सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. CT/25/000119

To,

M/s Veeda Clinical Research Limited,
Shivalik Plaza-A Near I.I.M Ambawadi,
Ahmedabad (India) – 380015.

Sir,

With reference to your application No. GCT/CT04/FF/2025/51536 dated 20-Aug-2025, please find enclosed herewith the permission in Form CT-06 for conduct of **phase I** clinical trial titled, "**A randomized, double-blind, parallel-group study to compare pharmacokinetics of JPB898 (proposed nivolumab biosimilar) and US-licensed Opdivo® in participants with resected stage IIB, IIC, or III melanoma requiring adjuvant treatment with nivolumab" Protocol No. CJPB898A12101 Version No. 2.1 dated 28-Nov-2025 with a total of up-to 70 subjects from India** under the provisions of New Drugs and Clinical Trial Rules, 2019

The permission granted by the Central Licensing Authority to conduct clinical trial shall be subject to following conditions, namely:-

(i) **Human biological samples i.e. Whole blood, serum, plasma and urine related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO. Further, ICMR/DHR permission shall be obtained for export of optional biological samples as per DGFT notification number 72/2023 dated 11.03.2024.**

(ii) 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;

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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 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;

(xiii) 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 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(xix) Merely granting permission to conduct the **clinical trial** with the Investigational Drug Product does not convey or imply that, based on the **clinical trial study data** generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;

(xx) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.01.19 17:52:11 -08'00'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority

Stamp

FORM CT-06
(See rules 22,25,26,29 and 30)

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

1. The Central Licensing Authority hereby permits **M/s Veeda Clinical Research Limited, Shivalik Plaza-A Near I.I.M., Ambawadi Ahmedabad (India) - 380015** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No. CJPB898A12101 Version No. 2.1 dated 28-Nov-2025** in the below mentioned clinical trial sites [As per Annexure].-

2. Details of new drug or investigational 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 _____

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.01.19 17:52:19 -08'00'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	JPB898 (Nivolumab) 10mg/ml (240mg/24ml) Concentrate for solution for infusion
Therapeutic class:	Monoclonal antibodies
Dosage form:	Solution for infusion
Composition:	JPB898 (Nivolumab)=240.0000mg/24ml In House Specification Active
Indications:	Resected stage IIB, IIC, or III melanoma a requiring adjuvant treatment

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Saveetha Medical college and Hospital, Saveetha Nagar, Thandalam Chennai Tamil Nadu-602105	IEC-Saveetha Medical College Hospital Saveetha Medical College Hospital Saveetha Nagar Thandalam Chennai Tamil Nadu-602105 India ECR/724/Inst/TN/2015/RR-24	Dr Anita Ramesh
2.	Mahamana Pandit Madan Mohan Malaviya Cancer Centre, Sundar Bagiya, Nr. Nariya Gate, Banaras Hindu University Campus Varanasi Uttar Pradesh-221005	IEC, MPMMCC and HBCH Varanasi Mahamana Pandit Madan Mohan Malaviya Cancer Centre Sundar Bagiya, Near Nariya Gate Banaras Hindu University Campus Varanasi Uttar Pradesh-221005 India ECR/150/Inst/UP/2021	Dr Anuj Gupta
3.	Aman Hospital and Research Centre, Aman Hospital and Research Centre, 15 Shashwat, opp. ESI hospital, Gotri road Vadodara Gujarat-390021	Institutional Ethics Committee Aman Hospital and Research Centre 15 Shashwat Opp, E.S.I Hospital Sarabhai, Gotri Road Vadodara Gujarat-390021India ECR/857/Inst/GJ/2016/RR-24	Dr Joshi Archit Girishchandra

4.	Max Superspeciality Hospital, Dept, of Medical Oncology, service floor, Max superspeciality Hospital, Saket, East Block-4, unit of devki devi foundation New Delhi Delhi-110017	Institutional Ethics Committee Devki Devi Foundation 2, Press Enclave Road Saket New Delhi New Delhi Delhi-110017 India ECR/110/Inst/DL/2013/RR-24	Dr Atul Sharma
5.	Marengo CIMS Hospital, 2nd floor, west building, Research department, Plot No. 671, opp. Panchamrut bunglows, Near shukan mall, off. Science city road, Sola Ahmadabad Gujarat-380060	Ethics Committee of CIMS Care Institute of Medical Sciences Care Institute of Medical Sciences Nr. Shukan Mall, Off Science City Road, Sola Ahmedabad Gujarat-380060 ECR/206/Inst/GJ/2013/RR-24	Dr Bhavesh Bhupatrai Parekh
6.	Nirmal Hospital, Ring Road Surat Gujarat-395002	NIRMAL HOSPITAL ETHICS COMMITTEE NIRMAL HOSPITAL PVT. LTD. SURAT 2/1423-B-6 SAGRAMPURA RING ROAD Surat Gujarat-395002 India ECR/390/Inst/GJ/2013/RR-24	Dr Ghanshyam Nanubhai Patel
7.	SRV Agadi Hospital and Research Centre, 35, H. Siddaiah road, Wilson garden Bengaluru Karnataka-560027	Medstar Speciality Hospital Ethics Committee Medstar Speciality Hospital No 641/17/1/3 Kodigehalli Main Road sahakarnagar Post Bangalore Bengaluru (Bangalore) Urban Karnataka-560092 ECR/1324/Inst/KA/2019/RR-24	Dr Lokesh K.N.
8.	KLEs Dr Prbhakar Hospital and research Centre, 2nd floor, Nehru nagar Belagavi Karnataka-590010	Institutional Ethics Committee, KLE University KLE University KLE Dr. PK Hospital and MRC Nehru Nagar Belagavi Belagavi (Belgaum) Karnataka-590010 ECR/211/Inst/KA/2013/RR-24	Dr Mahesh kumar Veeranna Kalloli
9.	SMS Medical College, State Cancer Institute, SMS Medical College and Attached Hospital, Ground Floor, JLN marg Jaipur Rajasthan-302004	Ethics Committee S.M.S. Medical College and Attached Hospitals J.L.N. Marg Jaipur Jaipur Rajasthan-302004 India ECR/26/Inst/RJ/2013/RR-24	Dr Mukesh Kumar
10.	Somani Hospital, 277-278, Shri Gopal Nagar, 80-feet road, Gopalpura Bypass Jaipur Rajasthan-302019	Somani Hospital Ethics Committee Somani Hospital Somani Hospital, 277, Shri Gopal Nagar 80 Feet Road, Gopalpura Byepass Jaipur	Dr Naresh Somani

