

F. No. 01/Phase IV/Biocad/19-BD  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Biological Division)

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated:

26 DEC 2019

To,

M/s Biocad India Private limited,  
163/C, 3<sup>rd</sup> Cross, 3<sup>rd</sup> Phase,  
J.P. Nagar, Bengaluru- 560 078,  
Karnataka.

Subject:- Application for grant of No Objection Certificate (NOC) to conduct Phase IV study entitled "A Multicenter Non-Comparative Phase IV study of the safety and Immunogenicity of Heticad (INN: Trastuzumab, CJSC BIOCAD, Russia) Plus Standard Chemotherapy in Patients with Early HER2-Positive Breast Cancer" via Protocol No. BCD-022-4, Version 1.1, dated 25.03.2019 – regarding

- Ref:- (1). Your letter Ref. No. Nil, dated 19.12.2018 received by this office vide Diary No. 36381, dated 24.12.2018  
(2). Your response to query letter Ref. No. Nil, dated 06.06.2019 received by this office vide Diary No. 7179, dated 10.06.2019.  
(3). Minutes of 83<sup>rd</sup> SEC (Oncology & Haematology) held on 09.04.2019

Sir,

This Directorate has no objection to your conducting subject mentioned study under the provisions of New Drugs and Clinical Trial Rules, 2019 under the supervision of the investigators mentioned below as per Protocol No. BCD-022-4, Version 1.1, dated 25.03.2019 forwarded to this Directorate.

S. No	Name of Investigator	Clinical Trial Site address	Name and Address of the Ethics Committee
1	Dr. Shewalkar Balaji Keshavrao	Marathwada Regional Cancer Center & Research Institute, Near Jama Masjid, Aam Khas Maidan Road, Aurangabad – 431 001, Maharashtra.	Institutional Ethics Committee, Department of Pharmacology, Govt. Medical College, Aurangabad – 431 001, Maharashtra.  Registration No. ECR/314/Inst/MH/2013/RR-16
2	Dr. Rajnish Vasant Nagarkar	HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka, Nashik – 422 002, Maharashtra.	Manavata Clinical Research Institute Ethics Committee (MCRI EC), Curie Manavata Cancer Centre, Opposite Mahamarg Bus stand, Mumbai Naka, Nashik –

			422 004, Maharashtra. Registration No. ECR/500/Inst/MH/2013/RR-17
3	Dr. Satya Pal Kataria	H Block Extension Department of Medical Oncology, Vardhman Mahavir Medical College & Safdarjung Hospital, New Delhi – 110 029.	Institutional Ethics Committee, Vardhman Mahavir Medical College & Safdarjung Hospital, New Delhi – 110 029. Registration No. ECR/593/Inst/DL/2014/RR-17
4	Dr. Lalit Sharma	Marudhar Hospital, A-93-99, Singh Bhoomi, Khatipura Road, Jaipur – 302 012, Rajasthan.	Ethics Committee, Marudhar Hospital, A-93-99, Singh Bhoomi, Khatipura Road, Jaipur – 302 012, Rajasthan. Registration No. ECR/586/Inst/RJ/2014/RR-17
5	Dr. Bodhisatta Roy	Netaji Subhash Chandra Bose Cancer Hospital, 3081, Nayabad, New Garia, Kolkata – 700 094, West Bengal.	Institutional Ethics Committee, Netaji Subhash Chandra Bose Cancer Hospital, 3081, Nayabad, New Garia, Kolkata – 700 094, West Bengal. Registration No. ECR/286/Inst/WB/2013/RR-16
6	Dr. Koushik Chatterjee	Department of Radiotherapy, Institute of Post Graduate Medical Education & Research, 244 Acharya J.C. Bose Road, Kolkata – 700 020, West Bengal.	Institute of Post Graduate Medical Education & Research Oversight Committee, Institute of Post Graduate Medical Education & Research, Office of the Dean, College Building, 5 <sup>th</sup> Floor, 244 Acharya J.C. Bose Road, Kolkata – 700 020, West Bengal. Registration No. ECR/35/Inst/WB/2013/RR-16
7	Dr. Jain Minish Mahendra	Grant Medical Foundation Ruby Hall Clinic, 40, Sassoon Road, Pune – 411 001, Maharashtra.	Poona Medical Research Foundation, Ruby Hall Clinic, 40, Sassoon Road, Pune – 411 001, Maharashtra. Registration No. ECR/24/Inst/MH/2013/RR-19
8	Dr. Maheshkumar Veeranna Kalloli	KLES Dr. Prabhakar Kore Hospital & MRC, Second Floor, Nehru Nagar, Belagavi	Institutional Ethics Committee, KLE University, JN Medical College, Nehru Nagar, Belagavi –

		- 590 010, Karnataka.	590 010, Karnataka. Registration No. ECR/211/Inst/KA/2013/RR-16
9	Dr. Shekar Patil	HealthCare Global Enterprises Limited, HCG Towers, No. 8, P. Kalinga Rao Road, Sampangi Ram Nagar, Bangalore- 560 027, Karnataka.	Ethics Committee, HCG-Central Ethics Committee, HCG - Bangalore Institute of Oncology, HCG - Towers, Tower I, 1 <sup>st</sup> Floor, No. 8, P. Kalinga Rao Road, Sampangi Ram Nagar, Bangalore- 560 027, Karnataka. Registration No. ECR/386/Inst/KA/2013/RR-16
10	Dr. Saroj Kumar Das Majumdar	Department of Radiotherapy, AIIMS, Sijua, Patrapada, Bhubaneshwar, Odisha - 751 019.	Institutional Ethics Committee, AIIMS, Village Sijua, Patrapada, PO Dumduma, Bhubaneshwar, Odisha - 751 019. Registration No. ECR/534/Inst/OD/2014/RR-17
11	Dr. Suresh Singh Damachayan	R.K. Birla Cancer Centre, Department of Surgical Oncology, SMS Medical College and Attached Hospitals, J.L.N. Marg, Jaipur - 302 004, Rajasthan.	Ethics Committee, S.M.S Medical College and attached Hospitals, Jaipur First Floor, Dhanvantri OPD Block, S.M.S Hospital, J.L.N. Marg, Jaipur - 302 004, Rajasthan. Registration No. ECR/26/Inst/RJ/2013/RR-16
12.	Dr. M.S Vishveshwara	HCG Bharath Hospital and Institute of Oncology, # 438, 1 <sup>st</sup> Stage, Outer Ring Road, Hebbal Industrial Area, Lakshmikanth Nagar, Mysuru - 570 017.	Institutional Ethics Committee, HCG Bharath Hospital and Institute of Oncology, # 438, 1 <sup>st</sup> Stage, Outer Ring Road, Hebbal Industrial Area, Lakshmikanth Nagar, Mysuru - 570 017. Registration No. ECR/994/Inst/KA/2017

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.

Yours faithfully



(Dr. V. G. Somani)  
Drugs Controller General (India)

