



Government of India
Central Drugs Standard Control Organisation (Headquarter)
(Directorate General of Health Services)
FDA Bhavan, ITO, Kotla Road
New Delhi - 110002 (Delhi)
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File No. BIO/CT/22/000049

Dated 29-Jan-2024

To,

M/s Takeda Biopharmaceuticals India Pvt. Ltd,
6th Floor, Building 8, Tower C, DLF Cyber City,
Gurgaon 122002, Haryana, India.

Subject: Application for grant of permission to conduct Phase IV clinical trial entitled "A Multicenter, Single-arm, Open-label, Phase 4 Study to Evaluate the Safety and Efficacy of Brentuximab Vedotin plus Doxorubicin, Vinblastine and Dacarbazine in Indian Patients with Untreated Stage 3/4 Classical Hodgkin Lymphoma", vide Protocol No.: Study No. C25030 Protocol Version 4.0 dated 08 Aug 2023— regarding
Sir,

With reference to your application No. BIO/CT04/FF/2022/31422, dated 20.04.2022, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

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

- 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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 Licensing 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;
- 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 Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorised by the Central Licensing 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

Licensing 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 Licensing 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. The sponsor shall submit the clinical study report after completion of the study.

Yours faithfully

**RAJEEV SINGH
RAGHUVANSHI**

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

FORM CT-06

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

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

The Central Licencing Authority hereby grants M/s Takeda Biopharmaceuticals India Pvt. Ltd. 6th Floor, Building 8, Tower C, DLF Cyber City, Gurgaon 122002, Haryana, India to conduct clinical trial of the new drug or investigational new drug as per vide Protocol No.: C25030 Protocol Version 4.0 dated 08 Aug 2023 in the below mentioned clinical trial sites.

2. Details of 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: 29.01.2024



**RAJEEV SINGH
RAGHUVANSHI**

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

Annexure:**Details of new drug or investigational new drug:**

Name of the new drug	Brentuximab Vedotin 50 milligram (mg)			
Therapeutic class	Anticancer			
Dosage form:	Powder for concentrate for solution for infusion in vial			
Composition:	Each vial contains			
	Sr.No.	Name of Ingredient	Unit Formula per vial	Referenced Monograph
	1	Brentuximab Vedotin (rDNA Origin)	50 mg	In-house monograph
	2	Citric Acid monohydrate	2.1 mg	USP, EP and JP
	3	Sodium Citrate Dihydrate	56.1mg	USP, EP and JP
	4	α,α -Trehalose dihydrate	700mg	USP/NF, EP and JP
5	Polysorbate 80	2.0mg	USP/NF, EP and JP	
Indications:	<p>1.Previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with chemotherapy</p> <p>2. Classical Hodgkin lymphoma (cHL) consolidation</p> <p>3.Relapsed classical Hodgkin lymphoma(cHL)</p> <p>4. Previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), in combination with chemotherapy</p> <p>5. Relapsed systemic anaplastic large cell lymphoma (sALCL)</p> <p>6. Relapsed primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF)</p>			

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	Sujan Surgical Cancer Hospital and Amravati Cancer Foundation, 52/B Shankar Nagar, Main Road, Amravati-444605, Maharashtra, India	Amravati Ethics Committee, 52/B Shankar Nagar, Main Road, Amravati-444605, Maharashtra, India. <u>EC Reg. No.</u> <u>ECR/432/Inst/MH/2013/RR-19</u>	Dr. Rajender Singh Arora
2.	AllMS, Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi - 110029	Ethics Committee All India Institute of Medical Sciences (AllMS), Room No. 102, 1 st Floor, Old O.T. Block,	Dr. Deepam Pushpam

		Ansari Nagar, New Delhi – 110029, India <u>EC Reg. No.</u> <u>ECR/538/Inst/DL/2014/RR-20</u>	
3.	Nil Ratan Sircar Medical College & Hospital, Department of Haematology, 138, AJC Bose Road, Kolkata 700014, West Bengal, India	Institutional Ethics committee, Nil Ratan Sircar Medical College and Hospital 138, AJC Bose Road Kolkata 700014, West Bengal, India <u>EC Reg. No.</u> <u>ECR/609/Inst/2014/RR-20</u>	Dr. Tuphan Kanti Dolai
4.	AIIMS Hospital, AIIMS campus ,G.E road, Opp.to Gurudwar, Tatibandh, Raipur Chhattishgarh- 492099	Institutional Ethics Committee, AIIMS Raipur, Academic Section, 2 nd floor, Medical College Complex, Gate no-5, Tatibandh, Raipur Chhattishgarh -492099 <u>EC Reg. No.</u> <u>ECR/714/Inst/CT/2015/RR-21</u>	Dr. Yashwant Kashyap