		Rajasthan 302019 India ECR/1531/Inst/RJ/2021	
11.	HCG Manavta Cancer Centre, Behind Shining Auto, Mumbai Naka Nashik Maharashtra-422002	Manavata Clinical Research Institute Ethics Committee HCG Manavata Cancer Centre Behind Shivang Auto Mumbai Naka Nashik Maharashtra-422002 India ECR/500/Inst/MH/2013-RR-20	Dr Raj Nagarkar
12.	Apollo Hospital, Apollo Health city, Arilova, Chinnagadilli, 1st floor, oncology block Visakhapatnam Andhra Pradesh-530040	Institutional Ethics Committee-Clinical Studies Apollo Hospitals Enterprise Limited Apollo Hospitals Health City Chinagadhili Visakhapatnam Andhra Pradesh-530040 ECR/1369/Inst/AP/2020	Dr Rakesh Reddy Boya
13.	Nizams Institute of Medical Sciences, 1sr Floor, Medical Oncology Department, Room No. 26, Old Building, Panjagutta Hyderabad Telangana-500082	NIMS Institutional Ethics Committee Nizams Institute of Medical Sciences Punjagutta Hyderabad Telangana-500082 India ECR/303/Inst/AP/2013/RR-24	Dr Sadashivudu Gundeti
14.	AIIMS, New Delhi, Room 216, 2nd floor, dept of medical Oncology New Delhi Delhi-110029	Institute Ethics Committee All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29 New Delhi South Delhi-110029 ECR/538/Inst/DL/2014/RR-20	Dr Sameer Rastogi
15.	Spandana Oncology Centre, 919, New No. 68, 28th mainroad, 9th block, Jayanagar Bengaluru Karnataka-560069	IEC for SPANDANA ONCOLOGY CENTRE SPANDANA ONCOLOGY CENTRE No 919 New No 68 28th Main Road 9th Block Jayanagar Bengaluru (Bangalore) Urban Karnataka-560069 India ECR/1950/Inst/KA/2024	Dr Satheesh C T
16.	AIIMS, Bhubaneshwar, Dept of Medical Oncology, Ground Floor, G-Block, Sijua, Patrapada Bhubaneswar	INSTITUTIONAL ETHICS COMMITTEE, Faculty Research, AIIMS Bhubaneswar All India Institute of Medical Sciences, BBSR AIIMS Bhubaneswar Sijua P/O Patrapada Bhubaneswar	Dr Sourav kumar Mishra

		Khordha Orissa-751019 ECR/534/Inst/OD/2014/RR-25	
17.	PGIMER, Regional Cancer Centre, Department of Radio therapy and Oncology, PGIMER, Sector 12 Chandigarh Chandigarh-160012	Institutional Ethics Committee Post Graduate Institute of Medical Education and Research Room No. 6006, IEC Office, 6th Floor PN Chuttani Block Chandigarh Chandigarh-160012 India ECR/25/Inst/CH/2013/RR-25	Dr Srinivasa G Y
18.	S.P. Medical College and AG Hospital, Department of Medical Oncology, RCC Bikaner Rajasthan-334003	ETHICS COMMITTEE, S.P. MEDICAL COLLEGE, BIKANER S.P. Medical College, Bikaner S.P. Medical College, Bikaner Pawanpuri, Bikaner Rajasthan-334003 ECR/27/SP/Inst/RJ/2013/RR-19	Dr Surender Kumar Beniwal
19.	Medical College, Kolkata, Department of Medical Oncology, Medical College Kolkata, 88, College Street Kolkata West Bengal-700073	Institutional Ethics Committee for Human Research Medical College, Kolkata Medical College, Kolkata 88, College Street Kolkata West Bengal-700073 India ECR/287/Inst/WB/2013/RR-19	Dr Swarnabindu Banerjee
20.	Nanavati Max Super Speciality Hospital, Basement-III, CRD, Near Auditorium, Aero OPD Mumbai Maharashtra-400056	Ethics committee Dr. Balabhai Nanavati Hospital SVROAD, VILEPARLE WEST, MUMBAI SV ROAD, VILEPARLE WEST, MUMBAI Mumbai City Maharashtra-400056 ECR/566/Inst/MH/2014/RR-20	Dr Vaibhav Choudhary
21.	Sparsh Super Speciality Hospital, OPD number 1, ground floor, No. 41 Tumkur road yeshwanthpur Bangalore Karnataka-560022	Institutional Ethics committee Sparsh Hospital Sparsh Hospital For Advanced surgeries No.146 Oppostite Police commissioner Office Infantry Road Bengaluru (Bangalore) Urban Karnataka-560001 India ECR/520/Inst/KA/2014/RR-20	Dr Vijay Kumar Srinivasulu

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