ND/CT04/FF/22/31704
Dated: 20.04.2022

Tele No.011-23236965
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F. No. ND/CT/22/000025
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:

30 MAY 2022

To
M/s Abbott Healthcare Pvt. Ltd.,
Unit No. 3, Corporate Park,
Sion Trombay Road Chembur,
Mumbai (India) – 400071.

Subject: Grant of Permission to conduct "An Open-label, Single-arm, Multi-centric Phase IV Clinical Study to Evaluate the Safety and Effectiveness of Triamcinolone Hexacetonide Injectable Suspension 20 mg/ml - reg.

Sir/madam,

With reference to your application no. ND/CT/22/000025 dated 20.04.2022, please find enclosed herewith the permission in Form CT-06, No. **CT/ND/28/2022** 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

Condition 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;

(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 authorized 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 utilized 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 study with the drug doesn't convey or imply that based Clinical Trial data generated with the drug, permission to market this drug will automatically be granted to you.

(xx) **The firm should modify exclusion criteria to exclude patients with significant (requiring surgical correction) deformity of the target joint.**

(xxi) **The firm should modify secondary objective as patient global scale assessment from baseline to weeks 1, 4, 8 and 12.**

(xxii) **Accordingly revised protocol should be submitted to CDSCO.**

FORM CT-06

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

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

Number of the permission and date of issue **CT/ND/28/2022** dated 30 MAY 2022

1. The Central Licensing Authority hereby permits M/s Abbott Healthcare Pvt. Ltd., Unit No. 3, Corporate Park, Sion Trombay Road Chembur, Mumbai (India) – 400071 to conduct clinical trial of the new drug as per **protocol number-TRIA-422-0200 Version No. 1.0 Protocol Date 12-04-2022** in the below mentioned clinical trials sites.

2. Details of new drug or investigational new drug and clinical trial sites: -

Names of the new drug or investigational new drug:	Triamcinolone Hexacetonide injectable suspension
Therapeutic class:	Glucocorticoid
Dosage form:	Injectable suspension
Composition:	Each ml suspension for injection contains: Triamcinolone Hexacetonide..... 20 mg Benzyl alcohol I.P. (as preservative) .....0.9%w/v Water for Injection I.P.....q. s.
Indications	For intraarticular, intra-synovial or periarticular use in adults and adolescents for the symptomatic treatment of subacute and chronic inflammatory joint diseases including Rheumatoid arthritis and Juvenile Idiopathic Arthritis (JIA), Osteoarthritis and post-traumatic arthritis, Synovitis, tendinitis, bursitis and epicondylitis.

Details of Clinical trial Sites			
Sl No	**Name of Investigator**	**Name and Address of Clinical trial Site**	**Ethics committee details**
01	Dr. Kaushal R. Anand.	B.J. Medical College and Civil Hospital office of medical superintendent civil hospital Ahmedabad Gujarat - 380016 India.	Institutional Ethics Committee B.J. Medical College and Civil Hospital office of medical superintendent civil hospital Ahmedabad Gujarat - 380016 India. **ECR/72/Inst/GJ/2013/RR-19**

02	Dr.Saurabh Shah	Aartham Multispeciality Hospitals Opp. Polytechnic ,Near Panjarapole Cross Road, Ambawadi, Ahmedabad Gujarat - 380015 India.	Aartham Ethics Committee Aartham Hospitals LLP Opp. Polytechnic, Near Panjarapole Cross Road, Ambawadi, Ahmedabad Gujarat - 380015 India. **ECR/1520/Inst/GJ/2021**
03	Dr. Aashish Chaudhry	Aakash Healthcare Super Specialty Hospital, Plot, Road No. 201 Sector 3 Dwarka New Delhi - 110075 India.	Aakash Healthcare Institutional Ethics Committee Aakash Healthcare Super Specialty Hospital Plot, Road No. 201 Sector 3 Dwarka New Delhi - 110075 India. **ECR/1265/Inst/DL/2019.**
04	Dr.Praganesh Kumar	G.S.V.M Medical College, Swaroop Nagar, Kanpur Uttar Pradesh – 208002.	Ethics Committee GSVM Medical College Kanpur, swaroop nagar swaroop nagar Kanpur Uttar Pradesh - 208002 India. **ECR/680/Inst/UP/2014/RR-20**

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

New Delhi
Date: 30 MAY 2022

Stamp
डॉ. वी. जी. सोमानी
औषधि महानियंत्रक (भारत)
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
एफ.डी.ए. भवन, कोटला रोड़, आई.टी.ओ.
नई दिल्ली-110002