

File No. SND/CT/23/000078
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:

22 MAR 2024

To

M/s Intas Pharmaceuticals Limited,
Corporate House, Near Sola Bridge, S. G. Highway, Thaltej,
Ahmedabad, Gujarat (India) - 380054.

Subject: Permission to conduct Phase II Clinical trial of Lipid based Cabazitaxel tablets 50 mg, Title:- "A Phase-2, Open-label, Randomized, Parallel-group, Three-arm, Study to Assess Efficacy and Safety of Cabazitaxel Lipid Tablet in Combination with Prednisone for the Treatment of Adult Men with Metastatic Castration-Resistant Prostate Cancer Previously Treated with a Docetaxel containing Treatment Regimen". (Protocol No. 0128-23; Version 1.1; Date 16.09.2023) - Reg.

CT NOC No.: CT/SND/05/2024

Sir,

With reference to your Application No. SND/CT04/FF/2023/40244 dated 27.10.2023 please find enclosed herewith the permission in Form CT-06, CT NOC No. **CT/SND/05/2024** 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. Rajeev Singh Raghuvanshi)
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 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) 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) **Firm should include adequate number of Government hospital Clinical trial sites.**

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/05/2024

The Central Licensing Authority hereby permits **M/s Intas Pharmaceuticals Limited, Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad, Gujarat (India) – 380054** to conduct clinical trial of the new drug ~~or investigational new drug~~ as per **Protocol No. 0128-23, Version 1.1, Date 16.09.2023** in the below mentioned clinical trial sites.

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

Names of the new drug:	Lipid based Cabazitaxel tablets 50 mg
Therapeutic class:	Anticancer
Dosage form:	Tablets
Composition:	Each enteric coated tablet contains: Cabazitaxel.....50 mg
Indications:	For the treatment of adult men with metastatic castration resistant prostate cancer previously treated with a docetaxel containing treatment regimen.

Details of Clinical trial sites

Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/ Registration Number
1	Dr. Dr Prakash S S, K R Hospital, Mysore Medical college and Research Institute and Associate Hospitals, Irwin Road, Mysore Karnataka - 570001.	IEC-MMC and RI and Associated Hospital ECR/134/Inst/KA/2013/RR-19
2	Dr. K Velavan, Erode Cancer Centre, 1/393 Velayan Nagar, Perundurai Road, Thindal, Erode Tamil Nadu – 638012.	Institutional Ethics Committee, Erode Cancer Centre ECR/319/Inst/TN/2013/RR-19
3	Dr. Bhushan Nemade, Sankalp Speciality Hospital, Dhanvantari Marg, Vallabh Nagar, Behind Chhan Hotel. Mumbai Agra Highway, Mumbai Naka, Nashik-422009, Maharashtra, India	Navsanjeevani Hospital Ethics Committee ECR/1036/Inst/MH/2018/RR-21

4	Dr. Lagudu Bhaskar Bhuvan, HCG Cancer Centre, Plot No 10, APIIC Health City, Arilova Chinnagadili, Mudasarlova Road, Visakhapatnam, Andhra Pradesh - 530040	Institutional Ethics Committee HCG Cancer Centre ECR/864/Inst/AP/2016/RR-20
5	Dr. Aakash Patel, HCC Happiness care and cure Multispeciality Hospital, 302, 303, 305 and 407 Shital Varsha Mall, Shivranjani Cross Road, Satellite Ahmedabad Gujarat - 380015	Parth Hospital Ethics Committee ECR/1530/Inst/GJ/2021
6	Dr. L K Priyadarshini, HCG City Cancer Centre, 33-25- 33, CH Venkata Kriahnayya Street, Suryarao Pet, Vijayawada, Andhra Pradesh - 520002	Institutional Ethics Committee - HCG Curie CCC ECR/869/Inst/AP/2016/RR-19
7	Dr. Rajendersingh Arora, Sujan Surgical Cancer Hospital and Amravati Cancer Foundation, 52B, Shanakar Nagar, Main Road, Amravati Maharashtra – 444605.	Amravati Ethics Committee ECR/432/Inst/MH/2013/RR-19
8	Dr. Anil MR, Oncoville Cancer Hospital and Research Centre, No. 4, 80Ft. Road, 7th Block, Nagarbhavi, 2nd Stage, Bengaluru Karnataka – 560072.	Institutional Ethics Committee of Oncoville Cancer Hospital & Research Centre ECR/1490/Inst/KA/2021
9	Dr. Deepak Kumar Singh, Swami Harshankaranand Ji Hospital and Research Centre, N 8 237 , BHU Rd, Near Bhikaripur Crossing, Opposite Union Bank of India, B. H. U., Sundarpur, Newada, Varansi Uttar Pradesh – 221004.	Independent EC Namaste Integrated Services EC/340/Indt/UP/2021

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:

22 MAR 2024



(Dr. Rajeev Singh Raghuvanshi)

Central Licensing Authority

Stamp

Dr. RAJEEV SINGH RAGHUVANSHI
Dr. RAJEEV SINGH RAGHUVANSHI
Central Drugs Controller General (India)
Central Drugs Standard Control Organisation
Central Drugs General of Health Services
Director of Health & Family Welfare
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road,
FD New Delhi (India)
New Delhi