



File No: BIO/CT/23/000103

Dated 01-12-2023

To,

M/s Reliance Life Sciences Pvt. Ltd.,  
Dhirubhai Ambani Life Sciences Centre,  
R-282, TTC Area of MIDC, Thane-Belapur Road,  
Maharashtra (India) – 400701,  
Telephone No.: 022-35338000 FAX: 022-35338099

Subject: Application for grant of permission to conduct Phase IV clinical trial entitled “A prospective, multi-centre, open label, phase IV study to evaluate safety and efficacy profile of UstekiRel™ in patients with moderate to severe plaque psoriasis” vide Protocol No.: RLS/PMS/2023/05; Version 1.0, Dated: 31 Jul 2023 - regarding

Ref. No.: Your Application No. BIO/CT04/FF/2023/39009 dated 17-AUG-2023

Sir,

With reference to your application No. BIO/CT04/FF/2023/39009 dated 17-AUG-2023, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter 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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing 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) 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.
- (XV) The Central Licensing 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.
- (XVI) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

Yours faithfully,

**RAJEEV SINGH**  
**RAGHUVANSHI**  
(Dr. Rajeev Singh-Raghuvanshi)  
Drugs Controller General (India)  
Central Licensing Authority

Digitally signed by RAJEEV SINGH RAGHUVANSHI  
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL  
ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI,  
2.5.4.20=80c276a234e4ef0e8239774cde405c27690410  
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st=TAMIL NADU,  
serialNumber=657F5E47D940985D8F038DC902D0E1F7  
3CFA12A1A126EA94F5701124A19013, cn=RAJEEV  
SINGH RAGHUVANSHI

**FORM CT-06**

(See rules 22, 25, 26, 29 and 30)

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

The Central Licensing Authority hereby permits M/s Reliance Life Sciences Pvt. Ltd., Dhirubhai Ambani Life Sciences Centre, R-282, TTC Area of MIDC, Thane-Belapur Road, Maharashtra (India) – 400701, Telephone No.: 022-35338000 FAX: 022-35338099 to conduct Phase IV clinical trial entitled "**A prospective, multi-centre, open label, phase IV study to evaluate safety and efficacy profile of Ustekisel™ in patients with moderate to severe plaque psoriasis**" as per Protocol No.: RLS/PMS/2023/05; Version 1.0, Dated: 31 Jul 2023 in the below mentioned clinical trial sites.

2. Details of 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: 01-Dec-2023

RAJEEV SINGH  
RAGHUVANS  
HI (Dr. Rajeev)

(Dr. Rajeev Singh Raghuwansi)  
Drugs Controller General (India)  
Central Licensing Authority

**Digitally signed by RAJEEV SINGH RAGHUVERSI  
DN: c=IN, o=CENTRAL DRUGS STANDARD  
CONTROL ORGANIZATION, ou=RAJEEV SINGH  
RAGHUVERSI,  
2.5.4.20=80c62f6a23caefab7e8a239774cdeb03c276  
9041015a06564fe67f54fb765d1db1,  
postalCode=600034, st=TAMIL NADU,  
serialNumber=657F5E47D0A99B5DF83BDCA92DDC  
AF735CEAE12BA9A9945FA561A10  
cn=RAJEEV SINGH RAGHUVERSI**

Date: 2023.10.06 11:57:00 +05'30'

**Annexure:****Details of new drug or investigational new drug:**

|                                                    |                                                                               |                                                      |
|----------------------------------------------------|-------------------------------------------------------------------------------|------------------------------------------------------|
| Names of the new drug or investigational new drug: | Ustekinumab Solution for Injection 45mg (r-DNA origin)                        |                                                      |
| Dosage form:                                       | Solution for injection                                                        |                                                      |
| Therapeutic Class                                  | Monoclonal antibody                                                           |                                                      |
| Composition:                                       | Each 0.5 ml in pre-filled syringe contains:                                   |                                                      |
|                                                    | <b>Name of Ingredients</b>                                                    | <b>Quantity in each 0.5 ml in pre-filled syringe</b> |
|                                                    | Ustekinumab IHS                                                               | 45 mg                                                |
|                                                    | L-histidine and L-histidine monohydrochloride monohydrate Ph.Eur              | 0.5 mg                                               |
|                                                    | Polysorbate 80 I.P.                                                           | 0.02 mg                                              |
|                                                    | Sucrose I.P.                                                                  | 38.00 mg                                             |
|                                                    | Water for Injection I.P.                                                      | QS to 0.5 ml                                         |
| Indications:                                       | For the treatment of adult patients with moderate to severe plaque psoriasis. |                                                      |

