Diary No: 30555
Date: 16.08.2018

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F. No 12-20/05-DC (Pt. E)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, New Delhi – 110002 (India)
New Drugs Division

Dated: 7 - NOV 2018

To

M/s Reddy's Laboratories Limited,
8-2-337, Road No. 3,
Banjara Hills, Hyderbad - 500 034.

Subject: Permission for conducting Phase IV clinical study entitled, "A Phase IV, open label, single arm, multicentric, prospective study to evaluate the efficacy and safety of Injection Azacitidine 100mg in adult subjects with myelodysplastic syndrome" - regarding.

CT NOC No. CT/ND/62/2018

Reference: Your application no. DRL/NRA/1515-18 dated 14.08.2018 on the subject mentioned above.

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 investigator and as per the **Protocol No: DRL-INDG02-AZA/2015, Version No: 02, Dated 03.08.2018** submitted to this Directorate.

S. No	Investigator and Trial site	Ethics Committee Name and Registration Number
1.	**Dr. Sandip A. Shah,** Medical Hematologist, Hemato-Oncology Clinical Ahmedabad Pvt. Ltd., 1st Floor, Vedanta Institute of Medical Sciences, Near Samved Hospital, Stadium Commerce College Road, Navarangpura, Ahmedabad - 380 009.	Care Institute of Medical Sciences at Care Institute of Medical Sciences, NR Shukan Mall, Off Science City Road, Ahmedabad, Gujarat. **ECR/206/Inst/Guj/2013/RR-16**
2.	**Dr. Ganesh S Jaishetwar,** Consultant Hematologist, Yashoda Hospital, Raj Bhavan Road, Somajiguda, Hyderabad - 500 082.	Yashoda Academy of Medical Education and Research, Yashoda Hospital Behind Harihara, Kala Bhawan Secunderabad - 500003. **ECR/49/Inst/AP/2013/RR-16**

3.	**Dr. Kanna Subramanian,** KEM Hosiptal Research Centre, Sardar Moodliar Road, Rasta Peth, Pune - 411 011.	KEM Hosiptal Research Centre Ethics Committee, KEM Hospital Research Centre, Sardar Moodliar Road, Rasta Peth, Pune - 411 011. **ECR/272/Inst/MH/2013/RR-16**
4.	**Dr. Sandip Bartakke,** Oyster & Pearl Hosiptal, 1671-75, Ganeshkhind Road, Near Hotel Pride, Shivaji Nagar, Pune - 411 005.	Oyster & Pearl Institutional Ethics Committee, 1671-75, Ganeshkhind Road, Near Hotel Pride, Shivaji Nagar, Pune - 411 005. **ECR/71/Inst/MH/2013/RR-16**
5.	**Dr. Rashmi Gudur,** Krishna Institute of Medical Sciences, Deemed University, Karad, Near Dhebewadi Road, Malkapur, District - Satara, Karad - 415 539.	Krishna Institute of Medical Sciences, Deemed University, Karad, Near Dhebewadi Road, Malkapur, District - Satara, Karad - 415 539. **ECR/307/Inst/MH/2013/RR-16**
6.	**Dr. Sangeeta Jiwatani,** Mangal Anand Hospital, 48, Swastik Park, Sion, Trombay Road, Chembur, Mumbai - 400 071.	BSES Municipal General Hospital, 2nd Floor, BSES MG Hosiptal, S. V. Road, Andheri (W), Mumbai - 400 058 **ECR/343/Inst/MH/2013/RR-16**
7.	**Dr. Vijay Ramanan,** Hemato-Oncologist, Inamdar Multispeciality Hospital, Hospital Building, S. No. 15, Fatima Nagar, Pune - 411 040.	Inamdar Multispeciality Hospital, Hospital Building, S. No. 15, Fatima Nagar, Pune - 411 040. **ECR/354/Inst/MH/2013/RR-16**
8.	**Dr. Shipla Bhartia,** Consultant-Hemato-Oncology & Bone Marrow Transplantation, Apollo Gleneagles Hospital, Kolkata - 700 054.	Apollo Gleneagles Hospital, Kolkata, 58 Canal Circular Road, Kolkata - 700 054. **ECR/373/Inst/WB/2013/RR-16** .
9.	**Dr. Rayaz Ahmed,** Rajiv Gandhi Cancer Institute & Research Centre, Sector 5, Rohini, New Delhi - 110 085.	Rajiv Gandhi Cancer Institute & Research Centre, Sector 5, Rohini, New Delhi - 110 085. **ECR/10/Inst/DC/2013/RR-16**
10.	**Dr. Kajal M. Shah,** Medical Oncologist, Shalby Hospitals, Opp. Karnavati Club, S. G. Highway, Ahmedabad - 380 015.	Krishna Shalby Hospital, 319-Green City, Ghuma, Via Bopal, Ahmedabad - 380 058, Gujarat. **ECR/711/Inst/GJ/2015**

Kindly note that the clinical trial permission is subject to the following conditions:-

a) Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations.

b) Approval of Institutional Ethics Committee duly registered with CDSCO (under Rule 122DD of Drugs & Cosmetics Rules) should be obtained and submitted to this Directorate before initiation of the study.

c) Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study.

d) Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority, and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority.

e) Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y.

f) In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority.

g) The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites shall be open to inspection by the officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations.

h) The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, investigational drugs, etc. related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

i) Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.

j) The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facility available with the Investigator etc.

k) The details of payment/honorarium/financial support/fees paid by the Sponsor to the Investigator(s) for conducting the study shall be made available to this directorate before initiation of each of the trial sites.

l) In addition to the requirement of obtaining written informed consent, an audio-video recording of the informed consent process in case of vulnerable subjects in clinical trial of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record; provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record, as per Government of India, Gazette Notification vide G. S. R. no. 611(E) dated 31.07.2015.

m) Informed consent documents (ICD) viz. Patient Information sheet (PIS) and Informed Consent form (ICF) complete in all respect as per the requirements specified in Appendix V of Schedule Y of the Drugs and cosmetics Rules, 1945 must got approved from the respective Ethics Committee and Submitted to CDSCO before enrolling first subject at the respective site.

n) Primary objective should be changed to safety (same to be changed also in the title).

o) In inclusion criteria no. 2, one indication 5q deletion syndrome should be deleted.

Accordingly, revised Phase IV clinical trial protocol should be submitted to CDSCO.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)