

P. File No.: 1111430
Date: 02.11.2018

F. No. 12-139/08-DC (Pt-A)

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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road,
New Delhi

Dated: 27-06-2019

To,
M/s BDR Pharmaceuticals International Pvt. Ltd.,
407/408, Sharda Chambers,
15 New Marine Lines,
Mumbai 400020.

Subject: "An open label, balanced, randomized, multicentre, multi-dose, two-treatment, parallel, comparative Phase III clinical trial to determine the safety and efficacy of Biapenem 300 mg injections manufactured by BDR Pharmaceuticals Internationals Pvt. Ltd., India with I-NEM (Imipenem 500 mg + Cilastin 500 mg) injection manufactured by Glenmark Pharmaceuticals, Indian human adult patients with various complicated infections"– regarding.

Reference: Your application, P. File No.: 1111430 dated 02.11.2018 on the subject mentioned above.

CT NOC No.: CT/ND/60/2019

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigators and as per the protocol submitted to this Directorate.

Sr. No.	Investigator & Trial site	Ethics Committee Name/Registration Number
1.	Dr. Madhav Prabhu, MD Medicine KLEs Prabhakar Kore Hospital, Belgaum, K.L.E.S. Dr. Prabhakar Kore Hospital & Medical research centre, Nehru Nagar, Belagavi-590010, Karnataka, India Telephone No.: 0091-0831-2473777	Institutional Ethics Committee, KLE University, ECR/211/KA/2013/RR-2016
2	Dr. M Satheesh, DM Urologist Anu Hospital, Vijayawada #33-18-1, Chalasani Venkatakrishnaiah street, Near Puspa Hotel, Suryaraopet, Vijayawada, Andhra Pradesh 520002 Ph: 0866-2438881 anuhospitalscr@gmail.com	Institutional Ethics Committee, Anu Hospitals ECR/1049/Inst/AP/2018

3	Dr. S K Agarawal, DM Urologist All India Institute of Medical Sciences New Delhi Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029 skagarwalnephro@gmail.com	Ethics Committee, All India Institute of Medical Sciences ECR/538/Inst/DL/2014/RR-17
4	Dr. Usha Datta, DM Gastroenterologist PGI Chandigarh Sector 12, Chandigarh, 160012 Ph: 0091-172-2747585, 2747586 ushadatta@gmail.com	Institutional Ethics Committee, Post Graduate Institute of Medical Education and Research ECR/25/Inst/CH/2013/RR-16
5	Dr. J S Kushwaha, General Physician & MD Medicine Prakhar Hospital & Research Centre, Kanpur, 8/219, Arya Nagar, Kanpur, Uttar Pradesh 208002 Ph: 09918002225 pi.clintrial@gmail.com	Ethics Commiittee, Prakhar Hospital Private Ltd., ECR/1017/Inst/UP/2017
6	Dr. Brij Mohan, General Physician & MD Medicine Brij Medical Center, Kanpur 94 E, Near Panki Police Station, Gangaganj Colony, Panki, Kanpur, Uttar Pradesh – 208020 Lobe1617@gmail.com	Ethics Committee, Brij Medical Center ECR/642/Inst/UP/2014/RR-17
7	Dr. Nihil Gupta, General Physician & MD Medicine Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow, Ram Manohar Lohia Institute AYURVIGYAN sansthan, Vibhuti Khand, Uttar Pradesh 226010 Ph: 05226692000, 001, 004 nike2in1977@gmail.com	Institutional Ethics Committee, Dr. Ram Manohar Lohia Institute of Medical Sciences ECR/913/Inst/UP/2017
8	Dr. Rajat Chaudhuri & MD Emergency & Critical Care IPGME&R and SSKM Hospital, Kolkata 244, A.J.C Bose Road, Bhowanipore, Kolkata, West Bengal 700020 Ph: 033 22041100 rajat.choudhuri@gmail.com	Ethics Committee, IPGME&R Research Oversight Committee ECR/35/Inst/WB/2013/RR-16
9	Dr. Tushar Sudarshan Mishra & MS (Gastrointestinal surgeon) All India Institute of Medical Sciences, Bhubaneswar AIIMS road, Sijua, Patrapada, Bubhaneswar, Odisha 751019 Ph: (0674) 2476789 Surg_tushar@aiimsbhubaneswar.edu.in	Institutional Ethics Committee, All India Institute of Medical Sciences ECR/534/Inst/OD/2014/RR-17

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10	Dr. D. Pavan Kumar & MD General Medicine Mahatma Gandhi Memorial Hospital, Kakatiya Research Centre, Mahatma Gandhi Road, Mattewada, Warangal, Telangana, India-506007 Drpavankumar.krcwgl@gmail.com	Kakatiya Institutional Ethics Committee, Kakatiya Medical College ECR/840/Inst/TG/2016
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Kindly note that 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:

- (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 Licencing 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 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 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 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;
 - (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 utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be

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- (xvi) 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) 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.
- (xx) One microbiologist should be part of study team at each site.
- (xxi) The firm should ensure that the patients to be enrolled in the trial be proportionately distributed according to the bed strengths of the sites.

Yours faithfully,



(Dr. S. Eswara Reddy)
Drugs Controller General India
(Name & Designation of Licensing Authority)

