File No. SND/CT/22/000010
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Subsequent New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 23 MAY 2022

To

M/s. Sun Pharmaceutical Industries Ltd.,
Tandalja, Vadodara, Gujarat (India) – 390012.

Subject: Permission to conduct Phase IV Clinical trial of Teriperatide Injection, Solution for injection in a pre-filled pen 600mcg/2.4ml (Synthetic Origin) - A Prospective, Multi-Centre, Single-Arm, Phase IV Study to Assess the Safety and Efficacy of Teriparatide Injection for the Treatment of 'Men and Postmenopausal Women with Osteoporosis who are at High Risk of Fracture' and 'Men and Women with Osteoporosis Associated with Sustained Systemic Glucocorticoid Therapy who are at Increased Risk for Fracture (Protocol No. ICR/22/01, Version No.: 1.0, Date: 09.02.2022) - Reg.

CT NOC No.: CT/SND/011/2022

Sir,

With reference to your Application No. SND/CT04/FF/2022/30815 dated 24-02-2022 please find enclosed herewith the permission in Form CT-06, CT NOC No. **CT/SND/011/2022** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

This permission is subject to the conditions, as mentioned below.

Yours faithfully,

(Dr. V. G. Somani)
Central Licensing Authority

Conditions of Permission

(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 Licencing 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 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;

(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 of the New Drugs and Clinical Trials Rules, 2019;

(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 the Chapter VI of the said Rules 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 the 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 Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing 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) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

(xix) It may kindly be noted that merely granting permission to conduct Clinical trial with the drug does not convey or imply that based on the Clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.

(xx) **Age of the post-menopausal women should be revised to 45 to 85 years.**

(xxi) **Both Frax score and BMD should be estimated and it should be done with the equipment throughout the period of study.**

FORM CT-06

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

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

CT NOC NO.: CT/SND/011/2022

The Central Licensing Authority hereby permits **M/s Sun Pharmaceutical Industries Ltd., Tandalja, Vadodara, Gujarat (India) - 390012** to conduct clinical trial of the new drug ~~or investigational new drug~~ as per **Protocol No. ICR/22/01, Version No.: 1.0, Date: 09.02.2022** in the below mentioned clinical trial sites.

2. Details of new drug or ~~investigational new drug~~:

Names of the new drug:	Teriparatide Injection solution for injection in a pre-filled pen 600 mcg/2.4 ml (Synthetic Origin)
Therapeutic class:	Parathyroid hormones and analogues
Dosage form:	Injection solution for injection in a pre-filled pen
Composition:	Each ml contains: Teriparatide (Synthetic Origin).....250mcg Mannitol.....45.4 mg Glacial Acetic Acid .....0.41mg Sodium Acetate Anhydrous .....0.1mg Metacresol.....3.0mg (as Preservative) Sodium Hydroxide IP q.s. for pH adjustment Hydrochloric Acid IP q.s. for pH adjustment Water for Injections IP q.s. to 1.0ml
Indications:	1. For the treatment of men and postmenopausal women with osteoporosis who are at a high risk of fracture. It increases bone mineral density (BMD) and reduces the risk of vertebral and non-vertebral fractures. 2. It is also indicated for the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture.

Details of clinical trial sites

Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/ Registration Number
1	Dr. Shukla Dhaiwat Mrugeshbhai (Consultant Rheumatologist) V S General Hospital, Paldi, Ahmedabad, Gujarat.	Riddhi Medical Nursing Home IEC, Riddhi Medical Nursing Home, Maninagar, Ahmedabad, Gujarat. ECR/886/Inst/GJ/2016/RR-19
2	Dr. Pawar Eknath Deosing (Professor and Head) Grant Government Medical College and Sir JJ group of Hospitals, Byculla, Mumbai, Maharashtra	Institutional Ethics Committee, GGMC, Grant Govt Medical College, Mumbai, Maharashtra ECR/382/Inst/MH/2013/RR-19

3	Dr. B. Valya (Professor of Orthopedics) Gandhi Hospital, Musheerabad, Secunderabad, Telangana.	Institutional Ethics Committee Gandhi Medical College And Hospital, Secunderabad, Telangana. ECR/180/Inst/AP/2013/RR-19
4	Dr. Sharth Kumar PV (Professor) Victoria Hospital, Bangalore Medical College and Research Institute, Bangalore, Karnataka	Ethics Committee Of BMCRI, Bangalore Medical College And Research Institute, Bangalore, Karnataka ECR/302/Inst/KA/2013/RR-20
5	Dr. Sameer Mittal (Consultant) Suyash Super Speciality Hospital, Raipur, Chhattishgarh	Suyash Hospital Institutional Ethics Committee, Suyash Hospital, Raipur, Chhattishgarh ECR/1546/Inst/CG/2021
6	Dr. Markade Pravin Narayanrao (Consultant Orthopedics) Ishwar Institute of Health Care, Padegaon, Aurangabad, Maharashtra	Ethics Committee of Ishwar Institute of HealthCare, Ishwar Institute of Health Care, Padegaon, Aurangabad, Maharashtra ECR/988/Inst/MH/2017/RR-20
7	Dr. Patil Vishal Supada (Consultant Orthosurgeon) Medipoint Hospital Pvt. Ltd., Aundh, Pune, Maharashtra	Penta-Med Ethics Committee, Medipoint Hospitals Pvt. Ltd, Aundh, Pune, Maharashtra ECR/357/Inst/MH/2013/RR-20
8	Dr. Srivastava Rajesh Kumar (Consultant M.S (Ortho)) Sanjivini Hospital And Research Center, Gomti Nagar, Lucknow, Uttar Pradesh	Sanjivani Lung Centre Ethics Committee, Sanjivani Lung Centre, Gomti Nagar, Lucknow, Uttar Pradesh ECR/963/Inst/UP/2017/RR-20
9	Dr. Shetty Sunil (Professor & Unit Head of the Department- Orthopedics) D. Y. Patil Hospital and Research Centre, Nerul, Navi Mumbai, Maharahtra	Institutional Ethics Committee, D Y Patil Medical College, Nerul, Navi Mumbai, Maharahtra ECR/195/Inst/MH/2013/RR-19
10	Dr. Mayani Niharkumar Jerambhai (Consultant Orthopedics) Shivam Hospital, Maninagar, Ahmedabad, Gujarat	Shivam Ethics Committee, Shivam Hospital, Maninagar, Ahmedabad, Gujarat ECR/63/Inst/GJ/2013/RR-20
11	Dr Mahesh G (Orthopaedic Surgeon) NRR hospital, Bangalore, Karnataka	CLINISYD Research Global Solutions Pvt Ltd, Bangalore, Karnataka ECR/328/Indt/KA/2020

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.

(Dr. V. G. Somani)
Central Licensing Authority
Stamp

डॉ. वी. जी. सोमानी
औषधि महानियंत्रक (भारत)
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवं परिवार कल्याण
एफ.डी.ए. भवन

Place: New Delhi
Date: 23 MAY 2022