148, new # 72, Luz Church Road, Mylapore, Chennai – 600004, Tamil Nadu, India | Chennai Meenakshi Multi Speciality Hospital Ethics Committee, Old # 148, new # 72, Luz Church Road, Mylapore, Chennai – 600004, Tamil Nadu, India ECR/516/Inst/TN/2014/RR-20 | Dr. Jayaraman Murugaiya |
| 2. | Calcutta National Medical College, 32, Gorachand Road, Kolkata-700014, West Bengal, India | Ethics Committee Calcutta National Medical College, Calcutta National Medical College 32, Gorachand Road, Kolkata-700014, West Bengal, India ECR/771/Inst/Wb/2015/RR-18 | Dr. Abhishek De |
| 3. | NRR Hospital, Janapriya Apartments 3 & 3A & Hesarghatta Main Road, Chikkasandra, Near Chikkabanavara Railway Station, Bangalore – 560090 | CLINISYD Research Global Solutions Pvt. Ltd., 24/2, 14 th Cross, Malagala, Nagarabavi 2 nd Stage, Bangalore, Karnataka-560091, India ECR/328/Inst/KA/2020 | Dr. Akhilesh A |
| 4. | Ajanta Research Centre, Ajanta Hospital & IVF Centre, 765, ABC Complex, Kanpur Road, Alambagh, Lucknow-226005, Uttar Pradesh, India | Institutional Ethics committee, Ajanta Hospital & IVF Centre, 765, ABC Complex, Kanpur Road, Alambagh, Lucknow-226005, Uttar Pradesh, India ECR/611/Inst/UP/2014/RR-20 | Dr. Madan Amit |
| 5. | Rising Medicare Hospital, S.No.4/1, Off Kharadi Bypass Road, behind | Rising Medicare Hospital Ethics Committee, S.No.4/1, Off Kharadi Bypass Road, behind Radission | Dr. Ingale Ashwini Ashok |

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| S. No. | Name and address of clinical trial site | Ethics Committee Details | Name of Investigator |
|---------------|--|--|-----------------------------|
| | Radission blu Hotel, Kharadi, Pune-411014 | blu Hotel, Kharadi, Pune-411014 ECR/1578/Inst/MH/2021 | |
| 6. | Prakash Institute of Medcial Science & Research, Urun Islampur (PIMS&R), Islampur-Sangli road, Islampur-Tal:- Walwa, Dist-Sangali-415409, Maharashtra, India | Prakash Medical College Institutional Ethics Committee. C/o Prakash Institute of Medcial Science & Research, Urun-Islampur (PIMS&R), Islampur-Sangli road, Islampur- Tal:- Walwa, Dist- Sangali-415409, Maharashtra, India ECR/1052/Inst/MH/2018/RR-21 | Dr. Deshpande Avdhut B |
| 7. | Krishna Rajendra Hospital, Irwin Rd, Devaraja Mohalla, Yadavagiri, Mysuru, Karnataka-570001 | Mysore Medical College & Research Institute and Associated Hospitals, Irwin Road, Mysuru (Mysore), Karnataka-570001 ECR/134/Inst/KA/2013/RR-19 | Dr. Bangaru H |
| 8. | Pulse Hospital, 2/4, Gurudwara Road, Nehru Nagar (W), Bhilai, Durg, Chhattisgarh, India-490020 | Institutional Ethics Committee - Pulse Hospital, 2/4, Gurudwara Road, Nehru Nagar (W), Bhilai, Durg, Chhattisgarh, India-490020 ECR/1446/Inst/CG/2020 | Dr. Bharat Chawda |
| 9. | AIIMS Bhubaneswar, Sijua, Patrapada, Dumduma, Odisha, India-751019 | Institutional Ethics Committee, AIIMS Bhubaneswar, Sijua, Patrapada, Dumduma, Odisha, India-751019 ECR/534/Inst/OD/2014/RR-20 | Dr. Chandra Sekhar Sirka |
| 10. | Department of Dermatology, Venereology & Leprology, 2nd floor, D Block, Nehru hospital, Sector 12- Chandigarh-160012, India | Institutional Ethics Committee, Post Graduate Institute of Medical Education and Research, Room No. 6006, IEC Office, 6th Floor P N Chuttani Block, Sector 12-Chandigarh -160012, India | Dr. Davinder Parsad |