|                                                    |                                                                               |                                                    |
|----------------------------------------------------|-------------------------------------------------------------------------------|----------------------------------------------------|
| Names of the new drug or investigational new drug: | Ustekinumab Solution for Injection 90mg (r-DNA origin)                        |                                                    |
| Dosage form:                                       | Solution for injection                                                        |                                                    |
| Therapeutic Class                                  | Monoclonal antibody                                                           |                                                    |
| Composition:                                       | Each 1 ml in pre-filled syringe contains:                                     |                                                    |
|                                                    | <b>Name of Ingredients</b>                                                    | <b>Quantity in each 1 ml in pre-filled syringe</b> |
|                                                    | Ustekinumab IHS                                                               | 90 mg                                              |
|                                                    | L-histidine and L-histidine monohydrochloride monohydrate Ph.Eur              | 1.0 mg                                             |
|                                                    | Polysorbate 80 I.P.                                                           | 0.04 mg                                            |
|                                                    | Sucrose I.P.                                                                  | 76.00 mg                                           |
|                                                    | Water for Injection I.P.                                                      | QS to 1.0 ml                                       |
| Indications:                                       | For the treatment of adult patients with moderate to severe plaque psoriasis. |                                                    |

**Details of clinical trial site:**

| <b>Names and address of clinical trial site</b>                                                                                                                         | <b>Ethics committee details</b>                                                                                                                                                                                                                       | <b>Name of Investigator</b> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Shlok Multispeciality Hospital,,<br>Opposite Radhaswami<br>Samyak,Lambhvel Rd, behind<br>Crescent Hotel Anand Gujarat -<br>388001                                       | Shlok Superspecialty Care 4Th Floor, B/H<br>Crescent Hotel Opp. Radhaswami, Samyak,<br>Lambhvel Road Anand Anand, Gujarat -<br>388001 India<br>EC Reg. No. ECR/1718/Inst/GJ/2022                                                                      | Dr Ankush Ajbani            |
| K R Hospital, Attached to<br>Mysore Medical College and<br>Research Institute, Room No.<br>14, Department of<br>Dermatology, Irwin Road<br>Mysuru Karnataka -<br>570001 | IEC-MMC and RI and Associated<br>Hospital, Mysore Medical College and<br>Research Institute Mysore Medical<br>College and Research Institute Irwin<br>Road Mysuru Mysuru (Mysore)<br>Karnataka – 570001<br>EC Reg. No. ECR/134/Inst<br>/KA/2013/RR-19 | Dr B L Nanjunda<br>Swamy    |
| Shri Nidan Hospital and Hope<br>fertility centre, Block A, 27,<br>Princeroad, Vidhyut Nagar<br>Jaipur Rajasthan - 302021                                                | Swastik ethics committee shri Nidaaan<br>hospital and hope fertility centre 27-<br>Vibhut Nagar A Ajmer road Jaipur<br>Rajasthan 302021<br>EC Reg. No ECR/434/Inst/RJ/2013                                                                            | Dr Bindiya Bansal           |
| AIIMS, Sijua, Patrapada,<br>Dumduma Bhubaneswar<br>Orissa- 751019                                                                                                       | Institutional Ethics Committee, AIIMS,<br>Sijua, Patrapada, Dumduma,<br>Bhubaneswar Odisha, India,751019<br>EC Reg. No EC/534/Inst/OD/2014/RR20                                                                                                       | Dr Chandra<br>Sekhar Sirka  |
| Belagavi Institute of Medical<br>Sciences, Dr. B R Ambedkar<br>Road, Sadashiv Nagar<br>Belagavi Karnataka - 590019                                                      | Institutional Ethics Committee BIMS Belagavi<br>Institute Of Medical Sciences, Belagavi Dr B<br>R Ambedkar Road Belgaum Belgaum<br>Belagavi(Belgaum) Karnataka - 590001 India<br>EC Reg. No ECR/801/Inst/KA/2016/RR<br>-20                            | Dr Gajanan Pise             |
| HBT Trauma Care Hospital,<br>Ajgaonkar Plot Western<br>Express Highway,<br>Jogeshwari, East Mumbai<br>Maharashtra - 400060                                              | Trauma Care Hospital, Ajgaonkar Plot,<br>Western Express Highway, Jogeshwari<br>E, Mumbai City, Maharashtra – 400060<br>EC Reg. No. ECR/1623/Inst/MH/2021                                                                                             | Dr Geoffrey Vaz             |

