F. No. ND/CT/23/000056
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road,
New Delhi-110002

To
M/s GSK Pharma India Private Limited,
C/o GlaxoSmithKline Pharmaceuticals Limited,
Dr. Annie Besant Road, Worli, Mumbai,
Maharashtra (India) - 400030

Subject: Permission to conduct Phase-IV Clinical Trial of Niraparib Tablets 100mg, entitled "A Prospective, Multicentre, open labelled, single arm Phase IV Clinical Trial of Niraparib in Indian Patients with advanced or relaped Ovarian Cancer who are in Complete or Partial Response Following Platinum based Chemotherapy" vide protocol no. 220168, version no. 1, dated 29-May-2023 – regarding.

Ref: Your application no. ND/CT04/FF/2023/38346 dated 30.06.2023

Sir,

With reference to your application, please find enclosed herewith the permission in **Form CT-06 vide no. CT/ND/48/2023** 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

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
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) The informed Consent Document including ICF and Patient Information Sheet should clearly mention in understandable language about the details of the drug therapy that the patient may or may not receive.

(xx) It may kindly be noted that merely granting permission to conduct Clinical Trial study with 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.

(xxi) **The firm should submit revised Form CT-04 indicating Clinical trial sites along with investigators, ethics committee details, and details of the person responsible for payment of compensation before initiation of the study to the CDSCO.**

(xxii) **The firm should submit the Financial disclosure agreement for study sites before initiation of the study to the CDSCO.**

FORM CT-06

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

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

Permission No. CT/ND/48/2023

The Central Licensing Authority hereby permits **M/s GSK Pharma India Private Limited, C/o GlaxoSmithKline Pharmaceuticals Limited, Dr. Annie Besant Road, Worli, Mumbai, Maharashtra (India) - 400030, Telephone No. 912224959595, FAX: 912224959494, E-MAIL: GSK.PHARMAINDIA1@GSK.COM**, to conduct clinical trial of the new drug or investigational new drug as per Protocol No. 220168, Version No. 1 Dated 29-May-2023 in the below mentioned clinical trials sites.

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

Names of the new drug or investigational new drug:	**Niraparib Tablets 100 mg**
Therapeutic class:	Poly ADP ribose polymerase PARP inhibitors
Dosage form:	Film coated Tablets
Composition:	Each film-coated tablet contains Niraparib tosylate monohydrate equivalent to 100mg Niraparib
Indication:	Niraparib is Indicated • as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO stage-III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. • as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum based chemotherapy.

Details of clinical trial sites-

Sr. No.	Name of Principal Investigator & Trial Sites	Ethics Committee Name/ Registration Number
1	Dr. Sudeep Gupta, Tata Memorial Centre, Tata Memorial Hospital, Dr. Ernest Borges Marg, Parel, Mumbai- 400012, Maharashtra, India	TMH, Institutional Ethics Committee-I, Tata Memorial Hospital, Dr. E. Borges Road, Parel, Mumbai City, Maharashtra–400012, India EC Reg. No. ECR/170/Inst/MH/2013/RR-2
2	Dr. Raj Nagarkar, HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka,	Manavata Clinical Research Institute Ethics Committee, HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai

	Nashik-422002, Maharashtra, India	Naka, Nashik, Maharashtra–422002, India. EC Reg. No. ECR/500/Inst/MH/2013/RR-20
3	Dr. Tushar Mule, Marathwada Cancer Hospital & Research Institute Plot No. 2, Dyaneshwar Nagar, In Front of Stadium Garkheda, Aurangabad, Maharashtra-431005, India	Ikon Ethics Committee For Research On Human Subject, Ikon Multispecialty Hospital, Rose Park H.no.2-7-79, Noor Manzil Majnu Hills, Aurangabad, Maharashtra – 431001, India EC Reg. No. ECR/1669/Inst/MH/2022
4	Dr. Aswin Kumar, Regional Cancer Centre, Dept of radiation oncology, E-block, 8th floor, Medical college campus, Trivandrum-695011, Kerala, India	Human Ethics Committee RCC, Regional Cancer Centre, Medical College Campus, Thiruvananthapuram, Kerala - 695011, India EC Reg. No.: ECR/21/Inst/Ker/2013/RR-19
5	Dr. Mukesh S, Mysore Medical College & Research Institute, Sayyaji Rao Road, Devaraja Mohalla, Mandi Mohalla, Mysuru, Karnataka- 570001	IEC-MMC and RI and Associated Hospital, Mysore Medical College and Research Institute, Mysore Medical College and Research Institute, Irwin Road, Mysuru (Mysore), Karnataka–570001, India EC Reg. No.ECR/134/Inst/KA/2013/RR-19
6	Dr. Tarun Kumar, Institute of Medical Sciences, Banaras Hindu University Lanka, Varanasi-221005, Uttar Pradesh, India	Institutional Ethics Committee, Institute of Medical Sciences, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh – 221005, India EC Reg. No. ECR/526/Inst/UP/2014/RR-20
7	Dr. Chandrakant MV, Narayana Superspeciality Hospital, 1, Andul Rd, Shibpur, Howrah, West Bengal- 711103	NSH Ethics Committee, Narayana Superspeciality Hospital, 120/1, Andul Road, Near Nabanna, Howrah, West Bengal –711103, India EC Reg. No. ECR/1006/Inst/WB/2018/RR-21
8	Dr. Amit Rauthan, Manipal Hospital, HAL Old Airport Rd, Kodihalli, Bengaluru, Karnataka 560017	Ethics Committee of Manipal Hospitals, No 98, HAL Airport Road, Bengaluru (Bangalore), Urban Karnataka - 560017, India EC Reg.No. ECR/34/Inst/KA/2013/RR-19
9	Dr. Ashish Singhal, Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow, Uttar Pradesh -226010	Dr. Ram Manohar Lohia, Institute of Medical Sciences, Research Cell Office Room, No. 35, 2nd Floor, Administrative Block, RMLIMS, Lucknow, Uttar Pradesh – 226010, India EC Reg. No. ECR/913/Inst/UP/2017/RR-20
10	Dr. Kaushik Chatterjee, Institute of Post-Graduate Medical Education and Research & Seth Sukhlal Karnani Memorial Hospital, 244, A.J.C. Bose Road, Kolkata, West Bengal, India -700020	IPGMER and Research Oversight Committee, IPGME and R244, Acharya J. C. Bose Road – Kolkata, West Bengal – 700020, India EC Reg. No. ECR/35/Inst/WB/2013/RR-19

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.

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority

New Delhi