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| S. No. | Name and address of clinical trial site | Ethics Committee Details | Name of Investigator |
|---------------|--|---|-----------------------------|
| | | ECR/25/Inst/CH/2013/RR-20 | |
| 11. | 7-Orange Hospital, Pawana Nagar, Next to Jain Hospital, Near Chapekar Chowk, Chinchwad, Pune-411033, Maharashtra, India | Institutional Ethics Committee of Sai Sneh Hospital & Diagnostic centre, Opp. PMT Bust Depot, Pune-Satara Road, Katraj, Pune-411046, Maharashtra, India ECR/989/Inst/MH/2017/RR-20 | Dr. Jogaikar Dilip Gopal |
| 12. | Victoria Hospital, Bangalore Medical College & Research Institute, Fort, Krishna Rajendra Rd, Bengaluru, Karnataka-560002 | Ethics Committee of BMCRI, Bangalore Medical College & Research Institute, Fort, KR Road, Bangalore Urban, Karnataka-560002, India ECR/302/Inst/KA/2013/RR-20 | Dr. Eswari L |
| 13. | Sri Venkateshwara Hospital, #27, 29 th Main Road, Rashtra Kuvempu Nagara, BTM 2 nd Stage, BTM Layout, Bangalore-560076, Karnataka, India | Sri Venkateshwara Hospital Ethics Committee, Sri Venkateshwara Hospital, #27, 29 th Main Road, Rashtra Kuvempu Nagara, BTM 2 nd Stage, BTM Layout, Bangalore-560076, Karnataka, India ECR/298/Inst/KA/2013/RR-19 | Dr. Harish Prasad B.R |
| 14. | Department of Skin, VD & Leprosy, Government Medical College & Hospital, Medical Square, Hanuman Nagar, Nagpur-440003 | Institutional Ethics Committee (IEC), Department of Pharmacology, Government Medical College & Hospital, Medical Square, bagpur ECR/43/Inst/MH/2013/RR-22 | Dr Mukhi Jayesh Ishwardas |
| 15. | Dr. D. Y. Patil Medical College, Hospital & Research Centre, Sector-5, Nerul, Navi Mumbai-400706, Maharashtra, India | Institutional Ethics Committee, 5 th Floor, Department of Pharmacology, Dr. D. Y. Patil Medical College, Hospital & Research Centre, Sector-5, Nerul, Navi Mumbai-400706, Maharashtra, India | Dr. Godse Kiran Vasant |

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| S. No. | Name and address of clinical trial site | Ethics Committee Details | Name of Investigator |
|---------------|---|---|----------------------------------|
| | | ECR/195/Inst/MH/RR-19 | |
| 16. | Department of Skin and VD, Indira Gandhi Institute of Medical Sciences (IGIMS), Sheikhpura, Patna, Bihar-800014, India | Institutional Ethics Committee, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna Bihar-800014, India ECR/640/Inst/BR/2014/RR-20 | Dr. Kranti Chandan Jaykar |
| 17. | Department of Dermatology, GMERS Medical College and Civil Hospital Sola, Nr. Gujrat High Court, S.G. Highway, Sola, Ahmedabad-380060, Gujarat, India | Institutional Ethics Committee GMERS Medical College, Sola S.G. Highway, Nr. Gujrat High Court, Ahmedabad-380061, Gujarat, India ECR/404/Inst/GJ/2013/RR-20 | Dr Krina Bharat Patel |
| 18. | Medistar Multispecialty Hospital, Trimurti Avenue, Medistar Cross Road, NH8, Industrial Area, Himatnagar-383001 | Medistar Hospital Ethics Committee (MHEC), Trimurti Avenue, Medistar Cross Road, NH8, Industrial Area, Himatnagar-383001 ECR/794/Inst/GJ/2015/RR-22 | Dr. Patel Maheshkumar Chaturbhai |
| 19. | BAPS Pramukh Swami Hospital Clinical Research Department, Shri Pramukh Swami Maharaj Marg, Adajan Char Rasta, Adajan, Surat-395009, Gujarat, India | BAPS Pramukh Swami Hospital Ethics Committee, Shri Pramukh Swami Maharaj Marg, Adajan Char Rasta, Adajan, Surat-395009, Gujarat, India ECR/639/Inst/GJ/2014/RR-20 | Dr. Patel Mehul Rajendrabhai |
| 20. | Kempegowda Institute of Medical Sciences Hospital and Research Centre, Krishna Rajendra Road, Parvathipuram, Vishweshwarpura, Shankarapura, Bengaluru, Karnataka-560002 | KIMS Institutional Ethics Committee, Kempegowda Institute of Medical Sciences, Attimabbe Road, Banashankari, 2 nd Stage, Bangalore-560002 ECR/216/Inst/Kar/2013/RR-19 | Dr Nandini A.S. |