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Rajarejeswari Medical College and Hospital, No.202, Kambipura, Mysore Road BengaluruKarnataka - 560074                                                              | Rajarajeswari Medical College& Hospital no.202, Kambipura Mysore Road , Bangluru, Karnataka ,560074.<br>EC Reg. No. ECR/56/Inst/KA/2013/RR19                                          | Dr Hari Kishan           |
| Oyster and Pearl Hospital, Shivajinagar, Pune 1671-75 Ganeshkhind road, ShivajinagarPune Maharashtra - 411005                                                       | ONP Ethics committee Phadnis clinic pvt ltd 1671-75 behind hotel pride Shivaji Nagar<br>EC Reg. No. ECR/71/Inst/MH/2013                                                               | Dr Hemant kumar Talnikar |
| PGIMER, Dept of Dermatology,Venerology and Leprology, Sector-12,ChandigarhChandigarh Chandigarh - 160012                                                            | Institutional Ethics Committee, Room no 6006,6th Floor, P.N Chuttani Block, PGIMER, Sector-12, Chandigarh,UT,India-160012<br>EC Reg. No. ECR/25/Inst/CH/2013/RR20                     | Dr Sanjeev Handa         |
| Sangvi Multispeciality Hospital Pvt, Sr. no. 71 1 2 189, city survey no 2387 Krushna chauk, Krushna nagar New Sangvi Maharashtra - 411027                           | IEC Sai sneh hospital and diagnostic centre opp PMT Bus depot Pune Satara Road Katraj Pune<br>EC Reg. No. ECR/989/Inst/MH/2017                                                        | Dr Sarita Tippannawar    |
| Calcutta School of Tropical Medicine, Department of Dermatology 108, Chittaranjan Avenue, College Square KolkataWest Bengal - 700073                                | Clinical Research Ethics Committee School of Tropical Medicine, Kolkata, 108, Chitta Ranjan Avenue, Kolkata, West Bengal – 700073<br>EC Reg. No. ECR/194/Inst/WB/2013/RR-20           | Dr Saswati Halder        |
| SMS Medical College and Hospital, SMS Medical College and Hospital, Department of Skin,VD and Leprosy, Charak Bhavan,OPD Block, JLN Marg Jaipur, Rajasthan - 302004 | Ethics Committee, S.M.S. Medical College and Attached Hospitals J.L.N. Marg Jaipur Jaipur Rajasthan -302204<br>EC Reg. No. ECR/26/Inst/RJ/2013/RR19                                   | Dr Surender Kumar        |
| NKP Salve Institute of Medical Sciences and Research Center,Hingna Road, Digdoh Hills Nagpur Maharashtra - 440019                                                   | Institutional ethics committee NPK salve institute of medical sciences Digdoh hills hingna road Nagpur Maharashtra 440019<br>EC Reg. No. ECR/88/Inst/MH/2013/RR19                     | Dr Sushil Pande          |
| BJ Medical College and Civil Hospital, Department of Dermatology , STD and Leprosy ,New Civil Hospital Aswara Gujarat - 380016                                      | Institutional Ethics Committee, BJ Medical College & Civil Hospital office of medical Superintendent Civil Hospital, Ahmdabad, Gujarat-380016<br>EC Reg. No. ECR/72/Inst/GJ/2013/RR19 | Dr Umesh Karia           |

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|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Amrita Institute of Medical Sciences and Research Centre, Amrita lane, Ponekkara Kochi Kerala - 682041 | IEC Amrita institutional ethics committee<br>AIMS ponekkarra Kochi 682041.<br>EC Reg. No. ECR/129/Inst/KL/201                                                                                                                         | Dr Vinita Varghese  |
| Bhate Hospital, Opposite civil Hospital, Dr. B R Ambdekar road Belagavi Karnataka - 590002             | Institutional Ethics Committee Arihant Hospital Arihant Hospital A Unit Of<br>Dixit Health Care C Square, CST No. 10632/A1/B Nehru Nagar Belgaum Belagavi (Belgaum) Karnataka - 590010<br>India.<br>EC Reg. No. ECR/1840/Inst/KA/2023 | Dr Shivakumar Patil |

