

File No: BIO/CT/19/000082
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

From:

The Drugs Controller General, India
Directorate General of Health Services,

FDA Bhawan Kotla Road,
New Delhi-110002

To,

M/s Dr. Reddy's Laboratories Limited,
8-2-337, Road No. 3, Banjara Hills,
Hyderabad - 500034, India

Subject: Application for grant of permission to conduct clinical trial entitled – “A Prospective, Multi-centre, Phase IV study to evaluate Safety and Efficacy of Dr. Reddy's Bevacizumab (DRL_BZ) in patients with Solid Tumors vide Protocol No.: BZ-02-001, Version No. 3.0, Date: 27-Aug-2019” - regarding

Ref.: Your Application No. BIO/CT04/FF/2019/16679 dated 30-Sep-2019

Sir,

With reference to your Application No.: BIO/CT04/FF/2019/16679 dated 30-Sep-2019, please find enclosed herewith the permission in FORM CT-06 for conduct of subject Phase IV clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

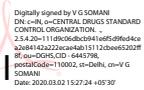
The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

- (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 authorized 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) 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;
- (XV) 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;
- (XVI) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

Yours faithfully,

V G
SOMANI
(Dr. V. G. Somani)
Central Licensing Authority



Digitally signed by V G SOMANI
DN: cn=V G SOMANI, o=CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION,
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Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Bevacizumab (r-DNA origin) drug product 100mg/4ml & 400mg/16 ml
Therapeutic class:	Angiogenesis Inhibitor
Dosage form:	Concentrate for Solution for Infusion in single use vial
Composition:	Each ml contains 25 mg of Bevacizumab
Indications:	<ol style="list-style-type: none"> 1. Non-resectable Metastatic colorectal cancer (mCRC) 2. First line Non Squamous Non small cell lung cancer (NSCLC) 3. Persistent, Recurrent or Metastatic Carcinoma of the Cervix 4. Platinum sensitive recurrent epithelial ovarian cancer

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	Medica Superspeciality Hospital, Clinical Research Ethics Committee, Medica Superspeciality Hospital, 127 Mukundapur, E.M. Bypass, Kolkata - 700099, West Bengal, India	Ethics Committee, Medica Superspeciality Hospital, 127, Mukundpur, E.M. Bypass, Kolkotta-700099, West Bengal, India EC Reg. No.: ECR/202/Inst/WB/2013/RR-19	Dr Chanchal Goswami
2	HCG City Cancer Center, 33-25-33, Ch. Venkata Krishnappa Street, , Suryarao Pet, Vijaywada - 520002, Andhra Pradesh, India	IEC, HCG curie city cancer centre, Padavala Revu, Machawaram down, Gundala, Vijaywada - 520004, Andhra Pradesh, India EC Reg. No.: ECR/869/Inst/AP/2016	Dr Gopichand M.
3	Government Medical College, Dept. of Pharmacology, Govt. Medical College, Nagpur - 440003, Maharashtra, India	IEC, GMC, Nagpur, Hanuman Nagar, Nagpur - 440003, Maharashtra, India EC Reg. No.: ECR/43/Inst/MH/2013/RR-19	Dr Ashok Kumar Diwan
4	Mahatma Gandhi Cancer Hospital & Research Institute, 1/7 MVP Colony,, Visakhapatnam - 530017, Andhra Pradesh, India	IEC, Mahatma Gandhi Cancer Hospital & Research Institute, Institutional Review Board, 1/7 MVP Colony, Visakhapatnam - 530017, Andhra Pradesh, India EC Reg. No.: ECR/529/Inst/AP/2014/RR-17	Dr Kartik Chandra Vallam
5	Sahyadri Hospitals Ltd., A Unit of Sahyadri Hospitals Ltd., 30C Erandwane, Karve Road, Pune - 411004, Maharashtra, India	Sahyadri Hospitals Ltd., Ethics Committee, situated at Sahyadri Clinical Research & Development Center, 33/34 B, Makarand Bhave Path, Karve Road, , Pune - 411004, Maharashtra, India EC Reg. No.: ECR/493/Inst/MH/2013/RR-19	Dr Tushar Patil

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
6	Healthcare Global Enterprises Ltd., HCG Towres, # 8, P. Kalinga Rao Road, Sampangi Ram Nagar, Bangalore – 560027, Karnataka, India	HCG, Central Ethics Committee, HCG-Bangalore institute of oncology, HCG towers, Tower 1, 1st floor No. 8, P. Kalinga rao road, Sampangiram nagar, Bangalore 560027, Karnataka, India EC Reg. No.: ECR/386/Inst/KA/2013/RR-19	Dr Srinivasa B J
7	Apollo Speciality Hospital, No. 320, Padma Complex, Anna Salai, Chennai – 600035, Tamil Nadu, India	IEC - Clinical Studies, Apollo hospital Enterprise Ltd., No. 21 Greams lane, off Greams road, Chennai - 600006, Tamil Nadu, India EC Reg. No.: ECR/37/Inst/TN/2013/RR-16	Dr M. A. Raja
8	Nirmal Hospital Pvt. Ltd., Ring Road, Surat - 395002, Gujarat, India	EC, Nirmal Hospital Pvt. Ltd., Ring road, Surat - 395002, Gujarat, India EC Reg. No.: ECR/390/Inst/GJ/2013/RR-19	Dr Ghanshyam Patel
9	North East Cancer Hospital and Research Institute, 11 th Mile Amerigog, Jorabat, Guwahati – 781023, Assam, India	IEC NECHRI, Room No. 4, Mezannine floor, 11 th Mile, Amerigog, Jorabat, Guwahati - 781023, Assam, India EC Reg. No.: ECR/766/Inst/AS/2015	Dr. Amit Kumar Dutta
10	HCG Manavata Cancer Centre, Behind Shivang auto, Mumbai naka, Nasik 422001, Maharashtra, India	MCRI EC, Curie Manavata Cancer Centre, Opp. Mahamarg bus stand, Mumbai naka, Nashik - 422004, Maharashtra, India EC Reg. No.: ECR/500/Inst/MH/2013/RR-17	Dr. Rajnish Nagarkar