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| S. No. | Name and address of clinical trial site | Ethics Committee Details | Name of Investigator |
|---------------|--|---|--------------------------------|
| 21. | Gandhi Hospital, Department of Dermatology, Venereology, and Leprosy (DVL), 5 th Floor, Musheerabad, Secunderabad, Telangana, India-500003 | Institutional Ethics Committee , Gandhi Medical College & Hospital, Musheerabad, Secunderabad, Hyderabad, Telangana, India-500003 ECR/180/Inst/AP/2013/RR-19 | Dr. Gurram Narasimha Rao Netha |
| 22. | Clinical Research Room, Department of Dermatology, King George Hospital, Andhra Medical College, Maharanipeta, Visakhapatnam-530002, Andhra Pradesh, India | King George Hospital, Andhra Medical College. Institutional Ethics Committee King George Hospital, King George Hospital, Collector Office Junction, Maharanipeta, Visakhapatnam-530002, Andhra Pradesh, India ECR/197/Inst/KGH/2013/RR-20 | Dr. Patnala Guru Prasad |
| 23. | Father Muller Medical College Hospital, Father Muller Road, Kankanady, Mangalore, Karnataka-575002, India | Father Muller Institutional Ethics Committee Father Muller Medical College Hospital, Father Muller Road, Kankanady, Mangalore, Karnataka-575002, India ECR/540/Inst/KA/2014/RR-20 | Dr. Ramesha Bhat M |
| 24. | Grant Medical Foundation, Ruby Hall Clinic, 40 Sassoon Road, Pune-411001, Maharashtra, India | Institutional Ethics Committee, Poona Medical Research Foundation, E4-C to E4-F, 4 th Floor Fifth Avenue, Condominium, Dhole Patil Road, Pune-411001, Maharashtra, India ECR/24/Inst/MH/2013/RR-22 | Dr. Aderao Rashmi Badrinath |
| 25. | Shubham Sudbhawana Super Specialty Hospital, B31/80, 23B-Bhogabir, Lanka, Varanasi-221005, Uttar Pradesh, India | Institutional Ethics Committee Shubham Sudbhawana Super Specialty Hospital B31/80, 23B-Bhogabir, Lanka, Varanasi-221005, Uttar Pradesh, India | Dr. Rashmi Singh |

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| S. No. | Name and address of clinical trial site | Ethics Committee Details | Name of Investigator |
|---------------|---|--|-------------------------------|
| | | ECR/667/Inst/UP/2014/RR-20 | |
| 26. | Grant Medical College and Sir JJ Group of Hospitals, OPD-42, Department of Dermatology, OPD Building, Grant Medical College and Sir JJ Group of Hospitals, Byculla, Mumbai, Maharashtra, India-400008 | Institutional Ethics Committee Department of Pharmacology, Grant Medical College and Sir JJ Group of Hospitals, Byculla, Mumbai, Maharashtra, India-400008 ECR/382/Inst/MH/2013/Rr-19 | Dr. Kamath Ratnakar Raghunath |
| 27. | Sanjivani Super Speciality Hospitals Pvt. Ltd., 1, New Uday Park Society, Near Sunrise Park, Vastrapur, Ahmedabad-380015, Gujarat, India | Sanjivani Hospitals Ethics Committee, 1, New Uday Park Society, Near Sunrise Park, Vastrapur, Ahmedabad-380015, Gujarat, India ECR/183/Inst/Ahm/2013/RR-22 | Dr. Shah Ruchir Hitendrabhai |
| 28. | Sir Ganga Ram Hospital, SGRH marg, Rajinder Nagar, New Delhi-110060, India | Sir Ganga Ram Hospital Ethics Committee Room No 1643, 6th floor, casualty Building Sir Ganga Ram Hospital, SGRH marg, Rajinder Nagar, New Delhi-110060, India ECR/20/Inst/DL/2013/RR-2019 | Dr. Subhash Chandra Bharija |
| 29. | Mandya Institute of Medical Sciences (MIMS), Bangalore Mysore Road, Mandya, Karnataka-571401 | Institutional Ethics Committee, Mandya Institute of Medical Sciences, Bangalore Mysore Road, Mandya, Karnataka-571401 ECR/405/Inst/KA/2013/RR-21 | Dr. Shashi Kumar B.M |
| 30. | KLES Dr. Prabhakar Kore Hospital & MRC. Nehru Nagar, Belagavi, Karnataka- 590010 | Institutional Ethics Committee, KLE University (KAHER), KLES Dr. Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi, Karnataka- 590010 | Dr. Shivakumar Patil |

