F. No. CT/57/18-DCG(I)

F. No. CT/18/000060
GOVERNMENT OF INDIA
Directorate General of Health Services
Central Drugs Standard Control Organization
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
Te No: 01123236965, Fax: 01123236971
E-mail: dci@nic.in

To,

M/s. Parexel International Clinical Research Private Limited,
Coworks, Coworking Spaces Pvt. Ltd. - RMZ Eco World Ground Floor,
Bay Area – Adjacent to Building 6A,Outer Ring Road,
Devarabeesanahalli Village,Bengaluru(India)–560103

Subject: Clinical trial titled "A 12-week, randomized, double-blind, placebo-controlled, phase 3 study to evaluate the safety and efficacy of Relamorelin in patients with diabetic gastroparesis"- regarding**.**

Reference: Your Application No. GCT/Form44/FF/2018/10325 (GCT/57/18) dated 31/Aug/18.

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 investigators mentioned below and as per the **Protocol No: RLM-MD-01, Protocol Amendment Version 03, dated 25/March/2018** submitted to this Directorate.

1. Dr. Banshi Damodarlal Saboo, Dr. Jivraj Mehta Smarak Health Foundation Bakeri Medical Research Centre, Near Shreyas Crossing Road, Dr. Jivraj Mehta Marg, Jivrajpark, Vasna, Ahmedabad-380007, Gujarat, India.
2. Dr. Sanjay Chunilal Agarwal, Grant Medical Foundation Ruby Hall Clinic, 40, Sassoon Road, Pune-411 001, Maharashtra, India.
3. Dr. S. Prabhu, Victoria Hospital, Bangalore Medical College and Research Institute Fort, K. R. Road, Fort, Bangalore-560002, Karnataka, India.
4. Dr. Jugal Bihari Gupta, Eternal Hospital, Unit of Eternal Heart Care Centre and Research Institute Pvt. Ltd., 3A, Jagatpura Road, Near Jawahar Circle, Jaipur-302017, Rajasthan, India.
5. Dr. Paturi Vishnupriya Rao, Kumudini Devi Diabetes Research Center, Ramdevrao Hospital, Kukatpally, Hyderabad-500072, Telangana, India.
6. Dr. Sandeep Kumar Gupta, M.V. Hospital and Research Centre, 314/30, Mirza Mandi, Chowk, Lucknow-226003, UP, India.
7. Dr. Avinash Balekuduru, M S Ramaiah Clinical Research Centre, M S Ramaiah Medical College and Hospital, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka, India.
8. Dr. Ashish Joshi, Department of Gastroenterology, S.P Medical College & AG of Hospitals, Bikaner-3340031(Rajasthan), India.

9. Dr. Sreenivasa Murthy. L., Life Care Hospital and Research Centre, #2748/2152, M.L.N Enclave, 16th 'E' Cross Road, 8th Main, 'D' Block, Next to Corporation Bank, Sahakarnagar, Bangalore-560092, Karnataka, India.
10. Dr. Husain Salem Bohari, Chopda Medicare & Research Center Pvt. Ltd, Magnum Heart Institute, 3/5, Patil Lane No. 1, Laxmi Nagar, Near K B H Vidyalaya, Canada Corner, Nashik-422005, Maharashtra, India.
11. Dr. Mukesh Kalla, S.R. Kalla Memorial Gastro & General Hospital, 78-79 Dhuleshwar Garden, Behind HSBC Bank Sardar Patel Marg, C-Scheme Jaipur-302001, Rajasthan, India.
12. Dr Dipak Champaklal Dantara, Zydus Hospitals & Healthcare Research Pvt. Ltd., Zydus Hospital Road, Near Sola Bridge Thaltej, Off S. G. Highway, Ahmedabad-380054, Gujarat, India.
13. Dr Aravind S R, Diacon Hospital (Diabetes Care & Research Centre), No. 359-360, 19th Main, 1st Block, Rajajinagar, Bangalore-560010, Karnataka, India.
14. Dr. Ramesh Gajula, Anu Hospitals, #33-18-1, Kovelamudiwari Street, Near Pushpa Hotel, Suryaraopet, Vijayawada-520002, Andhrapradesh, India.
15. Dr Balamurugan Ramanathan, Kovai Diabetes Speciality Centre & Hospital, No: 15, Vivekananda Road, Ram Nagar, Coimbatore-641009, Tamilnadu, India.
16. Dr Arthur Joseph Asirvatham, Arthur Asirvatham Hospital, 42-A Kuruvikaran Salai, Anna Bus Stand Madurai-625020, Tamil Nadu- India.
17. Dr. Jaiganesh Muruganandam, M.V. Hospital for Diabetes Pvt. Ltd., #4 West Madha Church Street, Royapuram, Chennai-600 013, Tamilnadu, India.
18. Dr. Jadhav KiranKumar Puna, Department of Surgery, B.J. Medical College and Sassoon General Hospitals, Sassoon Road, Somwar Peth, Pune-411001, Maharashtra, India.
19. Dr. Kabrawala Mayank Vasantlal, Surat Institute of Digestive Sciences, Vijay Nagar Gate No-3, Besides Nirman Bhavan, Opposite Gandhi College, Majura Gate, Ring Road, Surat-395002, Gujarat, India.
20. Dr. Kandregula Appala Venkata Subrahmanyam, Department of Endocrinology, Superspeciality Block, King George Hospital, Maharanipeta, Visakhapatnam-530002, Andhrapradesh, India.
21. Dr. Hamsraj Alva, Vinaya Hospital and Research Centre, Karangalpady, Mangalore-575003 Karnataka, India.
22. Dr. Mane Abhay Kumar Anant, Universal Hospital, CTS 1420, Near Shaniwar Wada, Kasba Peth, Pune-411011, Maharashtra, India.
23. Dr. Reema Yuvraj Kashiva, Noble Hospital Pvt. Ltd., 153, Magarpatta City Road, Hadapsar, Pune-411013, Maharashtra, India.
24. Dr. Thacker Hemant Premji, Bhatia Hospital, G-1 Block, Ground Floor, Tardeo Road, Mumbai-400007, Maharashtra (India).
25. Dr. Surender Kumar, Sir Ganga Ram Hospital, SGRH Marg, Rajinder Nagar, New Delhi-110060, India.
26. Dr. Srinivasa Madaiah, Dept. Of General Medicine, K.R. Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysore-570001, Karnataka (India).
27. Dr. Giriraja K V, Rajalakshmi Hospital, Lakshmipura Main Road, Vidyaranyapura Post, Bangalore-560097, Karnataka, India.

28. Dr. Gaurav Kumar Gupta, Department of Gastroenterology, SMS Hospital, J.L.N. Marg, Jaipur-302004, Rajasthan India.
29. Dr. Surendra Kumar Sharma, Diabetes, Thyroid and Endocrine Centre, A-1, Madrampura, Near 4 No. ESI Hospital, Ajmer Road, Sodala, Jaipur (Rajasthan), India-302006.

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 the Ethics Committee shall be obtained 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 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.

k. An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials 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.

l. It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not convey or imply that based on the clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.

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 be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

Yours faithfully,

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
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Date: 2018.01.18 17:00:14 +05'30'

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