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| S. No. | Name and address of clinical trial site | Ethics Committee Details | Name of Investigator |
|---------------|---|---|---------------------------------|
| | | ECR/211/Inst/KA/2013/RR-19 | |
| 31. | Khyati Multi Speciality Hospital, S. No. 235/2, B/s, Tata Motors Showroom, Opposite Rajpath Club, S.G. Highway, Bodakdev, Ahmedabad-380015, Gujarat, India | Institutional Ethics Committee, Asian Education and Research Foundation, S. No. 235/2, B/s, Tata Motors Showroom, Opposite Rajpath Club, S.G. Highway, Bodakdev, Ahmedabad-380015, Gujarat, India ECR/698/Inst/GJ/2015/RR-21 | Dr. Nagpal (Mrs) Smita Anish |
| 32. | Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra, India | LPR Ethics Committee, Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad. Pune-411057, Maharashtra, India ECr/Inst/751/MH/2015/RR-21 | Dr. Shendkar Sonal Mahadev |
| 33. | Nil Ratan Sircar Medical College, 138, Acharya Jagadish Chandra Bose Rd, Sealdah, Raja Bazar, Kolkata, West Bengal-700014 | Institutional Ethics Committee, N.R.S Medical College, 138, Acharya Jagadish Chandra Bose Road, Kolkata- 700014 ECR/609/Inst/WB/2014/RR-20 | Das Dr. Suchibrata |
| 34. | Redkar Hospital and Research Centre, CROM Clinical Research and Medical Tourism Pvt. Ltd., Goa Highway, Oshalbag, Village, Dhargal, Tal-Pernem, Goa, 403513 | Redkar Hospital and Research Centre Institutional Ethics Committee (RHIEC) C/o Redkar Hospital and Research Centre, Mumbai Goa Highway, Dargalim, dhargal, Pernem, Goa, 403513 ECR/902/Inst/GA/2018/RR-21 | Dr. Sunil Kumar Prabhu B |
| 35. | Department of Skin, VD & Leprosy, Charak Bhavan, OPD Block, SMS Hospital, JLN Marg, Jaipur-302004, | Ethics Committee, SMS Medical College & Attached Hospitals, J.L. N. Marg, Jaipur, Rajasthan-302004 | Dr. Surendra Kumar |

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| S. No. | Name and address of clinical trial site | Ethics Committee Details | Name of Investigator |
|---------------|---|--|-------------------------------|
| | Rajasthan, India | ECR/26/Inst/RJ/2013/RR-19 | |
| 36. | B.J. Medical College & Civil Hospital, Department of Dermatology, STD and Leprosy, Civil Hospital, Asarwa, Ahmedabad-380016, Gujarat, India | Institutional Ethics Committee B.J. Medical College & Civil Hospital, Civil Hospital, Asarwa, Ahmedabad-380016, Gujarat, India ECR/72/Inst/GJ/2013/RR-19 | Dr. Karia Umesh Karsandas |
| 37. | Amrita Institute of Medical Sciences, Ponekkara, P.O, Kochi, Kerala-682041 | Institutional Ethics Committee, Amrita Institute of Medical Sciences and Research Centre, AIMS Ponekkara P.O, Kochi-682041 ECR/129/Inst/KL/2013/RR-19 | Dr. Vinitha Varghese Panicker |
| 38. | Global Hospital & Research Institute, 577/2, Off Sinhad Road, Near Dattwadi Police Chowki, , Dattawadi, Pune-411030, Maharashtra, India | Institutional Ethics Committee of Sai Sneh Hospital & Diagnostic Centre, Opp. PMT Bus Depot, Pune-Satara Road, Katraj, Pune-411046, Maharashtra, India ECR/989/Inst/MH/2017/RR-20 | Dr. Gore Vishal Laxman |
